

Alabama State University
Research Protection Program (RPP)
Policies and Procedures
Office of Research Compliance
Institutional Review Board

July 30, 2019

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Need to add limited IRB

Change language for consent forms

Abbreviation List	FULL PHRASE
AE	Adverse Event
AAHRPP	Association of Accreditation of Human Research Protection Programs
CFR	Code of Federal Regulation
CITI	Collaborative IRB Training Initiative
COI	Conflict Of Interest
COIR	Conflict Of Interest in Research
COIRO	Conflict Of Interest in Research Officer
DHHS	Department of Health and Human Services
FTE	Full Time Equivalent
FWA	Federal Wide Assurance
HIPAA	Health Insurance Portability and Accountability Act
EHS	Environmental Health and Safety Committee
IO	Institutional Official
IRB	Institutional Review Board
OHRP	Office for Human Research Protections
ORC	Office of Research Compliance
ORSP	Office of Research and Sponsored Programs
PI	Principal Investigator
PRIM&R	Public Responsibility in Medicine and Research
RCO	Research Compliance Officer
RIO	Research Integrity Officer
RPP	Research Protection Program
RSC	Radiation Safety Committee
SOP	Standard Operating Procedure
ASU	Alabama State University

SECTION 1:

Organizational Commitment to the RPP

RPP Policy: 1.01 The Institution and Its Commitment to the RPP

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe the Institution and the commitment to the Research Protection Program (RPP).

2. Policy

The Institution is committed to the human participant research protection program through establishment and funding of an Institutional Review Board (IRB) operating in full compliance with Health and Human Services regulations at 45 CFR §46.

- 2.1 The Institution is comprised of Alabama State University (ASU).
- 2.2 The Institution is committed to ensuring the existence and evolution of premier educational programs, high quality research, conducted with integrity, consistent with ethical standards, and with respect for all individuals and groups (RPP Policies #1.04 and #2.01)
- 2.3 The IRB has been authorized by the Institutional Official (**IO**) to review and approve all human participant research conducted by the faculty, students, staff, or other Institutional representatives regardless of where the research is conducted.
- 2.4 The **IRB** has been authorized by the **IO** to provide review services for local institutions. This service is provided after said institutions are added to ASU's FWA and will be in accordance with all policies and procedures by which the IRB acts at ASU.
- 2.5 ASU does not currently conduct FDA-regulated research.
 - a) If ASU *does* conduct FDA-regulated research, the ASU IRB will enlist the assistance of qualified IRB reviewers who have proven experience with FDA-regulated research proposals.

RPP Policy: 1.02 Federal Wide Assurance

1. Purpose

The purpose of this SOP is to describe the agreement with the Department of Health and Human Services Office of Human Research Protection (OHRP) through the Federal Wide Assurance (FWA).

2. Policy

It is the policy of the IRB that this Institution will file and maintain an agreement with OHRP through a FWA. This Institution has declared that all institutional components listed under the ASU FWA (#00001366) must comply with this assurance.

- 21** The Institution has determined that *all* human participant research will be governed by the Health and Human Services regulations at 45 CFR §46 and ethical standards regardless of funding source.
- 22** The Institution has determined that all of its activities related to human participant research, regardless of funding source, will be guided by the ethical principles found in the Belmont Report.
- 23** The Institution has designated establishment and registration of one IRB with provisions for sufficient meeting space and staff to support the IRB's review and recordkeeping duties (RPP Policies # 1.05 and # 2.03).
- 24** The Institution will maintain a list of IRB members identified by name, earned degree, representative capacity, as well as maintenance of current curriculum vitae for each IRB member. Changes in IRB memberships will be reported to OHRP through filing an IRB Registration Update.
- 25** The Institution has established RPP written policies and procedures as required under Health and Human Services regulations at 45 CFR §46.103.

The IRB will conduct initial and continuing review of research (at intervals appropriate to the degree of risk, but not less than once per year). The investigator, the Institution, and all signatories to the IRB proposal will be provided written notification of the findings and actions taken by the IRB (RPP Policies #s 3.02, 3.03, 3.04, 3.05, and 11.01). The IRB will determine which projects require review more often than annually (RPP Policy # 3.10) and which projects require verification from sources other than the investigators that no material changes have occurred since the previous IRB review.

A. The IRB shall ensure that proposed changes in approved research protocols are reported promptly and are not initiated without IRB review and approval, except when necessary to eliminate immediate risk to the participant (RPP Policies #s 12.01 and 13.01 and 14.01).

B. The IRB shall have the authority to observe, or have a third party observe, the consent process and the research.

C. The IRB shall ensure prompt reporting to the IRB, appropriate institutional officials, and federal regulatory officials (OHRP, National Science Foundation, and other department or agency heads) (RPP Policy # 14.02):

1. All incidences of unanticipated problems involving risk to participants and others.
2. Any serious or continuing noncompliance with federal or IRB requirements.
3. Suspension or termination of IRB approval. The IRB shall require confirmation by a qualified person of the RPP that a research proposal qualifies for an exemption (RPP Policy # 4.01).

RPP Policy: 1.03 Vision, Mission, and Values Statement of Alabama State University

1. Purpose

The purpose of this SOP is to describe the vision, mission, and values statements for ASU.

2. Policy

ASU has developed a comprehensive mission statement and objectives.

2.1 Mission

Alabama State University is a student-centered, nurturing, comprehensive and diverse public historically black University committed to achieving excellence in teaching, research and public service. The University fulfills its mission through fostering critical thought, artistic creativity, professional competence and responsible citizenship in its students; by adding to the body of knowledge to enhance the quality of life through research and discovery; and by helping to advance the state and nation through thoughtful public service. Offering baccalaureate through doctorate degrees, the University maintains a scholarly and creative faculty, state-of-the-art facilities, and a living atmosphere in which all members of the campus community can work and learn in pleasant and rewarding surroundings. Consistent with its assurance that neither race, gender nor economic status inhibits intelligence, creativity or achievement, ASU offers a bridge to success for those who commit to pursuing the building blocks of development, focus, persistence and reward.

2.2 Core Values

1. Alabama State University continues to pursue excellence in teaching, research, student services and public service while creating an environment conducive to teaching and learning.
2. Alabama State University demonstrates a strong commitment to integrity by holding all faculty, staff and students accountable to the policies and procedures of the University, and to general expectations of decent and civil conduct.
3. Alabama State University will continue to support an environment that respects people with open communication and the free exchange of ideas, while nurturing a diverse community.
4. Alabama State University has a commitment to research, service and the contribution of new knowledge that focuses upon solving problems that affect local, state, national and international communities.

2.3 Institutional Goals

Alabama State University has established eight enduring institutional goals for this strategic operating period:

1. To organize the University in such a manner as to provide sufficient and appropriate leadership, management and oversight to achieve its mission and goals;
2. To ensure the academic integrity of the University;
3. To ensure the fiscal integrity of the University;
4. To enhance the public's perception of the University in order to increase external support;
5. To develop and maintain the physical campus so that the University is a productive, pleasant place to work, study and live;
6. To ensure that the University responds to all of its constituents;
7. To improve programs and services that will contribute to the development of wholesome student life; and
8. To foster continuous improvement of daily operations to be a world-class institution of higher learning.

RPP Policy: 1.04 Vision, Mission, and Values Statement for the RPP

1. Purpose

The purpose of this policy is to (a) ensure research involving human subjects is appropriately reviewed and (b) describe the vision, mission, and values statement for the Research Protection Program (RPP) at Alabama State University (ASU).

2. Policy

The RPP has developed a comprehensive vision, mission, and values statement.

2.1 Vision

The RPP for ASU and affiliates will be one that ensures:

- A.** All research involving human subjects will be reviewed and approved before human subjects may be involved. Neither the source of funds or lack of funding for such research has any bearing on this requirement.
- B.** Investigators will conduct research with the highest thought, technical skill, and care.
- C.** Investigators will adhere to high standards of research ethics, comply with all applicable federal, state, and local laws and regulations, and always consider the rights and welfare of research participants.
- D.** Institutional Review Board (IRB) members and staff will keep abreast of the latest developments in the ethics and regulation of human participant research, and will perform thorough and consistent review of research proposals.
- E.** Any process that seeks to secure information from humans or about humans that differs in any way from customary professional practices will be reviewed by the IRB.

2.2 Mission

The mission of the RPP is to constantly improve and respond to new ethical and regulatory challenges in order to ensure the protection of human participants who choose to participate in research conducted by investigators at ASU and affiliates.

2.3 Values

- A.** Faculty, staff, students, and others who serve as investigators will emphasize the conduct of quality research, which is carried out with scientific integrity and in an ethical manner.
- B.** Investigators will respect all individuals and groups served by ASU and affiliates.

RPP Policy: 1.05 IRB Charter Appointments and Administrative Structure

1. Purpose

The purpose of this policy is to describe the IRB charter, appointments, and administrative structure.

2. Policy

It is the policy of the IRB that the structure and composition of the IRB be in full accordance with the code of Federal Regulations – 45 CFR §46 (Protection of Human Subjects) – as set forth by the Department of Health and Human Services.

2.1 IRB Charter

The ASU IRB is a duly constituted IRB that has established membership in full accordance with the requirements of Health and Human Services regulations at 45 CFR §46.107.

2.2 Institutional Official

The Provost/Vice President of Academic Affairs is the Institutional Official (IO) in accordance with the provisions of the Health and Human regulations at 45 CFR §46.103. The IRB Chair is nominated by the IRB and appointed by the IO.

2.3 Institutional Official Designate

The IO may appoint an individual who will serve as his or her designate for the administrative supervision of the IRB.

2.4 IRB Chair

The Chair of the IRB is nominated by the IRB and appointed by the IO. The IRB Chair may be chosen from existing members of the IRB and should be a tenured faculty member of ASU. The IRB Chair reports to the IO (or his/her designate) as necessary, on matters concerning compliance with 45 CFR §46 and RPP policies and procedures. The IO has delegated responsibility for the daily operation of the RPP to the IRB Chair. The IRB Chair is primarily involved in developing and promoting RPP policies and procedures, revising IRB forms, compliance issues, conflict resolution, conducting IRB meetings, reviewing protocols, appointing IRB members, and facilitating continuing education for IRB members and investigators. The IRB Chair's term of service is at least two years. The IRB Chair has a direct line to the IO designate and the Provost/Vice President of Academic Affairs (IO) as necessary. The IRB Chair receives a course release each semester and the salary of one summer course throughout the summer months during the course of tenure.

RPP Policy: 1.06 Authority Granted by ASU to the IRB Operating in the RPP

1. Purpose

The purpose of this policy is to describe the authority granted by ASU to the IRB operating in the RPP.

2. Policy

It is policy of the IRB that ASU provide sufficient resources and decisional autonomy for the IRB to carry out its duties independently of ASU in full accordance with Health and Human Services policies at 45 CFR §46.

2.1 ASU, through its IO, authorizes the IRB to independently review and approve all human participant research conducted or supported by the faculty, students, staff, or other representatives of ASU, when such research is part of their institutional responsibilities, regardless of where the research is conducted unless the IRB accepts the review and approval of another duly constituted IRB under the provisions of the Health and Human Services regulations at 45 CFR §46 for research conducted at other study sites.

2.2 The IRB shall review and approve all human participant research before it can be conducted by anyone on the premises of ASU property or facilities.

2.3 The IRB shall exercise its authority in full accordance with Health and Human Services regulations at 45 CFR §46 and RPP policies and procedures. This authority includes review and approval of *exempt* research under 45 CFR §46.101 (b); research, which qualifies for *expedited review* under 45 CFR §46.110; and research, which requires review by the full IRB. The IRB has the empowerment, flexibility, and discretion to raise the standards of protection above those afforded to research participants in 45 CFR §46 as it deems appropriate and necessary in particular cases although it may not lower the protections below those afforded by 45 CFR §46.

2.4 ASU will apply 45 CFR §46, including Subparts A, B, C, and D, to all human participant research regardless of funding. Subpart B is intended to apply to all human participant research including that performed in the social and behavioral sciences.

A. ASU does not conduct research involving investigational test articles.

B. Human participant research that would fall under the purview of the FDA will be referred to the IRB supplemental by qualified IRB reviewers who have proven experience with FDA registered research proposals.

- 2.5** Per Health and Human Services regulations at 45 CFR §46.112, the institution acknowledges that research approved by the IRB may be subject to further appropriate review by the IO or his/her designate. However, no official (including the IO) may approve research if it has not been approved by the IRB. In addition, any attempt to improperly influence the IRB from both within and outside ASU is strictly prohibited and must be reported to the IO or his/her designate to take appropriate action.
- 2.6** Approval of research by the IRB can be overturned by the IO or his/her designate. The reason(s) for administrative disapproval of research by the IO or his/her designate shall be provided in writing to the IRB. The IRB, which will act in this case as a communication conduit, will notify the Principal Investigator (PI) of any disapproval in writing and provide the reason(s) for the disapproval. The PI may appeal the disapproval through the IRB by submitting a written appeal that will be communicated to the IO or his/her designate.

Section 2: Membership and Standard Operating Procedures

RPP Policy: 2.01 IRB Membership Requirements and Responsibilities

1. Purpose

The purpose of this SOP is to describe IRB membership requirements and responsibilities.

2. Policy

It is the policy of ASU that the IRB will include an appropriately diverse mixture of backgrounds and experiences in accordance with the Health and Human Services regulations under 45 CFR §46.107.

2.1 IRB Members

The IRB will have at least ten (10) members. Members will include at least one representative from each of the academic colleges on campus the Levi Watkins Learning Center, and a member who is unaffiliated with ASU.

2.2 Members will represent varying academic disciplines and have the necessary credentials to provide appropriate review of protocols submitted for review. The IRB will represent the diversity of the community in order to provide guidance on varying perspectives and sensitivities. The IRB will be sufficiently qualified through experience, expertise, and diversity to provide appropriate review of research with a primary focus on protection of human participants.

2.3 The IRB will include at least one member who is not affiliated with the Institution. The unaffiliated member must not: 1) have any professional relationship with the Institution as an employee, consultant, volunteer faculty, or student, and 2) be a family member (first and second degree relative) of someone who has a professional relationship with the Institution.

2.4 The IRB will include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.

- 2.5** All IRB members are appointed by the IO. The IRB may make recommendations to the IO as to whom to appoint. The IO will issue a letter of appointment to the candidate. The letter will indicate the expected length of service.
- A.** The Chair/Director of the unit to which the member belongs will also receive a letter from the IO:
- 1.** It will acknowledge the importance of the service being rendered
 - 2.** Establish the length of service
 - 3.** Request that the IRB member be available for Full Board meetings:
 - a) Towards that end, the standard meeting time will be identified and the IO will request that the new member the new member not have schedule conflicts--including teaching and other assignments-- during the scheduled time of the IRB meetings.
 - 1) This protection of availability is to be implemented as soon as possible, preferably within one semester of appointment to the IRB.
- 2.6** The Research Compliance Officer is an ex-officio non-voting member of the IRB.
- 2.7** The IRB will have access to the University's General Counsel to offer legal counsel to the Board.
- 2.8** In situations where a vulnerable population (children, prisoners, or persons with a mental or physical impairment) is involved in research under IRB review and the Board does not already have a member with appropriate background and experience working with said population, the Board will include an ad-hoc expert to serve in that capacity. This individual must have a close working knowledge, understanding, and appreciation of the needs of said vulnerable population.
- 2.9** In situations where a prisoner is involved in research under IRB review and the Board does not already have a member with appropriate background and experience to serve in the capacity of prisoner representative, the Board will include an ad-hoc prisoner representative to serve in that capacity. This individual must have a close working knowledge, understanding, and appreciation of the prison conditions in the facility where the research will be conducted from the perspective of the prisoner.
- 2.10** Where IRB members have conflicts of interest (as defined by RPP Policy # 2.05) pertaining to the research to be reviewed, members must absent themselves from the meeting room before the final review discussion and vote. IRB members with conflicts of interest must not participate in all types of reviews associated with said project.

- 2.11** When review of a proposal requires expertise that is not available on the Board, the IRB will request assistance from an expert consultant. These individuals have access to all documents submitted to the IRB relevant to the specific project under review and may participate at the deliberations and make recommendations on the project but will not vote (see RPP Policy # 2.03).
- 2.12** IRB members are expected to be fully engaged in the RPP and will
- A.** Carry out the following responsibilities:
 - B.** Be an active member of the IRB:
 - 1.** Keep certification at the level decided by the Board (currently Group II CITI training) valid
 - 2.** Serve as a reviewer
 - 3.** Be available when to fulfill responsibilities as reviewer
 - 4.** Notify RCO when unable to fulfill obligation to:
 - a) Attend Full Board meetings
 - b) Serve as a reviewer for a new protocol
 - c) Be available for a review of a revision to a previously assigned protocol
 - d) Respond to requests for revision in a timely manner
 - C.** Serve as a primary or secondary reviewer for new protocols.
 - 1.** Complete reviews in a timely manner
 - a) Respond to co-reviewer promptly
 - b) Adhere to the 30-working-days turnaround time
 - D.** Serve as a primary/secondary reviewer for applications for continuing review.
 - E.** Serve as a primary or secondary reviewer for internal unanticipated problems involving risk to the participant or others.
 - F.** Serve as a primary reviewer for external AEs or serious problems.
 - G.** Serve as a primary / secondary reviewer for modifications in protocol and/or consent documents.
 - H.** Serve as a primary reviewer for incidents of noncompliance.
 - I.** Attend continuing educational opportunities: at least one such experience a year and other off-campus educational experiences as arise or are necessary.

2.13 IRB Alternate Members

A. Alternate members are appointed by the IO, and may be based on the recommendation of the IRB.

B. Each college is to have at least one alternate member.

C. Alternate members will substitute for, or, replace a member who anticipates a long-term absence – at least more than two consecutive Full Board meetings, or a full month of duty as a reviewer.

D. Alternate members may attend any IRB meeting, but are not permitted to vote unless the designated ASU member(s) is/are not present.

1. In order to maintain their status as Alternate IRB members, the individuals are expected to:

a) Keep their certification at the level decided by the Board (currently Group II CITI training) valid

b) Keep certification (currently CITI) valid

1) Attend at least three Full Board meetings each semester

2) Serve as a “silent” partner on at least one protocol a semester

3) Complete at least one IRB sanctioned continuing education opportunity per year.

2.14 When the IRB membership changes, the RCO will prepare the notice that will be submitted by the IO to OHRP within thirty (30) business days.

2.15 The IRB roster is public information. The names of the IRB members who reviewed specific protocols will not be released unless a FOIA request is made.

RPP Policy: 2.02 IRB Meetings and Member Responsibilities

1. Purpose

The purpose of this SOP is to describe the structure of IRB meetings and IRB member responsibilities.

2. Policy

It is the policy of the IRB that the structure of the IRB meetings and responsibilities of IRB members are clearly defined.

2.1 IRB meeting dates are determined at the beginning of the academic year.

2.2 Five (5) business days before the scheduled IRB meeting, the IRB staff will send an email notification to each member. The IRB members are officially notified of the date, time, and location of the IRB meeting. The email asks the member to respond concerning his/her availability to attend the upcoming IRB meeting.

2.3 Five (5) business days before the IRB meeting, IRB applications and supporting materials for review will be disseminated to IRB members by email unless the size of the supporting documents is prohibitive.

2.4 For reviews by a convened IRB, all IRB members are provided with the full protocol containing all the relevant information needed to determine whether the proposed research fulfilled the criteria for approval.

A. A primary reviewer will be assigned to a protocol being brought before the Full Board. This reviewer will perform an in-depth review of all pertinent documentation available. All other IRB members will review the provided material so that they can discuss the materials at the convened meeting.

2.5 A quorum will be established in accordance with federal requirements. If quorum is not met or is lost, voting will not occur. If elected by the chair, the meeting will be postponed and re-convened as soon as possible (see RPP Policy #2.11).

2.6 Members will review and vote on IRB policies as required (see RPP Policy #2.13).

2.7 Persons may be invited to attend IRB meetings as guests under the following conditions:

A. Guest attendance is at the discretion of the IRB Chair;

B. Guests may be asked to leave at any time;

C. Guests will be asked to state the purpose of their visit;

D. Guests attending a meeting where a proposed project has been submitted will be asked to provide information about a proposed study and answer any question the IRB may have regarding the study under review.

E. All requests for guest to attend an IRB meeting must be directed to the Chair of the IRB. The request must include the name(s) of the visitors, the rationale for the visit, and the proposed visit date. The attendance of guests, who are not the authors of a protocol under review, will be discussed at the next IRB meeting. If the IRB approves the request, the visitor will be scheduled to attend a meeting of the IRB in the future.

F. If the request is granted; the guest will be required to sign a confidentiality statement (See Forms for IRB) and may be requested to leave the room during any discussion as necessary. Visitors may not vote.

RPP Policy: 2.03 IRB Consultants

1. Purpose

The purpose of this SOP is to describe the identification, appointment, and role of IRB consultants.

2. Policy

It is policy of the IRB that services of expert consultants will be obtained as needed.

- 2.1** Either before or during review of a protocol, the IRB Chair, assigned IRB reviewer, or the IRB itself will determine if there is a need for appointment of an expert consultant, either a scientist or a non-scientist, in accordance with the provisions of 45 CFR §46.107(f). Depending upon the nature and magnitude of the problem or concern, the IRB may seek more than one (1) consultant.
- 2.2** Consultants will be selected from within the Institution as well as from outside the Institution based upon the required expertise.
- 2.3** Consultants will generally produce written reviews, and they may participate in the IRB's discussion of the protocol.
- 2.4** Written reviews will be provided to the primary and secondary IRB reviewers. When warranted, copies of written reviews will be provided to all IRB members.
- 2.5** Consultants who attend an IRB meeting may not vote and are excused upon conclusion of discussion of the protocol in question.
- 2.6** Potential consultants will be queried by the IRB Chair or the Research Compliance Officer before any services are rendered, as to whether they have any potential conflicts of interest with the relevant investigators or funding agencies. If they do, they will be excused and another consultant found.
- 2.7** When the IRB reviews research that involves categories of participants vulnerable to coercion or undue influence, the IRB Chair or Research Compliance Officer will ensure that one or more individuals who are knowledgeable about, or experienced in, working with such participants will be present at the meeting.

RPP Policy: 2.04 Orientation and Initial Training for New IRB Members and ORC Staff

1. Purpose

The purpose of this SOP is to describe the orientation and initial training for new IRB members and the staff of the Office of Research Compliance.

2. Policy

It is the policy of the IRB to provide new IRB members and ORC staff with an orientation and initial training that includes the information necessary to facilitate the performance of assigned responsibilities.

2.1 All new IRB members and ORC staff will receive an orientation packet which will include:

- A.** IRB Membership Roster
- B.** Code of Federal Regulations: 45 §CFR 46
- C.** The Belmont Report
- D.** Federal Wide Assurance (FWA 00001366) which is renewed
- E.** IRB Policies and Procedures Manual
- F.** All Current ASU IRB forms and checklists
- G.** It is recommended that members purchase a copy of the latest edition of Institutional Review Board: Member Handbook by Robert J. Amdur and Elizabeth A. Bankert, Jones & Bartlett Publishers.

2.2 All IRB members and staff are required to complete the web-based program, Collaborative IRB Training Initiative (CITI), accessible through www.citiprogram.org. IRB members and the ORC staff are required to complete the social science/behavioral research training track.

- A.** A minimum passing score of 80 is required.

2.3 New members must serve as “silent” reviewers on 10 IRB proposals before they can serve as a full-fledged primary or secondary reviewer. The primary reviewer will provide feedback to the new member. Feedback will also be provided to the IRB Chair and the ORC on the timeliness and quality of responses offered by the new member.

RPP Policy: 2.05 IRB Member Conflict of Interest Management

1. Purpose

The purpose of this SOP is to describe the identification and management of IRB member conflict of interest (COI).

2. Policy

It is the policy of the IRB to identify and appropriately manage all IRB member potential conflicts of interest. However, all IRB members themselves should be sensitive to potential conflicts of interest, and act appropriately.

- 2.1** Preferably upon receipt of IRB meeting materials, all IRB members must notify the IRB Chair or the Research Compliance Officer of a COI in advance of the upcoming meeting or upon assignment as an expedited, continuing, primary, or secondary reviewer. If the IRB member is uncertain if a potential COI exists, they are encouraged to consult with the IRB Chair or the Research Compliance Officer.
- 2.2** Prior to the beginning of each meeting, IRB members will be asked to declare, but are not required to describe, any COI related to the protocols under review, which already have not been declared.
- 2.3** The individual can be a member of the IRB; however, he/she cannot participate in the review and approval process for any project in which he/she has a COI. In cases where the assigned initial reviewer has a COI, the IRB protocol is re-assigned to another reviewer. When the member has a conflicting interest, he/she will not be present during final discussion and vote, and may be present only at the beginning of the meeting to provide information if requested by the IRB. He/she must be absent from the meeting room during the subsequent discussion and voting phases of the review and may not participate in the vote. The absent member is not counted towards a quorum when the vote on the protocol in question is taken. Minutes must reflect whether or not these requirements have been met.

2.4 COI exists when the IRB member (or an immediate family member):

A. serves as a Principal Investigator (PI) or Supervising Investigator and is, accordingly, listed on the IRB application, or has served as a scientific advisor to the PI.

B. is an advisor (e.g., thesis/dissertation committee chair) or a direct supervisor of a trainee's (e.g., graduate or undergraduate student) research.

C. has received payments in excess of \$2,000 (when aggregated for the investigator and the investigator's immediate family member) including salary, consulting fees, royalty, or licensing payments from intellectual property, honoraria and/or gifts from the commercial company sponsoring the research, or their representative(s) or with a company with a financial interest in the product or service being tested over the past 12 months or anticipates receiving such payment during the next 12 months.

D. has equity interest in the commercial company sponsoring the research or in the product or service being tested, which is worth more than \$2,000 (when aggregated for the investigator and the investigator's immediate family member) or more than 5% of the business entity (when aggregated for the investigator and the investigator's immediate family member) determined by reference to publicly listed prices (excluding mutual funds).

E. has any equity interest in the commercial company sponsoring the research and the value cannot be determined by reference to publicly listed prices (e.g., startup companies).

F. holds a paid or unpaid position as director, officer, partner, trustee, or any other significant position (e.g., scientific advisory board/consultant) in the company sponsoring the research or with a company with a financial interest in the product or service being tested.

G. holds patent rights or royalties from such rights whose value may be affected by the outcome of the research, including royalties under any royalty-sharing agreements involving ASU.

H. has a financial interest (as defined above in items C, D, E, F, or G) in a company, which has a marketed product, or is in the process of developing a new product, which is, or will be, in direct market competition with the product in the protocol under IRB review.

I. has a personal relationship, or a conflict, with any investigator(s) listed on the IRB application, which would potentially cause the IRB member to be perceived as less than objective in his/her review.

J. has an ownership interest or compensation related to the research whose value may be affected by the outcome of the research.

- 2.5** The IRB meeting minutes will record the name of the IRB member with the COI and indicate that he/she was recused and did not vote.

RPP Policy: 2.06 Continuing Education Requirements for IRB Members and ORC Staff

1. Purpose

The purpose of this SOP is to describe the IRB's program of continuing education for IRB members and ORC staff.

2. Policy

It is the policy of the IRB to provide IRB members and ORC staff with ongoing continuing education concerning new regulations, new OHRP guidance documents, Association for the Accreditation of Human Research Protection Programs (AAHRPP) accreditation standards, issues in the field of research ethics, OHRP compliance citations, and other subjects of interests, which are related to human participant protection.

- 2.1** When re-certification is required, IRB members and Office of Research compliance staff must complete the continuing education modules available through the CITI based training program. They must attain a score of 80% or better to be considered certified by ASU standards.
- 2.2** IRB members and Office of Research Compliance staff are encouraged to access the IRB on the ASU website and the IRB website which maintains all pertinent information on the IRB process.
- 2.3** IRB members and staff are provided educational items at Board meeting. These items may be current journal articles addressing issues of human participant research; new or updated guidance issued by OHRP; or other items of interest.
- 2.4** Publication of new books on research ethics and protection of human participants are available in the Office of Research Compliance to IRB members and staff.
- 2.5** On a rotating basis, the IRB Chair will attend the national conferences on human research participant protections for the purposes of continued education. This educational experience is supported through the ORC budget.
- 2.6** Members of the RPP staff and IRB Board members are offered the opportunity, on a rotating basis, to attend regional and national conferences on human subject protections. This educational experience is supported through the ORC budget.
- 2.7** Office of Research Compliance staff is encouraged to obtain national Certification for IRB Professionals (CIP) or Managers (CIM) obtained through passing a national examination.

- 2.8** The IRB Chair and IRB members are expected to pursue the appropriate advanced training and certification (currently advanced CITI training).

RPP Policy: 2.07 Evaluation of IRB Members

1. Purpose

The purpose of this SOP is to describe evaluation of the performance of IRB members.

2. Policy

It is the policy of the IRB to carry out evaluations of IRB members and provide feedback as necessary to individual IRB members.

2.1 IRB members are evaluated on an annual basis by the IRB Chair.

2.2 Performance assessment is based upon meeting attendance records, thoroughness of reviews, participation in IRB discussions, and service on subcommittees.

2.3 IRB members may be granted an extended leave due to medical, personal, or professional reasons, then return to complete their term.

2.4 If an IRB member's performance is judged to be deficient, the IRB Chair will discuss his/her concerns with the member and seek a satisfactory resolution.

2.5 Members who do not adequately fulfill their responsibilities may be asked to step down from IRB membership by the IO, at his or her instigation and, or, based on IRB recommendation.

2.6 If an IRB member's appointment is terminated, the IO (or his designate) will notify the member in writing. The IO (or his designate), at his/her discretion, may notify the IRB member's supervisor or other administrative officials of this decision.

2.7 Annually, the IO will issue a letter of acknowledgement of service to the IRB members and alternates:

A. It will include

- 1.** an average of the number of protocols reviewed in the previous year, and
- 2.** any educational undertakings related to their membership.

B. The letter will go to the IRB member, his or her Chair/Director, and the Dean of the College.

C. Information for the letter will be prepared by the RCO and the Chair and forwarded to the IO.

- 2.8** The Chair may be evaluated on an annual basis by the IO which may include feedback from the IRB.
- 2.9** The appointment of the ORC staff is conducted by the RCO. The ORC staff members are annually evaluated by the Research Compliance Officer, who, in turn, is evaluated by the IO or his designate.
- 2.10** The Research Compliance Officer, Chair, and IO (or his designate) may meet periodically to evaluate distribution of responsibilities within the RPP in order to maximize effectiveness.

RPP Policy: 2.08 IRB Member Confidentiality

1. Purpose

The purpose of this SOP is to describe the requirements for IRB members to maintain the confidentiality of protocol reviews.

2. Policy

It is the policy of the IRB to maintain strict confidentiality of all reviews and other actions.

- 2.1** All IRB members will keep confidential all protocols and other information pertaining to research reviewed by the IRB, which is unavailable to non-IRB members.
- 2.2** All IRB review material must be secured in a locked personal file cabinet or disposed of in a manner which preserves confidentiality. IRB material should not be left unsecured in the IRB meeting room. Materials are left in the room at the end of the meeting for proper filing/shredding by IRB staff.
- 2.3** Protocols without a proprietary information/confidentiality restriction may be discussed with expert internal or external consultants. In such cases, the ORC should be notified. Confidentiality should be safeguarded by assigned consultants.
- 2.4** In the case of protocols with a proprietary information/confidentiality restriction, which require consultation with an internal or external consultant, the ORC should be notified in advance and approval obtained from the IRB Chair. Confidentiality should be safeguarded by assigned consultants.
- 2.5** All IRB members will have a signed Institutional Review Board Confidentiality Agreement on file in the ORC.

RPP Policy: 2.09 IRB Reviewer Assignment

1. Purpose

The purpose of this SOP is to describe IRB reviewer assignment for *Full Board* meetings, *expedited*, *exemption*, *continuing* and *requests for modification* reviews.

2. Policy

It is the policy of the IRB to assign reviewers who have knowledge of IRB procedures and research, and specific knowledge of the issues in the area under review.

2.1 The RCO, if necessary in consultation with the IRB Chair, will assign primary reviewers for *Full Board* meetings.

A. The assigned reviewers for the *Full Board* meeting must prepare to present the protocol and propose recommendations to the Full Board.

B. After the Board has convened, if the *Full Board* deems it appropriate, the primary reviewer who presented the protocol will continue as primary for the protocol until its approval.

1. A secondary reviewer will then be assigned.

a) Only a member who attended the Full Board meeting in which the protocol was presented may serve as a secondary reviewer.

2.2 If the Chair or a member has a concern about a COI or an appearance of a COI, they should recuse themselves from reviewing the protocol in question.

2.3 A PI who is concerned about a COI on the part of any IRB member relative to his/her protocol is encouraged to contact the IRB Chair.

A. The Chair and the RCO will meet with the PI to hear his or her concerns.

1. Appropriate documentation will be maintained to reflect this process.

B. Irrespective of the findings, the protocol will be assigned to reviewers who are not associated with the PI's concerns.

2.4 The RCO, based on the duty roster, will assign reviewers (primary and secondary) for *expedited, exemption, continuing, and requests for modification* reviews.

A. The primary reviewer is responsible to summarizing issues raised by both the primary and the secondary reviewers and for forwarding them to the RCO.

1. If the contact between reviewers has not been initiated within five (5) calendar days after the protocol has been assigned, the RCO and/Chair must be contacted by the reviewer who has been attempting to make contact.

a) The RCO and Chair may reassign the protocol to a new member or the Chair may step in to replace the non-responding reviewer.

B. The summary will be sent by email to the RCO and will cc the secondary reviewer.

C. The summary will include:

1. Concerns raised by both reviewers, and if appropriate, recommendations for change.

2. Concerns raised by only one of the reviewers - and these must be noted as a minority concern.

3. A final disposition of the request:

a) Approval as is;

b) Approval pending minor changes;

c) Revise and resubmit for re-review; or

d) Refer to Full Board review.

D. Revisions, corrections and any changes to the protocol currently under review will be forwarded to the initial primary and secondary reviewers for evaluation.

1. If the disposition of the review is “Approval pending minor changes,” the final draft will be sent back to only the primary reviewer.

E. The responsibility to a protocol continues even when the reviewer is not on call for protocol evaluation.

F. If one of the reviewers is not available, the Chair:

1. may step-in to serve as a second reviewer.

2. The senior reviewer (the reviewer continuing on the protocol) will serve until the protocol is approved.

a) Or, the chair can select someone else to serve if the senior member is not available.

RPP Policy: 2.10 Written Reviews by IRB Members and Development of the IRB Review Letter

1. Purpose

The purpose of this SOP is to describe the procedures for submission of written reviews by IRB members.

2. Policy

It is the policy of the IRB for IRB reviewers to submit written comments regarding the IRB application, the detailed protocol, the consent/assent documents, and other pertinent issues.

2.1 Reviews for Full Board meetings are submitted orally during the IRB meeting.

A. The RCO will summarize the concerns raised by the presenting reviewer and additional ones raised by the Board.

2.2 Reviews for expedited and exempt protocols are submitted electronically to the Administrator.

A. Each review should be presented in a separate email or on the appropriate web-page.

B. The email should cc the Secondary Reviewer.

2.3 Significant deficiencies and/or major points for clarification which require revision of the IRB application should be described fully, sequentially, and referenced to sections of the IRB application using the IRB Review Form. The detailed protocol should be referenced as necessary.

2.4 Significant deficiencies in the consent form (i.e., errors, inadequate explanations, nondisclosure of pertinent information such as risks(s), or inappropriate readability level) should be described sequentially according to the section of the consent form (i.e., the elements of consent).

2.5 If an IRB member wishes to assist an investigator in carrying out revisions for minor improvement of language, this assistance should be accomplished via a post-IRB review personal consultation. The IRB review letter should refer to this consultation as the mechanism by which further details will be provided.

A. To ensure the ORC has complete documentation of all requested changes and revisions, the summary of such a consultation must be in writing, directed to the researcher and the Office of Research Compliance.

2.6 IRB review letters, issued following a *Full Board* meeting, which reflect the decisions of the board, are developed by the RCO.

2.7 IRB review letters, issued following an expedited, exempt or continuing expedited review, which reflect the decisions of the primary and secondary reviewers, are developed by the RCO in consultation with the said reviewers.

2.8 IRB review letters must be written in a clear, explanatory, and facilitative fashion in order to assist investigators in understanding the rationale for any IRB concerns and mandated changes to the protocol and consent/assent documents. The letter must include:

A. Mandated changes.

B. Reiteration that no research may commence until:

- 1.** A revised hardcopy with appropriate signatures is on file, and
- 2.** A letter granting permission is received from the IRB

RPP Policy: 2.11 IRB Quorum and Voting Requirements

1. Purpose

The purpose of this SOP is to describe IRB quorum and voting requirements.

2. Policy

It is the policy of the IRB to conduct *Full Board* meetings in compliance with Health and Human Services regulations at 45 CFR §46.108(b).

2.1 A duly constituted quorum must include: a) a simple majority of the voting membership and b) at least one member whose primary concerns and interests are in a non-scientific area. One IRB member may fulfill both criteria of non-scientist and non-affiliate (see RPP Policy #2.01) at the same meeting. The minutes reflect what capacity each member is serving for that meeting.

2.2 When the IRB reviews any protocols, amendments, unanticipated problems involving risk to the participants or others, AEs, or compliance problems related to research involving prisoners an individual prisoner representative (external consultant or IRB member) must be present in accordance with 45 CFR §46.304(b).

2.3 The RCO has the responsibility to monitor the members present at convened meetings and determine that meetings are convened appropriately and remain so.

2.4 IRB members who abstain from voting (recorded as an abstention) are included in the quorum.

2.5 Any IRB member who has a COI will be recused in accordance with Health and Human Services regulations at 45 CFR §46.107(e). IRB members with a COI are prohibited from participating in the discussion or from voting and will only provide information upon request of the IRB (see RPP Policy #3.07).

2.6 If attendance at a convened *Full Board* meeting falls below a quorum, voting does not occur. If elected by the chair, the meeting will be adjourned and reconvened at the earliest possible time, but in no case later than ten (10) business days after the adjourned meeting.

- 2.7** A *simple majority* of the IRB members, which constitute a quorum, must be present in order for a motion to pass.
- A.** Members may be present in person, audio or video conference, or web with video exchange, during the discussion and vote of the motion.
 - B.** If a member must leave the meeting *temporarily* (e.g., answer a call/conference) before the vote is taken, the vote can be delayed.
 - C.** Voting by absentee ballot is not permitted.
 - D.** If a motion fails to pass by a simple majority vote, other motions will be entertained.
 - 1.** If no further motions are made, the protocol or issue under discussion shall automatically be deemed to have been tabled and shall be referred, as needed, to an IRB subcommittee for further study.
- 2.8** At the discretion of the IRB Chair, voting may be by written ballot, a show of hands, or voice vote. The official minutes will record, without individual identification, the number of votes to approve, disapprove, table, or abstain.
- 2.9** Whenever a difference of opinions arises during an IRB meeting, the minority opinion will be included in the minutes of the meeting.

RPP Policy: 2.12 IRB Minutes

1. Purpose

The purpose of this SOP is to describe the requirements for the minutes of IRB meetings.

2. Policy

It is the policy of the IRB to maintain minutes of IRB meetings in accordance with Health and Human Services regulations at 45 CFR §46.115(a) (2).

2.1 The IRB minutes will include core minutes.

A. The core IRB minutes will identify the IRB members who are present, IRB alternates who are serving to replace an IRB primary member, IRB alternates who are non-voting and are present, consultants, and administrative staff who are present, and any guests in attendance at the meeting.

2.2 The core IRB minutes will include: 1) the names of IRB members who have a COI and are recused (absent) from the discussion and the vote, and 2) a notation indicating that a COI was the reason for the absence.

2.3 The core IRB minutes will include the names of IRB members who do not have a COI, but are absent from the room at the time of the vote.

2.4 The core IRB minutes will include only the vote counts for all board actions (e.g., for, against, and abstentions).

2.5 The core IRB minutes should include, if relevant, a written summary of the discussion and resolution of controversial issues. A controversial issue is clarified for the purposes of this policy as one, which generated an un-resolved discussion among members of the IRB over a human participant protection issue. Examples include, but are not limited to:

A. Concerns over the acceptability of the risk-benefit relationship of the research.

B. Concerns over additional protections for a vulnerable participant population, and whether the protocol meets the requirements of Subpart C or D.

C. Concerns over investigator's qualifications.

D. Concerns related to noncompliance.

2.6 The core IRB minutes will include a determination of when continuing review is required more often than annually, as required by Health and Human Services regulations at 45 CFR §46.109(e).

1. This determination will be based upon factors such as:

- a)** the risk level of the research,
- b)** inclusion of a vulnerable participant population,
- c)** and a history of PI noncompliance.

2.7 The core IRB minutes will include the duration of IRB approval accorded to a protocol, only if it differs from the 1 year time frame.

2.8 The core IRB minutes will include specific comments relevant to the inclusion of certain (e.g., vulnerable) populations.

3. Core minutes may also include justification of any deletion or substantive modification of information concerning risks or alternative procedures contained in the DHHS-approved sample consent document.

3.1 The core IRB minutes will include an IRB determination of which projects need verification from sources other than the investigator that no material changes have occurred since the previous IRB review. This determination will be based on a history of noncompliance as well as other factors as the IRB deems appropriate.

3.2 In addition to the review of pending applications, core meeting minutes will include information regarding *expedited*, *exemptions* and *continuing* approvals, modifications, and any other business appropriate for IRB meetings that have arisen since the last meeting.

3.3 The IRB minutes addenda (detailed review letters to investigators) may include any of the following:

- A.** The basis for requiring changes in or disapproving research.
- B.** Any IRB required modifications of the initial IRB protocol, consent/assent documents, requested clarifications, or request for additional information.
- C.** IRB required modifications of amendments to the IRB application and consent/assent documents.
- D.** IRB required actions in response to reports of unanticipated problems involving risk to the participant or others.
- E.** Documentation of compliance with the requirements of Health and Human Services regulations at 45 CFR §46 Subparts B, C and D as applicable. This may include documentation of determinations required by the regulations and the protocol-specific findings justifying those determinations.
- F.** Documentation of compliance with Health and Human Services regulations at 45 CFR §46.111(b), which require additional protections for vulnerable participants, such as persons who are decisionally impaired, persons who are economically or socially disadvantaged, and patients who are terminally ill.
- G.** Documentation of IRB determinations involving waiver or alteration of informed consent, in accordance with Health and Human Services regulations at 45 CFR §46.116(d) including protocol-specific findings justifying those determinations. (see RPP Policy # 9.06).
- H.** Documentation of IRB determinations involving a waiver of the requirement for obtaining a signed consent form in accordance with Health and Human Services regulations at 45 CFR §46.117(c) (1)(2) (<http://www.hhs.gov/ohrp/humansubjects/guidance/statute.htm>)

3.4 Copies of the core minutes are distributed to IRB members, the IO (or his designate), and other administrative officials as appropriate within ASU.

3.5 The IO (or his designate) and all IRB members have access to complete copies of IRB minutes and files.

3.6 The complete IRB minutes will be provided to OHRP, auditing groups, and the courts, in accordance with all applicable federal, state, and institutional requirements, when requested.

RPP Policy: 2.13 RPP Policy Review and Approval

1. Purpose

The purpose of this SOP is to describe the review and approval process for RPP policies.

2. Policy

It is the policy of the IRB to continually, and at least annually, assess the adequacy of existent policies and the need for new policies as the field of research ethics and human participant protection evolves. At least once every four years, in the Fall semester, the IRB will implement a process to review all of its policies and procedures to be completed and voted on that academic year.

2.1 Proposed RPP policies which impact significantly the IRB review system investigators, and the Institution will be reviewed and approved by the following:

A. The IRB with the Chair acting as designated signatory,

B. The RCO,

C. The IO designate, and,

D. In some cases, the IO.

2.2 RPP internal administrative procedures will be shared with the IRB for their information but do not require formal approval.

2.3 When a draft policy is scheduled for review at the IRB meeting, all members of the IRB will be given a copy of the draft policy approximately one week in advance of the meeting.

2.4 All IRB members will be invited to attend the meeting at which the policy will be reviewed.

2.5 In the case of policy changes, all IRB members have the right to cast their vote (for, against, or abstain) either in person at the IRB meeting or via email.

2.6 IRB members may provide arguments in support of their vote or, if absent, request that another IRB member present his or her position to the Board.

2.7 In instances where approval of a policy is necessary before the next regularly scheduled meeting, voting procedure by email alone will be allowed for consideration of a policy.

2.8 In order for a policy to be approved or disapproved, a majority of the entire IRB membership must vote in favor, either in person or by email, for the motion to carry.

- 2.9** If the motion to approve a policy fails to pass, the draft policy may be referred to the IRB Chair or an IRB subcommittee for further discussion and revision before reconsideration.

RPP Policy: 2.14 IRB Records

1. Purpose

The purpose of this SOP is to describe the maintenance and composition of IRB records.

2. Policy

It is the policy of the IRB that records will be maintained in full accordance with Health and Human Services regulations at 45 CFR §46.

2.1 Under Health and Human Services regulations at 45 CFR §46.115, the IRB will maintain documentation of all IRB activities.

2.2 Where appropriate, the ORC will maintain all records, reports, and other required documents as specified by federal regulations and ASU policies on record retention.

The following documentation will be maintained for a minimum of three years:

- A.** Copies of all research protocols reviewed.
- B.** Scientific evaluations, if any, which accompany the protocols.
- C.** Progress reports submitted by research investigators.
- D.** Reports of injuries to participants.
- E.** Reports of unanticipated problems involving risk to participants (including AE reports) and documentation of IRB review of these reports.
- F.** Minutes of IRB meetings.
- G.** Records of continuing review activities
- H.** Copies of all correspondence between the IRB, ORC, and the research investigator.
- I.** List of IRB members and alternates.
- J.** DHHS-approved sample consent documents.
- K.** Summary of the study that was provided to the participants if there were significant new findings.

- 2.3** The IRB protocol files will include:
- A.** IRB application.
 - B.** Detailed protocol.
 - C.** Federal grant applications (as appropriate).
 - D.** Approved informed consent/assent documents (as appropriate).
 - E.** Initial IRB review letter to the PI, including citations of appropriate federal regulations utilized during IRB review of research involving: prisoners (45 CFR §46 Subpart C) and/or children (45 CFR §46 Subpart D).
 - F.** PI response to the IRB review letter.
 - G.** Further correspondence regarding IRB review of the application.
 - H.** Final IRB approval letter. The letter must include documentation of approvals under Health and Human Services regulations for *exemption* status [45 CFR §46.101(b)], and *expedited* and *continuing* status [45 CFR §46.110].
 - I.** IRB approval of recruitment materials and copies of the IRB approved materials.
 - J.** All requests for changes and the correspondence pertaining to the request:
 - 1.** Copies of the modified protocol
- 2.** Copies of the modified IRB approved and stamped consent form.
- K.** All Continuing Reviews and the correspondence pertaining to the request.
 - 1.** Copies of the consent documents approved in conjunction with continuing review.
 - L.** All interim progress reports, if requested or required.
 - M.** Reports of unanticipated problems (internal AEs, internal fatal AEs, external AEs, and unanticipated problems involving risk to the participant or others) and the correspondence pertaining to the reports. (Copies of supporting documentation and consent documents will be attached to the report.)

N. Incidents of noncompliance, including documentation of investigation, correspondence, and reports to institutional officials and OHRP, where appropriate.

1. Results from correspondence regarding the findings.

2.4 The protocol file is maintained by order of date, with the most current records at the front of the file. Additional files are added as required.

2.5 Paper copies of the IRB protocol records are maintained in the ORC until the protocol is completed or terminated.

A. The complete file is maintained in the terminated files until three years after the original termination date.

B. Once a year (or more often as necessary), these files are scanned and archived on the secure server and also saved on an external computer media (flash drive etc.).

C. Original paper files are destroyed once a select group of files are reviewed for completeness.

D. The media discs are stored indefinitely for future reference or inspection by Health and Human Services, Food and Drug Administration, or other sponsor representatives during auditing visits.

2.6 The IRB maintains a secure database. The database is under constant revision to add information necessary to more efficiently provide service to the IRB and investigators. Current database will contain:

A. IRB protocol number.

B. Title of Protocol.

C. Review category (exemptions, expedited, continuing, or Full Board), and the specific category of exemption where applicable.

D. Date protocol was received, expected decision date by reviewers, dates of Full Board meeting(s), date of approval, begin and end dates for the project, continuing review, date for reminders (if necessary), date of approved protocol change, date by which additional information is needed.

E. Status of the study (approved, disapproved, pending review, preliminary approval, tabled, terminated, withdrawn, and preliminary review).

F. Principal investigator's name and contact information (department, address, phone number, and email address).

G. Supervising investigator's name and contact information (department, address, phone number, and email address).

H. Special considerations associated with the study (videotaping, audio taping, chemical materials, radioactive materials, photography, etc.).

I. Funding status and source.

J. Investigator type (faculty staff or student).

K. Project type (research or required classroom project)

L. Number of participants.

M. Types of participants (adults, ASU students, minors, adults with legal representatives, persons with limited civil freedom, person with psychological impairment, persons with mental retardation, persons with neurological impairment, HIV positive persons, pregnant women, fetuses, victims, others).

N. Waivers granted (type).

2.7 The IRB also maintains a separate password protected database for the purpose of tracking training completion.

Section 3: Initial IRB Review of Protocols

RPP Policy: 3.01 Investigational Activities Requiring IRB Review and Approval

1. Purpose

The purpose of this SOP is to describe investigational activities requiring IRB approval.

2. Definitions

2.1 Research is defined by HHS regulations at 45 CFR §46.102(d) as “*any systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.* Activities which meet this definition constitute research for purposes of this policy, whether or not they are or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.”

For purposes of this part, the following activities are deemed not to be research:

- (1) Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary, criticism, legal research, and historical scholarship), including the collection and use of information that focuses directly on the specific individuals about whom the information is collected.
- (2) Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health importance (including trends, signals, risk factors, patterns in diseases, or increase in injuries from using consumer products.) Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters),
- (3) Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.
- (4) Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.102>

A. The Belmont Report provides further clarification of “research” as follows: “... *the term ‘research’ designates an activity designed to test a hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge (expressed, for example, in theories, principles, and statements of relationships).*”

B. Research is defined by FDA regulations as *any experiment that involves a test article and one or more human subjects and that either is subject to requirements for prior submission to the Food and Drug Administration under Section 505(i) or 520(g) of the act, or is not subject to requirements for prior submission to the Food and Drug Administration under these Sections of*

the act, but the results of which are intended to be submitted later to, or held for inspection by the Food and Drug Administration as part of an application for a research or marketing permit.“ The term does not include, experiments that are subject to the provisions of part 58 of this chapter, regarding nonclinical laboratory studies. An activity is an experiment when: It involves any use of a drug, other than the use of a marketed (approved) drug device in the course of medical practice: It involves the use of a medical device (approved or unapproved) to evaluate the safety or efficacy of that medical device; OR it involves the collection of data to be submitted to or held for inspection by FDA.

C. Important in this definition are the words “designed to contribute to generalizable knowledge.” A study must be systematic and *designed* to contribute to generalizable or transferable knowledge in order to be considered research that must meet the requirements of the human subject regulations. Although publication is often viewed as evidence of research status, it is not the only criterion. “systematic investigations” often result in published studies, yet they do not qualify as research because they were not designed to contribute to generalizable knowledge. In general, activities that contribute to generalizable knowledge are those that attempt to make comparisons or draw conclusions from the gathered data; attempt to identify generalizable principles of historical or social development; seek underlying principles or laws of nature that have predictive value and can be applied to other circumstances for the purpose of controlling outcomes; create general explanations about all that has happened in the past; or predict the future.

D. Generalizable knowledge is not limited to quantitative studies designed to produce generalizations. Qualitative studies may also contribute to generalizable knowledge through the use of focus groups, case studies, ethnographies, interviews, or other means to identify general themes that the reader can choose to transfer to another situation.

2.2 Human Subject is defined by HHS regulations at 45 CFR §46.102(f) as, “*a living individual about whom an investigator (whether professional or student) conducting research obtains, 1) information or biospecimens through intervention or interaction with an individual, and, uses studies, or analyzes the information or biospecimens; or (ii) obtains, uses, studies, analyzes or generates identifiable private information or identifiable biospecimens*”.

A. Human Participant Research means an activity that either meets the DHHS definition of research and involves human participants as defined by DHHS regulations or meets the FDA definition of research and involves human participants as defined by FDA regulations.

2.3 Intervention *includes both physical procedures by which data are gathered (e.g., drawing blood) and manipulations of the participant or the participant’s environment that are performed for research purposes.*

2.4 Interaction *includes communication or interpersonal contact between investigator and participant.*

2.5 Private Information *includes information about behavior that occurs in a context in, which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (e.g., academic record information).*

2.6 Individually Identifiable Information *is information where the identity of the subject is or may readily be ascertained by the investigator or associated with the information (e.g., only male teacher in school is readily ascertainable.)*

2.7 Systematic Investigation, for the purposes of this policy, *is an activity that involves a prospective research plan that incorporates data collection, either quantitative or qualitative, and data analysis in order to answer a research question.*

2.8 Investigations designed to develop or contribute to **generalizable knowledge** *are those designed to draw general conclusions (i.e., knowledge gained from a study may be applied to populations outside of the specific study population), inform policy, or generalize findings.*

3. Policy

IRB approval is required for **all** research involving human participants as defined above, which is conducted by faculty, students, staff, or others under the jurisdiction of the IRB, (i.e. research performed on the premises of ASU, as well as research involving human participants conducted elsewhere by investigators as part of their institutional responsibilities, unless the investigation is conducted under a cooperative research agreement.)

A. In reviewing research involving human participants, the IRB will apply 45 CFR §46 in accordance with RPP Policy #1.02.

B. The IRB classifies research as social science/ behavioral or biomedical.

3.2 Classification of Human Participant Research

A. Social Science and Behavioral Research

1. Social science and behavioral research includes all research performed with intent to develop generalizable knowledge about behaviors, attitudes and interactions among and between individuals, groups, and cultures. Generally this category of research has no intent of producing a diagnostic, preventive, or therapeutic benefit to the participant who is not seeking nor expecting a health benefit from the research. There may, or may not, be any prospect of direct participant benefit associated with this category of research.

2. Types of research involving human participants that may fall under the social science and behavioral research category include, for example:

- a) Qualitative social science research
- b) Ethnographic research
- c) Oral history research
- d) Observational research
- e) Survey research
- f) Education research
- g) Criminal justice research
- h) Other – at various times other disciplines might perform research falling under the jurisdiction of the IRB. For example, an engineering protocol might research how individuals respond to certain engineering techniques.

B. Biomedical Research

1. Biomedical research at ASU generally, but not exclusively, refers to clinical/patient oriented investigations, biomedical engineering research, and exercise science and nutrition studies research. Such protocols will not be reviewed by the standing IRB, and, if need be, a special panel will be convened.

3.3 Examples of non-Research Activities

A. Quality Improvement

- 1. In general, quality improvement projects are not considered research unless there is a clear intent to use the data derived from the project to contribute to generalizable knowledge.
- 2. If a quality improvement project is completed (i.e., all the data are collected, analyzed, and conclusions have been drawn) and the decision is made to publish or present the data, it is research. Depending on whether or not participant identifiers are maintained, it may qualify for an exemption.

B. Student Projects or Classroom Demonstrations

1. Student projects are considered research when there is a clear intent to contribute to generalizable knowledge. However, a student project that is conducted *within the confines of the classroom only* is not considered research. In this case, the student's supervisor and/or department are responsible to exert appropriate oversight of the project.
2. Student research involving a vulnerable population or a special class of participants is never exempt from review and requires IRB approval.

3.4 Determination of When an Activity Constitutes Human Participant Research

A. Any individual who is unsure whether or not a proposed activity constitutes "research involving human subjects" should contact the ORC for guidance.

1. ORC staff and/or the IRB Chair will determine whether a given project is subject to 45 CFR §46 and any other requirements dictated by a federal sponsor.

- a) ORC staff and the IRB Chair will use the OHRP Human Subject Decision Charts (Human Subject Regulations Decision Charts, September 24, 2004) as necessary to determine whether the research meets the DHHS definition of "research" and involves "human subjects" as defined by DHHS regulations.

- b) ORC staff and/or the IRB Chair then will determine whether a given project meets the FDA definition of "research" and involves "human subjects" as defined by FDA regulations.

2. If the research meets the FDA definition of research and involves human subjects as defined by federal regulations, the project will be assigned to Alabama State University IRB for review assisted by consultants with previous experiences with IRB review of FDA studies.

B. When there is any question concerning whether or not an investigator will be engaged in research, ORC staff and/or the IRB Chair will consult with OHRP.

C. Decisions about whether an activity represents human participant research are made promptly and conveyed to the individual seeking an opinion. All decisions will be explained fully in order to ensure the Institution's faculty, staff, and students understand the criteria used in making the determination.

3.5 Type of Review

The type of IRB review required depends upon the nature of the proposal (e.g., *full board*, *expedited*, *exemption* or *continuing*). these categories (except for continuing review) are determined by the IRB based on perceived level of risk to the participants.

A. The IRB may make a determination that a project required *Full Board* or *expedited review* when the level of risk to participants is perceived to be more than minimal.

1. In protocols that represent more than minimal risk to participants, such as those reviewed by the Full Board or by expedited review, the procedures for consent, as outlined in the federal code of regulations, will be followed.

B. A project involving no more than minimal risk to human participants may qualify for an *exemption*.

1. When an exemption is granted by the IRB, it may elect to waive signed consent or assent.

C. A *continuing review* is a review of a project that has been approved by the IRB to extend past its original expiration date.

1. Projects approved after the implementation date of July 19, 2018 will no longer be subject to a continuing review, unless the IRB finds and documents the need to require a continuing review to enhance the protections of research subjects.

2. ASU's IRB may require continuing review for minimal risk research when the research involves:

a) As determined by the IRB because of a change in risk, protection or inclusion of subjects, or other concerns that require increased oversight;

b) Principal Investigator (PI) or co-PI's who have received a determination of continuing or serious non-compliance in the past two years;

c) Projects that involve deception that is not prospectively authorized; or

d) A conflict of interest management plan exists.

3. Existing projects will be assessed to determine if they should transition to the new rule.

D. Office of Research Compliance staff and the IRB Chair will use the OHRP Human Subject Regulations Decision Charts (September 24, 2004) as necessary, in determination of the type of review.

(<http://www.hhs.gov/ohrp/humansubjects/guidance/decisioncharts.htm>).

3.6 Post-hoc Approval

A. There is absolutely no post-hoc approval of a research project or approval of data collected under any conditions in which there was not a timely IRB approval of the project.

RPP Policy: 3.02 Ethical Principles Governing Research Under the Jurisdiction of the IRB

1. Purpose

The purpose of this SOP is to describe the ethical principles which govern research under the jurisdiction of the IRB.

2. Policy

It is the policy of the IRB that all research which is reviewed and approved by the Board and conducted under its jurisdiction will generally conform to the following guidance documents: 1) The Nuremberg Code and 2) The Belmont Report. Health and Human Services regulations (45 CFR §46) reflect the basic ethical principles for the conduct of human participant research found in these documents.

All researchers, participating personnel, and IRB members are charged with upholding the ethical principles contained in the aforementioned guidance documents as they apply to the research project in question. The IRB protocol and consent document review form and the process of IRB review are designed to help IRB members and investigators ensure that research reflects the highest possible ethical standards (RPP Policy # 3.04).

2.1 The Nuremberg Code

The Nuremberg Code contains 10 basic principles, which are presented in abbreviated form below:

A. The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, overreaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision.

B. The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.

C. The experiment should be so designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problem under study that the anticipated results justify the performance of the experiment.

D. The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.

E. No experiment should be conducted where there is an a priori reason to believe that death or disabling injury will occur; except, perhaps, in those experiments where the experimental physicians also serve as subjects.

F. The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.

G. Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability or death.

H. The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment.

I. During the course of the experiment the human subject should be at liberty to bring the experiment to an end if he has reached the physical or mental state where continuation of the experiment seems to him to be impossible.

J. During the course of the experiment the scientist in charge must be prepared to terminate the experiment at any stage, if he has probable cause to believe, in the exercise of the good faith, superior skill and careful judgment required of him, that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject.

2.2 The Belmont Report

In 1979, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research released the *Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research*". The three basic ethical principles described in the Belmont Report are:

A. Respect for Persons

1. The ethical principal of respect for persons has two components: acceptance of individual autonomy and protection of those with diminished autonomy. Autonomous individuals demonstrate the ability to make informed choices and act on those choices. These choices must be acknowledged and accepted by others as a demonstration of respect, as long as those choices are not harmful to others. Conversely, it must also be recognized that some individuals may be incapable of making informed choices and require special protection. The principle of respect for persons in the research context is demonstrated through the process of informed consent, including the process of assent and proxy consent for potential participants requiring special protections.

B. Beneficence

1. The principle of beneficence is defined in two ways: (1) do no harm, and (2) maximize the potential benefits and minimize all potential harms (e.g., risks) related to research participation. While there is an imperative that no harm comes to the participant, it should be recognized that there is potential for harm due to unknown factors associated with the research. To minimize this risk, the potential benefits to the participant and society must be determined and maximized.

C. Justice

1. The principle of justice implies a sense of “fairness.” Justice occurs when the burdens and benefits are equally carried by all. To achieve justice in the research context, recruitment of potential participants must occur without discrimination, bias, or undue influence in order to distribute the burdens and benefits of research equitably for individual and society good. Inequities must be justified.

RPP Policy: 3.03 Initial Application Submission

1. Purpose

The purpose of this SOP is to describe IRB deadlines, submission materials, and the IRB pre-review process.

2. IRB Deadlines

Application forms and submission deadlines can be obtained through the ASU website. Applications are reviewed in the order in which they are received.

2.1 Protocols that may require Full Board reviews must be submitted to the IRB office at least 10 business days before the next scheduled Full Board meeting to be considered at that meeting (dates are published annually and listed on the ASU website).

A. Incomplete submissions may result in delay of IRB review.

2.2 Proposals that qualify for *expedited review or exemption* may be submitted to the IRB at any time.

A. In order to qualify for *expedited* review, the protocol must be no more than minimal risk and classified under one or more of the categories listed in RPP Policy # 4.02.

B. In order to qualify for *an exemption*, the protocol must be no more than minimal risk and classified under one or more of the categories listed in RPP Policy # 4.01.

3. Materials to Include in the IRB Submission of Initial Applications

The original of each of the following (as applicable) must be submitted to the IRB in the order listed below.

3.1 IRB Application

A. ASU employs one general initial review form. There is no distinction made between the types of review being sought and the information that the PI must provide. The application must include sufficient detail to facilitate IRB review. This application form can be obtained from the ASU website.

3.2 Informed Consent and Assent Form(s)

A. The consent and assent forms must be appropriate for the proposed study population (e.g., adult, proxy, parental, youth, and child).

3.3 Participant Recruitment Material(s)

A. Copies of all advertisements, letters, transcripts of broadcast materials and other recruitment material may be required by the IRB for review and approval (where applicable). This includes letters requesting permission, and letters granting approval to collect data at a specific site.

3.4 Description of performance site for all non-Institutional sites

A. Performance sites are defined as (1) sites where Institutional investigators or staff interact with participants, collect data, or solicit consent, or (2) sites over which the IRB has responsibility. Performance sites do not include other sites participating in a multi-center study, which have an IRB. All performance sites must be identified and described (i.e., why this site is included in the study).

3.5 Other Relevant Materials

A. Originals or copies of all surveys, assessment tools, screen shots of websites and other relevant materials must be submitted for IRB review.

B. Where applicable, a copy of the detailed protocol and a copy of the *complete* grant narrative (i.e., excluding form pages, budget, biosketches, etc.).

4. IRB Pre-Review

4.1 As new applications are received by the IRB office:

A. The protocol will be officially registered in the IRB database and assigned an IRB protocol number.

B. The PI will be sent an email verifying receipt of the protocol and will be provided with an IRB protocol number.

1. This protocol number will be the identifier of the protocol for the life of the study.

4.2 All applications submitted for IRB review are screened by the IRB staff to determine that:

A. All required documents have been submitted and are complete

B. All personnel listed on the application (PI, Supervising Investigator, and other Participating Personnel) are currently CITI certified (required training in the protection of human participants - see RPP Policy #3.09).

4.3 The PI, or his/her designate, will be contacted by email or phone to correct errors, provide missing documents, or provide additional information.

4.4 The reviewer has 30 days from the date assigned by the IRB to complete the initial review. When revisions are required the PI will have 10 days to submit the revisions. *Due to the changes in terms resulting from COVID-19, the Institutional Review Board will review protocols within 15 calendar days. When revisions are required, the PI will have 5 days to submit the revisions.

RPP Policy: 3.04 Criteria for IRB Approval of Research

1. Purpose

The purpose of this SOP is to describe the criteria required for IRB approval of human subjects research.

2. Policy

It is the policy of the IRB that all requests for review (*Full Board, expedited, exemption, and continuing*) will undergo rigorous scrutiny, which will allow a determination that the protocol meets: 1) the criteria specified in Health and Human Services regulations at 45 CFR §46.111 and 2) IRB RPP policies and procedures.

3. Criteria for IRB Approval

3.1 Purpose of the study

A. The IRB may determine if the background and literature citations support the of the study (see RPP Policy #3.06) relative to the risks to participants.

3.2 Characteristics of the participant population

A. The IRB will examine the characteristics of the proposed participant sample to determine whether:

1. the eligibility criteria are appropriate with respect to the nature and goals of the research and

2. the selection of participants is equitable without any form of discrimination or bias. Any proposed exclusion of persons on the basis of age, sex, reproductive status, race/ethnicity, or any other stated factor must be justified scientifically by the investigator. In particular, the following will be examined:

a) **Accrual** The IRB must be assured that the maximum number of participants consented to this study is sufficient for the purpose of this study and sufficient justification is provided relative to risk to the participant.

b) **Gender** The IRB must be assured that the proposed distribution is suitable for the purpose of the study and appropriate justification for the inclusion or exclusion of males or females is provided. Furthermore, women of childbearing potential and pregnant women should not be excluded from participation in research unless sufficient justification is provided.

c) **Age range of participants** The IRB must be assured that the proposed age range is suitable for the purpose of the study and appropriate justification for the inclusion or exclusion of particular age groups or persons, such as children or the elderly, is provided.

d) *Race and ethnicity* The IRB must be assured that the proposed distribution of participants by race/ethnicity is suitable for the purpose of the study and appropriate justification for the inclusion or exclusion of particular persons or groups is provided.

e) *Vulnerable participants*

The IRB will determine if the research is approvable for inclusion of vulnerable populations under Health and Human Services regulations at 45 CFR §46, Subpart C (prisoners [RPP Policy # 5.03) and Subpart D (children RPP Policy # 5.004). In addition, the IRB will determine if special protections are required for persons who are decisionally impaired (RPP Policy # 5.05) as well as other potentially vulnerable populations.

f) *Inclusion/exclusion criteria*

The inclusion and exclusion criteria are appropriate for the purpose of this study. The stated exclusion criteria minimize risk to potential subjects.

3.3 Methods and Procedures

1. The IRB must determine if the interventions and follow-up procedures are appropriate for the stated purpose of the research and, whenever appropriate, procedures are used, which already will be performed on the participants for diagnostic or treatment purposes. Interventions and procedures considered standard of care must be clearly identified clearly.
2. The IRB accepts the need for certain types of behavioral and social science studies to employ strategies that include either deception and/or the withholding of information. Employment of such strategies must, however, be justified. In general, deception is not acceptable if, in the judgment of the IRB, the participant would have declined to participate had they been informed of the true purpose of the research. Studies that use deception and/or the withholding of information as part of their experimental design must meet all the requirements of 45 CFR §46.116(d), described below, and include a post-study debriefing, unless an exception is granted by the IRB.
3. In the event that a study includes the use of deception, the investigator must:
 - a) Provide a justification for the deception (i.e., why the study could not be conducted without deception);
 - b) Describe the manner of deception (e.g., the participants are not informed of the true intent of the study) and/or how the deception will take place (e.g., a confederate will simulate an accident);
 - c) Note whether the deception results in any increased risk to participants (e.g., confederates engage in a staged altercation, which could result in emotional upset); and

d) Describe how any additional risks would be minimized (where appropriate).

3.4 Data storage and confidentiality

1. The length of time required to store data is 3 years.
2. Special guidelines for storage of data are a function of the sensitivity of the material and are the responsibility of the Primary Investigator.
3. The IRB will review the methods to be used to protect confidentiality and will ensure that appropriate protections are in place in consideration of the nature of the research, the vulnerability of the participant population, and the risk associated with a breach of confidentiality.

a) If research data with participant identifiers will be made available to persons other than the listed investigators, sponsor, or federal agency, the IRB will review the justification for sharing this data and determine acceptability in accordance with all applicable regulations, including the HIPAA Privacy Rule (RPP Policies # 10.01 and #10.02).

b) If the research involves the collection of sensitive information where a breach of confidentiality would constitute a serious risk, the IRB will consider the need for a Confidentiality Certificate (RPP Policy # 3.11). The IRB may also waive documentation of informed consent in accordance with 45 CFR §46.117(c).

3.5 Risk – Benefit Assessment

The IRB will review the research design in order to be assured that the potential risks to the participants are minimized and the potential benefits maximized by utilization of procedures consistent with sound research design and, which do not unnecessarily expose participants to risk (see RPP Policy #3.06).

1. Potential Risks

a) Both immediate and latent (delayed) risks of any procedure involving human participants will be reviewed by the IRB to ensure that risks to participants are identified and minimized. The estimated probability, severity, average duration, and reversibility of any potential harm will be considered according to available empirical data. Furthermore, since certain populations of vulnerable participants may be at greater risk than others, the IRB will take into consideration the potential risk characterization of the participant and ensure that appropriate additional protections are in place.

2. Risk Classification

a) Risk is classified as: 1) minimal, 2) greater than minimal, or 3) significant. The IRB will review carefully the risk classification of the research, as it will determine the type of IRB review and interim review requirements.

b) Minimal risk is defined as follows: *"The probability (of occurrence) and magnitude (seriousness) of harm or discomfort (e.g., physical, psychological, social) associated with the research are not greater than those ordinarily encountered in daily life (of healthy persons in the general population) or during the performance of routine physical or psychological examinations or tests."*

c) A uniform standard of minimal risk based upon the daily life of a normal, average, healthy person living in a safe environment or during the performance of routine physical or psychological examinations or tests he/she would be expected to encounter will normally be used for research involving adults. However, under certain circumstances, application of the minimal risk classification will be based upon a consideration of the risks inherent in each participant's life thereby resulting in a relative standard of minimal risk, *which is more stringent*. Factors such as age, repetitive procedures, and vulnerability will be considered in determining if a study qualifies as minimal risk.

d) When research involves children, a uniform standard of minimal risk also will be employed, which is based upon the daily life of a normal, average, healthy child living in a safe environment or the performance of routine psychological and medical examinations he/she would be expected to encounter as part of a standard well-child examination.

3. Minimization of risk (data and safety monitoring)

a) The IRB will review data and safety monitoring that must fit the design, nature, and risk profile of the research. In some cases, the nature of the research may require a safety and monitoring plan (see RPP Policy #3.10). Such a plan is meant to assure that the research project has appropriate oversight. The oversight ensures the safety of the participants and the integrity of the data. The IRB will determine whether or not a research project requires review more often than annually (RPP Policy # 3.10) and will establish appropriate reporting and/or monitoring procedures that may include observation of the consent process, observation of on-going research, or review of research records (see RPP Policy #7.01).

b) The IRB also will determine whether a research project requires verification from sources other than the investigators that no material changes have occurred since the previous IRB review (RPP Policy #3.10).

4. Potential Benefits

a) The IRB will review the anticipated benefits to both the participant and to society. In addition, the IRB will consider whether the benefits are maximized to the greatest extent possible through proper protocol design. Financial or other forms of compensation are not considered a benefit to be derived from research participation. Although the participant may consider financial compensation a desirable outcome, this fact will not be used in the risk-benefit analysis.

5. Alternatives to Participation

a) The IRB will review the alternatives outside of the research context that are available and may be of reasonable benefit to the participant.

3.6 Participant Financial Obligations

A. The IRB may review the financial obligations of the participant relative to participating in the study. The IRB application should clearly identify who will be financially responsible for research-related interventions or procedures, as well as other potential costs of participation (e.g., travel, child care, food).

3.7 Compensation for participation

A. The IRB will review the amount of compensation for participation (monetary, as well as other forms) in order to ensure that it is not coercive and is fair (see RPP Policy # 3.15).

3.8 Conflict of Interest

- 1.** The IRB will review any potential COI on the part the principal investigator (see RPP Policy # 3.07). This review will be based upon the Board's charge to ensure protection of the rights and welfare of human participants. This charge includes authority to:
- 2.** Ensure disclosure in the consent document of any financial interests of the investigator, which are judged by the IRB to be material to the participant's decision whether or not to participate in research.
- 3.** Ensure there is an appropriate plan for monitoring of the research, which may involve observation of the consent process, auditing of records, and interim

reporting of research results to the IRB.

4. Require informed consent be obtained by a qualified individual other than the principal investigator. If the IRB finds that the COI management plan requires additional measures, the Board will alter the management plan in accordance with its charge and forward the revised plan to the COI Research Officer.

3.9 Participant identification and recruitment

1. The IRB may review the method of prospective participant identification and recruitment in order to be assured it is ethically and legally acceptable (see RPP Policy # 3.16). Advertisements (e.g., newspaper ads, fliers, radio ads, etc.) used to recruit participants are considered an extension of the recruitment and informed consent processes, and, therefore, must be reviewed by the IRB.

2. Informed consent and assent

a) Definition of Consent: A procedure to ensure that a participant knows all of the risks and costs involved in the proposed research project.

b) Definition of Assent: A child's active agreement to participate in research.

c) The elements of informed consent include:

- a) informing the participant of the nature of the research
- b) possible alternative to the research protocol
- c) the potential risks and benefits of participation.

d) In order for informed consent to be considered valid, the participant must be competent and the consent should be given voluntarily.

a) The IRB will review both the consent form and the process of informed consent as described in the IRB application to ensure that consent will be sought only under appropriate circumstances, which allow the prospective participant to engage in thoughtful decision making. Specifically, the IRB will determine the following:

1) The process of consent/assent is appropriate in consideration of the nature of the research, risks of the research, and characteristics of the participant population (see RPP Policy # 9.02).

2) All required consent/assent document(s) utilize the appropriate IRB-approved templates which can be found on the ORSP website.

- The informed consent/assent form(s) contain the elements of informed consent required by Health and Human Services regulations (see RPP Policy # 9.02).
- The assent form(s) contain the IRB-required elements of assent (see RPP Policies # 9.02 and # 9.04).
- The documentation of informed consent conforms to RPP Policy # 9.02.

3.10 Investigator qualifications

The IRB (see RPP Policy #3.08) will review the PI's qualifications and must be assured that:

1. The investigator has the appropriate qualifications and licensure (when appropriate) to carry out the procedures involving human participants with an acceptable degree of risk.
2. The investigator has adequate facilities and equipment to conduct the research with an acceptable degree of risk.

3.11 Scientific and scholarly merit and resource review

- A. The IRB must ensure that the research has undergone substantive scientific and scholarly merit and resource review (see RPP Policy #3.06) within the context of risk to participants.

3.12 Letters of Agreement

Prior to final approval by the IRB, letters of endorsement or agreement must be submitted from all performance sites, which include acknowledgement of any specifications regarding their own participation and what access, services, facilities, or personnel they are going to provide for the research project.

1. If ASU is the lead site for a multi-institutional protocol, and either data are collected and analyzed at ASU, or AEs or serious problems tracked at ASU, then a copy of the approval from the IRB of all reporting sites must be provided. If additional sites are added after approval of this application, then letters of IRB approval must be submitted as they become available.
2. Letters of agreement must be received from study sites not associated with ASU (such as schools, nursing homes, and prisons), stating that the site administrator is aware of the study and will allow the Institutional PI and study personnel to utilize their site to conduct the study.

3.13 IRB Review Checklist

A. IRB reviewers are encouraged to use review checklists (available on the ASU-IRB website) as a guide, but are not required to submit completed forms.

3.14 Office of Research and Sponsored Programs Review

A. All applications for funding must be submitted to Office of Research and Sponsored Programs (ORSP). If human participants are involved, ORSP will inform the PI to contact the IRB. It is the responsibility of the PI to secure IRB approval.

3.15 Additional Administrative Review (*exempt, expedited, continuing and Full Board protocols*)

A. Research that has been approved by the IRB may be subject to further appropriate review and approval or disapproval by officials of the institution. Those officials cannot, however, approve any research project unless it is first approved by the IRB. When a study is considered controversial, particular from a community-based standpoint, the IRB Chair will forward a copy of the protocol to the IO (or designate) and the PI will be so notified.

RPP Policy: 3.05 IRB Initial Review Categories

1. Purpose

The purpose of this SOP is to describe IRB initial review categories.

2. Policy

It is the policy of the IRB that initial review of research must be appropriately classified as an *exempt*, *expedited*, or *Full Board* review in accordance with Health and Human Services regulations at 45 CFR §46.

2.1 Expedited Review and Exemption

A. If a submitted proposal qualifies for *expedited* review or *an exemption*, in accordance with Health and Human Services regulations at 45 CFR §46.101(b) (1-6), the proposal will be reviewed using the appropriate review procedure. (For definitions see RPP Policy # 4.01).

B. The IRB is the final determinant of the type of a review that a protocol requires.

C. After a review takes place, the investigator will be notified of the IRB's decision concerning the proposal. Reviewed proposals will be assigned to one of three categories:

1. Approved

a) The proposal is approved and released. The investigator may begin the study.

2. **Further Action Required** contingent upon IRB reviewer acceptance of specific modifications and/or clarifications.

a) The investigator will be notified, in writing, as to the nature of the required modifications and/or clarifications. As soon as the investigator complies in writing with all requirements to the satisfaction of the reviewers, an approval letter will be issued and the investigator may begin the study.

3. Referred for Full Board Review

a) The IRB Chair, RCO, or the reviewers have a serious concern and has determined the proposal should be reviewed by the Full Board.

2.2 Full Board Review

A. Protocols that do not qualify for *expedited* review or an *exemption* will be submitted for review to the full IRB.

B. After the IRB meeting, the investigator will be notified in writing of the IRB's decision concerning the protocol.

1. In accordance with the IRB's decision, the IRB letter will specifically detail items requiring clarification, modification or justification.

2. The PI will be requested to respond to IRB concerns.

3. The IRB minutes should reflect the IRB determination.

C. Reviewed protocols will be assigned to one of six (6) categories:

1. Approval and full release: No modifications or clarifications are required and the investigator may begin the study.

2. Further Action Required contingent upon IRB Chair or designate acceptance of specific modifications/clarifications. This category is restricted to modifications/clarifications that are not directly relevant to the regulatory determinations.

a) The investigator will be notified in writing as to the nature of the required modifications and/or clarifications. These are to be reflected in a revised and resubmitted IRB protocol.

b) When the investigator complies, with all requirements as determined by the IRB Chair or designate, a release will be issued and the investigator may begin the study.

3. Further Action Required, contingent upon full board review of specific modifications/clarifications. This category is restricted to modifications/clarifications which are considered substantive in nature.

a) The investigator will be notified in writing as to the nature of the required modifications and/or clarifications. These are to be reflected in a revised and resubmitted IRB protocol.

b) When the investigator complies with all requirements as determined by the full board at a convened meeting, a

release will be issued and the investigator may begin the study.

4. Tabled. This category is restricted to applications where the IRB requires a significant amount of additional information and/or has a serious concern.

a) The investigator will be notified in writing of the IRB's decision concerning the protocol. The IRB Chair, or a member of the Board may be assigned to discuss the protocol with the investigator.

b) When the investigators submit the required materials for re-review, the tabled protocol will be reviewed at the next IRB meeting in adherence with published submission deadlines for *Full Board* meetings. Whenever possible, the IRB reviewer who performed the initial review will be assigned to re-review the protocol. When that is not possible, the IRB reviewer is encouraged to consult, as necessary, with the previous reviewer in order to resolve any problems or concerns which may still exist.

5. Disapproved. This category is restricted to applications which have very serious design flaws and/or participants will be placed at undue risk.

a) The investigator has the right to appeal to the IRB.

b) An appeal must be done in writing. Appeals of an IRB disapproval can be made to OHRP, via the IO.

c) When appropriate, the IRB will seek consultation from nationally recognized experts in the field, other IRBs, OHRP, or the National Science Foundation Office of the Inspector General (OIG). Every attempt will be made to resolve the identified problem(s). The IRB, however, retains final authority over whether or not a proposal can be approved.

6. Decline to complete the review. This category is restricted to applications which are significantly deficient in information, content, or clarity so that an adequate review of the protocol could not take place.

a) The application will be returned to the PI with instructions to review and revise the application in consideration of application instructions and guidelines and resubmit the application to the IRB when ready.

RPP Policy: 3.06 Scientific and Scholarly Merit Review of Proposals

1. Purpose

The purpose of this SOP is to describe the requirements for scientific and scholarly merit review of all research proposals submitted to the IRB for review.

2. Policy

It is the policy of the IRB that all research proposals must undergo a substantive scientific or scholarly merit and resource review per Health and Human Services regulations at 45 CFR §46.111(a)(1)(i) and 45 CFR §46.115(a)(1).

2.1 The IRB, utilizing member expertise and/or consultants, will evaluate the scientific and scholarly validity of a proposed study within the context of risk to participants.

The IRB has broad-based disciplinary expertise, which allows a judgment to be made that the proposed research meets the following criteria in consideration of the need to satisfy scientific and scholarly merit requirements:

A. The research uses procedures consistent with sound research design within the context of risk to participants.

B. The research design will allow the proposed research question to be answered within the context of risk to participants.

C. The knowledge to be gained from the research is sufficiently important from the research or training perspective within the context of risk to participants.

D. The risk/benefit relationship is acceptable.

2.2 When the IRB does not have sufficient expertise, the Board will utilize a consultant (RPP Policy # 2.03).

RPP Policy: 3.07 Conflict of Interest Review by the IRB and Office of Research and Sponsored Programs

1. Purpose

The purpose of this SOP is to describe the IRB review process for determining a PI COI.

2. Policy

It is the policy of the IRB that the Principal Investigator (PI), the responsible party for the research, declare all perceived significant financial interests.

2.1 Each grant or contract must include a completed financial disclosure form from the PI. (Consideration should be given, when appropriate, to including other key study personnel in financial disclosure requirements.) Grants or contracts received in ORSP without the disclosure will not be processed.

2.2 The Conflict of Interest in Research (COIR) Officer or his/her designate will perform the initial review to assess the completeness of the disclosure and to determine if there is a potential financial conflict of interest. If the research involves human participants, the Chair of the IRB, or his/her designate, will participate in the initial review, as necessary, to determine if there is a potential financial conflict of interest.

A. Any investigator, or his/her spouse, parent, spouse of a parent, and dependent children, who hold(s) a significant financial interest shall be deemed to have a potential conflict of interest, which requires review by the COIRC.

B. ASU will use the National Institutes of Health criteria for determination of whether an investigator has a “significant financial interest.” A significant financial interest is anything of monetary value (e.g., consultancy, honoraria, lecture fees) provided to an investigator from a sponsor who is not directly related to the reasonable costs of conducting the research and cumulatively exceeds \$2,000 per annum. A significant financial interest as determined by ASU also includes a 5% equity ownership, which has a value greater than \$2,000.

2.3 The COIR Officer will review all potential conflicts of interest and recommend an appropriate management plan. The COIRC will review and approve the COIR management plan. If no human participants are involved, this completes the review process.

2.4 If the research involves human participants, the COIRC will perform its review prior to IRB review. The IRB will be provided with a copy of the financial disclosure form and the COIR management plan.

- 2.5** The full board will review the potential conflict of interest and the COIR management plan in terms of the Board's obligation to ensure protection of the rights and welfare of human participants. This charge includes authority to:
- A.** Ensure disclosure in the consent document of any financial interests of the investigator that are judged by the IRB to be material to the participant's decision whether or not to participate in research.
 - B.** Ensure there is an appropriate plan for monitoring of the research, which may involve observation of the consent process, auditing of records, and interim reporting of research results to the IRB.
 - C.** Require informed consent be obtained by a qualified individual other than the principal investigator.
- 2.6** The IRB will forward the results of the COIRC review, including any modified management plan back to the COIR Officer. The COIRC will review and approve the COI management plan and the plan will be carried out by the COIR Officer. However it should be noted that the COIRC may not delete any IRB COIR management recommendation within the authority of the Board as previously specified under 2.5, A, B, and C.

RPP Policy: 3.08 Qualification and Responsibilities of Research Personnel

1. Purpose

The purpose of this SOP is to describe the qualifications and responsibilities of personnel involved in the conduct of human participant research.

2. Policy

It is the policy of the IRB that all personnel involved in the conduct of human participant research must possess the required experience, skill, and appropriate licensure.

2.1 All personnel listed on the IRB application are required to complete Human Subjects Protection training through the CITI program (see RPP Policy #3.09). The IRB will not approve new protocols, changes, or re-approve existing protocols until *all* listed personnel in the IRB application have been trained.

2.2 The following are the classifications of research personnel:

A. Principal Investigator (PI)

This individual assumes *overall* responsibility for the study design, and as such, for the development and submission of the protocol to the IRB; the obtaining of informed consent/assent from prospective participants on behalf of all authorized personnel listed on the application; the conduct of the research; and the publication of the findings that ensue from data collection.

1. Only one (1) individual may be listed as a PI for a study.
2. Students may serve as the PI, and therefore may be listed on the protocol as the PI. However, a faculty member-advisor must supervise the project and be listed on the protocol as a Faculty Advisor.

B. Faculty Advisor & Other Key Personnel

These individuals assume *shared* responsibility for the project design, and as such, contribute substantively to the development and submission of the protocol to the IRB; the obtainment of informed consent/assent from prospective participants; the conduct of the research; and the publication of the findings that ensue from data collection.

1. If the PI is a student, the Faculty Advisor must co-sign the protocol before it will be accepted by the IRB for review.

C. Limited Research Worker

These individuals are required to take CITI training but must meet all the criteria listed below to qualify for such status:

1. Have no responsibilities in project design
2. Are not enrolled as a student at UAL
3. Are not ASU faculty.

And must meet at least one of the following conditions:

1. Have very limited independent decision-making responsibilities in study implementation and data collection
2. Have no role in data collection, but may have access to participant identity and confidential data.

D. Participating Personnel

These individuals are faculty or undergraduate or graduate students who have a limited or no role in project design. Therefore, they typically do not participate in the development and submission of the IRB protocol. Regardless of their specific duties on the project, participating personnel must have sufficient knowledge about the protocol and study design to effectively perform their respective project role.

RPP Policy: 3.09 Required Training in the Protection of Human Participants

1. Purpose

The purpose of this SOP is to describe training requirements for all personnel involved in conducting human participant research.

2. Policy

It is the policy of the IRB that all personnel involved in the conduct of human participant research must receive training in the protection of human participants.

2.1 Collaborative IRB Training Initiative (CITI)

Training in the protection of human participants is primarily accomplished through completion of this web-based training program.

A. Personnel to be certified

Research personnel listed on the IRB application and consent document(s) *by name* must complete one of the existing CITI trainings. Research personnel are classified as follows:

1. PIs
2. Faculty Advisors (if any) and Key Personnel
3. Participating Personnel
4. Limited Research Workers

B. Training tracks

1. Behavioral/Social Science: Basic Course to be completed by PIs, faculty advisors, key and participating personnel at ASU who conduct behavioral or social science studies.
2. Biomedical: Basic Course to be completed by PIs, Supervising Investigators, and participating personnel at ASU who conduct biomedical studies (e.g., exercise science, nutrition, or any study determined by the IRB).
3. Limited Research Worker: Basic CITI training.

C. Student research

1. All students conducting human participant research and, or, who have responsibility for project design and, or, are integrally involved in data collection must take the Basic CITI course.

D. External investigators or subcontract recipients

1. The IRB will accept certificates of training from other institutions when

research personnel include external investigators or subcontract recipients who have been trained elsewhere and are under the legal jurisdiction of that institution with respect to compliance with federal regulations. A copy of any certification must be provided to the ORC.

E. New research personnel added to IRB-approved research via a Request for Change or Application for Continuing Review

1. All new employees serving as investigators, participating personnel, and Limited Research Workers must complete Basic CITI training prior to addition as research personnel to any research study. The IRB will accept certificates of training from prior institutions *only* if the other institution utilized the CITI training system.

F. IRB approval of research

1. All research personnel must be CITI trained/certified prior to IRB approval of initial research applications or continuing review applications.

2. Current project personnel whose prior certification may have lapsed must renew certification prior to IRB approval of any new application of annual continuing review.

G. Access to the CITI training program

1. A link to the CITI Training Program is available through the ASU website. Following registration, the individuals will be able to immediately access the system.

H. CITI-Test data confidentiality

1. Individual test scores are confidential. The webmaster and staff supporting the distance learning software at the University of Miami where the data are processed and stored have access to individually identifiable quiz scores. Additionally, the ORC staff will have access to the individual test scores to determine if the test taker achieved the minimum passing score. Aggregate, anonymous quiz data will be used by CITI course faculty to help improve course content and quiz questions. There will be no further disclosure of individually identifiable quiz results or aggregate institutionally identifiable results beyond that mentioned above.

I. Minimum passing score required for certification

1. The IRB requires a passing score of 80% overall to receive CITI certification.

J. CITI certification renewal

1. Certification by CITI course is valid for 3 years from the original date of completion. Certification must be renewed at that time in order for the individual to be listed as an authorized study personnel in new IRB applications or continuing review forms. Certification renewal is available through the CITI Continuing Education Course.

2. To renew certification:

- a) ASU faculty, students, and staff must complete the appropriate track in the Continuing Education Course in CITI or the Basic CITI course.
- b) The IRB requires an overall passing score of 80% for a renewal of CITI certification.

2.2 Other training requirements

A. All research personnel listed on the IRB application are expected to read The Belmont Report, which is posted on the OHRPP website (www.hhs.gov/ohrp/).

B. It is the responsibility of the PI to be familiar with policies and procedures relevant to the protocol.

C. All research personnel listed on the IRB application are to be familiar with ASU's IRB policies applicable to their research and accessible on the ASU website.

D. All research personnel listed on the IRB application are expected to be reasonably familiar with the requirement of Health and Human Services regulations at 45 CFR §46, which can be accessed on the OHRPP website (www.hhs.gov/ohrp/).

RPP Policy: 3.10 Assessing the Need for Interim Continuing Review, Monitoring and Verification for Sources Other than the Investigator

1. Purpose

The purpose of this SOP is to describe the criteria that the IRB will use at both initial and continuing review in determining the need for 1) IRB continuing review and 2) increased monitoring.

2. Policy

It is the policy of the IRB that that all research will be assessed for continuing review in accordance with the requirements set forth by Health and Human Services regulations at 45 CFR §46.103(b)(4).

2.1 Increased Monitoring and/or Interim Continuing Review

A. Unless specifically waived by the IRB, research that meets any of the following criteria will require review more often than annually:

1. Significant risk to research participants (e.g., death, permanent or long lasting disability or morbidity, severe toxicity) without the possibility of direct benefit to the participants;

2. The involvement of especially vulnerable populations likely to be subject to coercion (e.g., institutionalized psychiatric patients, incarcerated minors); or

3. A history of serious or continuing non-compliance on the part of the PI.

B. The following factors will determine which studies require review more frequently than on an annual basis:

1. The probability and magnitude of anticipated risks to participants;

2. The likely medical condition of the proposed participants;

3. The overall qualifications of the PI and other members of the research team;

4. The specific experience of the PI and other members of the research team in conducting similar research;

5. The nature and frequency of AEs observed in similar research at this and other institutions;

6. The novelty of the research making unanticipated AEs and/or serious problems more likely; and/or

7. Any other factors that the IRB deems relevant.

C. When the IRB determines the need for increased monitoring, the PI will be notified of these requirements in writing, and this oversight may be accomplished by either:

- 1.** submission of interim reports by the PI, or
- 2.** auditing of investigator records by the Office of Research Compliance.

D. If the IRB determines the need for more frequent continuing review, the PI will be notified in writing and the IRB approval period will be set accordingly. Based on the criteria factors of 2.1A and 2.1B, the IRB shall determine whether the research shall be reviewed more often than annually.

RPP Policy: 3.11 Certificate of Confidentiality

1. Purpose

The purpose of this SOP is to describe the process for applying for a Certificate of Confidentiality from the National Institutes of Health.

2. Policy

It is the policy of the IRB that a Certificate of Confidentiality may be required for certain research proposals where the potential of disclosure of sensitive, personally identifiable information creates significant risk of harm or damage to the participant. The Certificate of Confidentiality protects against compulsory legal demands such as court orders and subpoenas for identifying information or identifying characteristics of a research participant.

2.1 Purpose of the Certificate of Confidentiality

A. Certificates are issued by the National Institutes of Health for the purpose of protecting identifiable research information from compelled disclosure. The certificate allows the investigator and others who have access to research records to refuse to disclose identifying information on research participants in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level.

B. Federal funding of the research is not a prerequisite.

C. A Certificate does not prevent voluntary disclosures such as limited disclosure to protect the participant or others from serious harm, as in cases of child abuse.

D. A research protocol cannot rely on a Certificate to withhold data if the participant consents in writing to the disclosure.

2.2 Applicable Research

A. The project must be categorized as research (see RPP Policy # 3.01 for a definition of research. Additional examples may be found on the ORSP website).

B. The research must be IRB-approved.

C. The information collected must be “sensitive” (e.g., disclosure will involve significant harm or damage to the participant).

D. Personally identifiable information is collected during the research.

E. The investigator and/or the IRB determine that a Certificate is necessary to minimize risk to participants.

F. Certificates are issued for single, well-defined research projects rather than groups or classes of projects. Occasionally a Certificate can be issued for cooperative multi-site projects. A coordinating center or “lead” institution designated by the National Institutes of Health program officer can apply on behalf of all institutions involved in the protocol. The lead institution must ensure that all participating institutions conform to the application assurances and inform participants appropriately about the Certificate, its protections, and circumstances in which voluntary disclosures would be made.

2.3 Sensitive Research Categories

A. Information relating to sexual attitudes, preferences, or practices.

B. Information relating to the use of alcohol, drugs, or other addictive substances.

C. Information pertaining to illegal conduct.

D. Information that, if released, could damage a participant’s financial standing, employability, or reputation within the community.

E. Information that would normally be recorded in a patient’s medical record, and the disclosure of which could reasonably lead to social stigmatization or discrimination.

F. Information pertaining to an individual’s psychological well being or mental health.

G. Genetic information.

2.4 Application Process

A. Principal investigators conducting research collecting sensitive human participant information may apply for a Certificate of Confidentiality from the National Institutes of Health.

B. In addition to the completed application, the PI will be required to provide documentation of IRB approval and a copy of the informed consent form(s) as it would read if a Certificate of Confidentiality is obtained (e.g., explains the Certificate, its protections and the circumstances in which voluntary disclosures might be made).

C. Both the PI and the IO (or his designate) are required to sign the Certificate application.

D. Detailed instructions and further information may be found on the National Institutes of Health website at:

http://grants.nih.gov/grants/policy/coc/appl_extramural.htm.

RPP Policy: 3.12 External IRB Approval of Cooperative Research

1. Purpose

The purpose of this SOP is to describe the conditions under which the IRB will accept external IRB review and approval of cooperative research.

2. Policy

It is the policy of the IRB that, in recognition of the importance of cooperative, multi-site research and the potential for duplication of effort, the IRB may agree to enter into a joint review arrangement and rely upon the review of another qualified IRB, in accordance with Health and Human Services regulations at 45 CFR §46.114.

2.1 Conditions

A. ASU faculty, staff, or students will conduct the research solely at an external institution under the authority of that institution's IRB.

B. The external institution has accepted full responsibility to protect the rights and welfare of all participants enrolled within its institution, in accordance with Health and Human Services regulations at 45 CFR §46.

C. The external institution has a Federal Wide Assurance (FWA) approved by OHRP.

D. The ASU IRB has received a copy of the protocol, consent/assent document(s), and the external IRB approval.

2.2 IRB Review

A. The ASU IRB Chair will review the submission and is authorized to accept external IRB approval. The full IRB will be notified accordingly.

2.3 IRB Authorization Agreement

A. The external IRB will be notified of the decision to accept external IRB approval.

B. An IRB Authorization Agreement will be created and signed by the IO from each institution.

RPP Policy: 3.13 Research Records Retention and Security
Section: *Initial IRB Review of Protocols*

1. Purpose

2. The purpose of this SOP is to describe the requirements for retention and security of research records.

3. Policy

It is the policy of the IRB that the research record maintained by the IRB and PI must:

- Contain an accurate and complete account of the conduct of the study;
- Be maintained and stored securely; and
- Be retained for the required amount of time following completion of the research in accordance with Health and Human Services regulations under 45 CFR §46.115(b), and sponsor requirements as applicable, or as specified by the IRB.

3.1 Research Record

The research record must include, but is not limited to:

A. Initial proposal:

1. IRB application;
2. Detailed protocol;
3. Grant (if applicable);
4. Consent forms (if applicable);
5. Case report forms (if applicable)

B. Applications for continuing review and corresponding documents

C. Requests for change to the protocol and/or consent forms

D. Reports of AEs and unanticipated problems involving risk to the participant or Others.

E. Single participant protocol deviation and retrospective protocol by the violation reports.

F. Issues of noncompliance

G. IRB-PI correspondence

H. Any other protocol-related documentation not covered by the above.

I. The PI also will maintain copies of sponsor contracts and correspondence (if applicable) and subject files that should contain:

1. Signed consent documents;
2. Laboratory results; and
3. Other applicable information.

3.2 Security of Research Records

A. All research records must be maintained and stored securely, in a manner that protects participants' privacy and confidentiality by preventing unauthorized access (e.g., locked file cabinets and offices; fax machines placed away from high traffic areas, and use of study participant identifiers known only to research staff).

B. All research databases must comply with ASU Information Security policies and procedures relating to the safeguarding of electronic confidential information.

C. Records are accessible for inspection and copying by authorized representatives of federal agencies or departments at reasonable times and in a reasonable manner.

3.3 Retention of Research Records

A. Social science, behavioral and biomedical research records must be retained for at least *three (3) years* beyond the termination of the study, or longer as required by sponsors.

B. If the investigator resigns from ASU before the end of the designated period, the department of record must maintain the research records unless otherwise specified. The investigator, however, may have a copy of the research records in accordance with applicable ASU records policies.

C. If a protocol is cancelled without participant enrollment, IRB records and support documents are retained for at least three years after cancellation.

RPP Policy: 3.14 Appeals of IRB Decisions

1. Purpose

The purpose of this SOP is to describe the procedure a PI may take to express disagreement with IRB decisions.

2. Policy

It is the policy of the IRB that PIs have the right to disagree with IRB decisions and seek resolution.

2.1 The results of the IRB review will be conveyed to the PI by the IRB Chair, and/or ORC staff through written correspondence. Individual IRB members are not permitted to discuss the results of the IRB review with the PI unless instructed to do so by the IRB Chair or the Full Board.

A. If a PI disagrees with the IRB's written decision, he/she is encouraged to contact the Office of Research Compliance and/or the IRB Chair and provide a written response detailing justification for the disagreement.

B. If the disagreement is related to a substantive human protection issue and the protocol was reviewed by the full IRB, the protocol will be referred back to the full IRB.

1. An appeal of a disapproved research project must be reviewed at the next *Full Board* meeting.

2. If resolution of the disagreement requires direct interaction with the PI, the PI may attend a portion of the IRB meeting to address the Board's concerns.

2.2 If the re-review process does not satisfy the PI, the PI may choose to forward the matter to OHRP. In which case, the protocol and all attendant documents and correspondence will be forwarded to the IO, who will forward the matter to OHRP for resolution.

A. If the disagreement does not represent a substantive human protection issue, the IRB Chair will seek a resolution.

1. This may include two new reviewers to assess the protocol.

2. The IRB Chair will serve as a third reviewer.

2.3 If the re-review process by the full board does not satisfy the PI, the protocol and all attendant documents and correspondence will be forwarded to the full board and reviewed at the next Full Board meeting.

RPP Policy: 3.15 Compensation for Research Participants

1. Purpose

The purpose of this SOP is to describe compensation for research participants.

2. Policy

It is the policy of the IRB that compensation for research participants may be acceptable if:

- the possibility of coercion or undue influence is minimized, and
- the compensation is considered a recruitment incentive, not a benefit, in accordance with Health and Human Services regulations at 45 CFR §46.116.

2.1 Requirements

A. Compensation for participation is not an obligation of the researcher toward the participant. Compensation may be offered, but is not required.

B. Participation in research should not require financial sacrifice, but should be revenue neutral for participants.

C. Compensation should not be used as a “benefit” to offset risks (either quantitative or qualitative) associated with the research.

D. Generally, compensation should be based upon the premise that participation in research requires time and effort from the participant. Compensation, when offered, should be based on a reasonable consideration of the duration of time spent in preparation for, participation in, and recovery from, research interventions, in addition to the effort expended during the research activities.

1. Interventions are understood to include such elements as procedures performed, visits to a clinic or research setting, phone interviews, or surveys completed. If appropriate, such compensation should include all parties involved. For example, if a family member is required to be present to drive a research participant home after a procedure, his/her time can be compensated.

E. Compensation above these levels must be justified by the investigator and must comply with the enumerated principles.

F. In order to minimize the risk that cumulative compensation for prolonged participation could unduly influence participation, the compensation plan should be described clearly in the consent form, including the portion of compensation that will be received at each study milestone, as well as the total amount to be paid. Scientific rationale and justification for the specific compensation plan needs to be provided and comply with the enumerated principles.

1. Credit for payment is to accrue as the study progresses and not be contingent only upon the participant completing the study. Any amount paid as a bonus for completion should be reasonable and not so large as to unduly induce participants to stay in the study when they would otherwise have withdrawn.

G. Payments for involvement of young minors (<16 years) in research should not be made directly to the minor. Depending on scientific rationale and justification, minors can be offered an age appropriate item through their parents for their participation, such as a toy or gift certificate. With appropriate scientific rationale and justification, 16- through 18-year-olds may be compensated directly.

2.2 Use of Lottery

A. Due to the concerns relating to fairness and the potential for coercion and undue influence, the IRB will review carefully the use of a lottery or raffle as a mechanism for participant compensation. The IRB will consider such plans for participant compensation on a case-by-case basis, with appropriate scientific rationale and justification provided by the PI.

B. Under certain conditions, a lottery or raffle can be used as a recruitment incentive. In these cases, lotteries/raffles are not participant compensation, per se. The scientific rationale and justification for the use of a lottery or raffle as a recruitment incentive is required to be provided by the PI.

RPP Policy: 3.16 Recruitment of Participants Through Advertisements

1. Purpose

The purpose of this SOP is to describe the IRB requirements for recruitment of participants through advertisements.

2. Policy

It is the policy of the IRB that, as a function of perceived risk to participants, all participant recruitment strategies, including printed newspaper advertisements, bulletins, fliers, multimedia, radio, and television, will be reviewed and approved before they can be used to recruit potential participant.

2.1 *Design of the Advertisements.*

A. Advertisements should be limited to information a potential participant may need to determine if they are interested and eligible to participate in a study.

B. Appropriate items to include in an advertisement are:

1. Name and address of the investigator and associated institution.
2. Purpose of the research.
3. Eligibility criteria (in shortened form).
4. Listing of realistic benefits to the participant.
5. Time or other commitments required from the participant.
6. Location of the research, contact person, and phone number for further information.
7. If applicable, incentives, which are intended to motivate the potential participant to consider participating in the research project should be described, e.g., direct payment, lottery.

C. The following are not permitted to be included in advertisements:

1. Statement or implication of a certainty of favorable outcome or other benefits beyond what is outlined in the consent document and the protocol;
2. Claims, either explicitly or implicitly that the research procedures are safe or effective for the purposes under investigation; or
3. Any exculpatory language.

D. Printed advertisements (e.g., newspaper ads and bulletins) should use appropriate font size and bolding in order to ensure the prospective participant is not misled by having their attention inappropriately drawn to a particular section of the advertisement.

2.2 Submission of Advertisements.

A. Draft copies of all advertisements including radio and television scripts must be submitted to the IRB for review and approval. An advertisement may be reviewed by either the full IRB or by the *expedited continuing* method if it qualifies in accordance with Health and Human Services regulations at 45 CFR §46.110(b) (1) and (2).

2.3 IRB Record of Advertisements.

A. The investigator should provide a copy of the published newspaper ad to the IRB. All bulletins posted at the Institution must be kept on file in the IRB study file.

B. The IRB protocol will include:

1. The information contained in the advertisement.
2. The mode of its communication
3. The final test copy of printed advertisements.
4. The final audio/video taped advertisements.

C. The IRB will determine if the advertisement emphasizes the payment or the amount to be paid by such means as unduly large or bold type.

D. A final copy of the recruiting advertisement must be sent to the IRB upon final printing or publication.

Section 4: Exemptions and Expedited Reviews

RPP Policy: 4.01 Exemptions

1. Purpose

The purpose of this SOP is to describe the process for determining whether a research proposal is eligible for *exemption*.

2. Policy

It is the policy of the IRB that all requests for *exemption* are conducted by an IRB reviewer to determine that the research meets at least one of the categories of exemption from federal regulations for protection of human research participants in accordance with Health and Human Services regulations at 45 CFR §46.101(b).

2.1 Federal regulations recognize certain types of human subjects research as being exempt from IRB oversight.

A. OHRP requires that the determination of exemption be conducted by an individual that is not the PI or part of the research protocol.

B. At ASU, that review, and determination, is conducted by the IRB.

1. The IRB reviewer(s) has the ultimate responsibility for determining whether the project qualifies for exemption (see below).

2. In making this determination, the IRB reviewer(s) also considers any ethical issues including the possibility of coercion.

C. When the IRB reviewer(s) determines that the project does not qualify for exemption, the application is then reviewed as an expedited or Full Board review.

2.2 Categories of research eligible for exemption

Category 1: **Research** conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management (iii) research does not adversely affect students' opportunity to learn required educational content or the assessment of educators who provide instruction.

Category 2: Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met: (i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects; (ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or (iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and ***an IRB conducts a limited IRB review to make the determination required by 46.111(a)(7)***

Category 3: Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met: (A) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects; (B) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or (C) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and ***an IRB conducts a limited IRB review to make the determination required by 46.111(a)(7)***

Category 4: Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met: (i) The identifiable private information or identifiable biospecimens are publicly available; (ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects; (iii) The research involves only information collection and analysis involving the

investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); or (iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for non research activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.

Category 5: Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

Category 6: Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Category 7: (7) Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an ***IRB conducts a limited IRB review and makes the determinations required by 46.111(a)(8).***

Category 8: Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met: (i) Broad consent for the storage, maintenance, and secondary research use of the identifiable

private information or identifiable biospecimens was obtained in accordance with § 11.116(a)(1) through (4), (a)(6), and (d); (ii) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with § 11.117; (iii) ***An IRB conducts a limited IRB review and makes the determination required by 46.111(a)(7)*** and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; and (iv) The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

2.3 Categories of research ineligible for exemption

A. Sensitive survey research: A sensitive survey is one that deals with sensitive or highly personal aspects of the participant's behavior, life experiences or attitudes (e.g., chemical substance abuse; sexual activity or attitudes; sexual abuse; criminal behavior; sensitive demographic data; detailed health history).

1. The principal determination for sensitivity is whether or not the survey research presents a potential risk to the participant in terms of possible precipitation of a negative emotional reaction.
2. With respect to potential psychological risk associated with a survey, the presence or absence of participant identifiers is not necessarily a consideration since the risk may be primarily associated with the sensitive

nature of the survey as opposed to being dependent upon confidentiality. Participant identifiers may, however, become a factor when confidentiality is an issue.

3. An additional risk consideration is whether or not there is a risk associated with a breach of confidentiality. Where survey research guarantees confidentiality to participants, researchers should be cognizant that, if the violation of confidentiality may cause major difficulties to participants, the potential breach may influence the status of exempt.

- B. Research using surveys or interviews involving children as participants.
- C. Observational research involving children as participants, where the investigator participates in the activities being observed.
- D. Observational research involving sensitive aspects of a participant's behavior.
- E. Research, which involves photographing, audiotaping, or videotaping of participants during the research with some discretion as it relates to identification or sensitivity.
- F. Deception of participants: The researcher deceives the participant with regard to the purpose of the research and/or the results of the participant's actions in the study.
- G. Research involving prisoners, persons who are cognitively impaired, persons who are economically or educationally disadvantaged and other participant populations determined to be vulnerable.

2.4 Ethical Considerations

A. It is ASU policy that research with *exempt* status is not exempt from the ethical guidelines of the Belmont Report. Therefore the individual making the determination of exemption may require additional protections for participants in keeping with the guidelines of the Belmont Report. This may involve informed consent as necessary and confidentiality measures to protect data. In some research projects with exempt status, standard written informed consent must be obtained.

2.5 Renewal and modification of research eligible for exemption

A. Research qualifying for exemption, once approved, needs to be renewed annually, as long as data is being collected.

B. All modifications of protocols including research qualifying for exemption must be submitted to the IRB.

1. Research qualifying for exemption, which requires modification during the course of the study whereby it does no longer qualify for exemption, must be resubmitted to the IRB prior to implementation of the modification.

2.6 Review of research that may qualify for Exemption will be conducted by one reviewer, who is entitled to seek advice and input from other reviewers on duty that week and from the Chair.

2.7 Research that qualifies for exemption because it meets the criteria for standard educational practices and is being conducted in the classroom will be reviewed by two reviewers, who are entitled to seek advice and input from other reviewers on duty that week and from the Chair.

RPP Policy: 4.02 Expedited Reviews

1. Purpose

The purpose of this SOP is to describe the *expedited review* process for initial and continuing review.

2. Policy

It is the policy of the IRB that *expedited review* will be conducted in accordance with Health and Human Services regulations at 45 CFR §46.110. Protocols reviewed and approved by the *expedited* method must

- be no more than minimal risk;
- involve only procedures listed in one or more of the categories specified in the Federal Register (63 FR 60364-603-67, November 9, 1998); and
- meet all the criteria specified in Health and Human Services regulations 45 CFR §46.111.

Expedited review may be used to perform continuing review in accordance with RPP Policy # 11.01. *Expedited review* will not be used for research involving prisoners.

2.1 Three (3) applicable criteria must be met for the initial or continuing expedited review, these include:

A. The current and future research procedures present no more than minimal risk to participants.

B. The identification of the participants or their responses will not reasonably place them at risk of criminal or civil liability or be damaging to their financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

C. *The research is not classified.*

1. Classified research is research where knowledge of the procedures and results is restricted to certain individuals. This type of classification is most often associated with United States government security clearances.

2.2 Qualifying Categories of Expedited Review

A. Social Behavioral research that includes:

1. Collection of data from voice, video, digital, or image recordings made for research purposes;
2. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies;

a) Some research in this category may be exempt from the Health and Human Services regulations for the protection of human participants. This listing refers only to research that is not exempt.

B. Continuing review of research previously approved by the convened IRB that meets one of the following conditions:

1. Where the research is permanently closed to the enrollment of new participants; all participants have completed all research interventions; and the research remains active only for long-term follow-up of participants, **OR**

2. Where no participants have been enrolled and no additional risks have been identified, **OR**

3. Where the remaining research activities are limited to data analysis.

C. Clinical research categories that include:

1. Collection of blood sample by finger stick, heel stick, ear stick, or venipuncture as follows:

a) From healthy, non-pregnant adults who weigh at least 110 pounds. In studies in, which more than 400 ml of blood is to be drawn within an 8 week period, the participant must have a baseline hemoglobin level of 12.0 grams. After 250 ml of blood has been drawn, the hemoglobin level must be retested; anyone whose hemoglobin has fallen below 11.0 grams must be withdrawn from the study.

b) From other adults and children, considering the age, weight, and health of the participants, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these participants, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times (or research sessions) per week.

2. Prospective collection of biological specimens for research purposes by non-invasive means.

- a) Examples include:**
- b) Hair and nail clippings in a non-disfiguring manner;**
- c) Deciduous teeth (at time of dental exfoliation) or if routine patient care indicates a need for extraction;**
- d) Permanent teeth if routine patient care indicates a need for extraction;**
- e) Excreta and external secretions (including sweat);**
- f) Uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax, or by applying a dilute citric solution to the tongue;**
- g) Placenta removed at delivery;**
- h) Amniotic fluid obtained at the time of rupture of the membrane prior to, or during, labor.**
- i) Supragingival and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques.**
- j) Mucosal and skin cells collected by buccal scraping or swab, skinswab, or mouth washings.**
- k) Sputum collected after saline mist nebulization.**

3. Collection of data through non-invasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice (excluding procedures involving x-rays or microwaves). Where medical devices are employed, they must be cleared or approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for *expedited review*, including studies of cleared medical devices for new indications.) Examples include:

- a) Physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the participant or an invasion of the participant's privacy.**
- b) Weighing or testing sensory acuity.**
- c) Magnetic resonance imaging.**
- d) Electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, Doppler blood flow, and echocardiography.**
- e) Moderate exercise, muscASU strength testing, body composition assessment, and flexibility testing where appropriate for the age, weight, and health of the individual.**
- f) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis).**

g) Some research in this category may be exempt from the Health and Human Services regulations for the protection of human participants. This listing refers only to research that is not exempt.

2.3 Expedited continuing review process

A. ORC staff will screen applications and determine which qualify for *expedited review*, using the OHRP Human Subject Regulations Decision Charts (September 24, 2004) as necessary (<http://www.hhs.gov/ohrp/humansubjects/guidance/decisioncharts.htm>).

1. If necessary, ORC staff will obtain clarifications from the PI and ask, if necessary, for revision of submission documents and/or clarifications.

B. The ORC staff will assign a primary and secondary reviewer based on the weekly roster.

1. The reviewer will utilize the IRB review criteria specified in RPP Policy # 3.04.

2. After a protocol or amendment is approved using the *expedited review* procedure, it will be noted in the upcoming IRB meeting agenda distributed to the Full Board.

3. Any IRB member can request access to the protocol and can make any concerns known at the full IRB meeting.

4. Even if a protocol, or an amendment, has been approved using the *expedited review* procedure, the full IRB can require modification of the protocol and/or consent documents(s).

5. Additionally, the full IRB can suspend the study or halt accrual of data if it is deemed warranted.

2.4 Expedited review actions

A. Approval and full release

1. No modifications or clarifications are required. All of the criteria for IRB approval specified in Health and Human Services regulations at 45 CFR §46.111 are satisfied. The investigator will be notified of the approval in writing and is authorized to start the study.

B. Conditional approval, contingent upon IRB Reviewer's acceptance of specific modifications/clarifications

1. The investigator will be notified in writing as to the nature of the required modifications/clarifications. When the investigator complies, in writing, with all requirements as determined by the IRB Reviewer, approval and full release will be granted.

C. Referred for full IRB review

1. The protocol is referred to the full IRB for review.

2.5 Documentation of Expedited continuing review

A. Initial review conducted under an *expedited continuing review* will be documented in the IRB letter to the PI. This documentation will include:

B. Identification of the specific permissible categories justifying the *expedited continuing review*.

C. Documentation of the review and action taken by the IRB Chair, or designated reviewer and any findings required under the Health and Human Services regulations.

Section 5: Quality Improvement Assessment

RPP Policy: 5.01 Quality Improvement Assessment Program

1. Purpose

2. The purpose of this SOP is to describe the Quality Improvement Assessment Program.

3. Policy

It is the policy of the IRB that the Quality Improvement Assessment Program will be conducted in accordance with regulations at Health and Human Services 45 CFR §46.

4.1 Quality Improvement Assessment Program

A. The IRB Quality Improvement Assessment Program has been developed to reflect the vision, purpose, and mission of the Institution and the RPP.

B. The Quality Improvement Assessment Program is designed to be proactive, non-punitive, and focused on education of investigators, staff, and students about ethical and regulatory responsibilities in the conduct of human participant research. The focus of the program will encompass the IRB review system and IRB documentation.

4.2 Quality Improvement Assessment Program Objectives

A. To evaluate the IRB protocol review process, specifically focusing on ethical and compliance issues.

B. To determine if the PI adheres to the research protocol as approved by the IRB:

1. All IRB-required changes have been implemented.
2. Continuing review is up-to-date.
3. Participant recruitment methods and materials (e.g., posters, handouts, and letters) have been reviewed and approved by the IRB prior to use.

C. Identify the educational and training needs of the research community and determine the best methods for meeting those needs through:

1. Individualized training to meet the specialized needs of specific PIs and their research personnel.
2. General education programs designed for the research community at ASU.

D. Assess Effectiveness of the RPP

E. At least annually, the ORC will meet with the Institutional Official (or his designate) to review questions, concerns, and suggestions emanating from investigators with the purpose of assessing and improving the RPP.

4.3 Study Selection Criteria

A. The criteria for selecting the studies to be assessed must reflect the full range of the research reviewed by the IRB. The criteria include:

B. Specific categories of research, including:

1. Investigator-initiated research.
2. Research involving vulnerable populations (e.g., pregnant women, children, individuals who are decisionally-impaired, and prisoner).
3. Research approved by *expedited review*.
4. Research approved by *exemption review*.

C. Selected studies must have enrolled five (5) or more participants.

D. Selected studies must be currently IRB-approved and active for at least one (1) year.

E. Selected studies will be representative of the funding categories seen in the Institution:

1. Federal grant
2. Other
3. None

F. Some studies may be selected for assessment based on recommendations by the IRB Administrator, Chair, Vice Chair, or IRB members. The recommendations may be based on:

1. Issues related to non-compliance.
2. Problems with continuing review, informed consent, or other IRB review.
3. Monitoring reports issued by outside agencies (sponsors, OHRP or others) that revealed problems areas.
4. Other non-specified issues.

4.4 Review of IRB Records

Once a research protocol has been chosen for Quality Improvement Assessment, the ORC staff will carefully review, in advance, the entire IRB file. Specifically, the following questions must be addressed:

A. Does the IRB file contain all the records required by 45 CFR §46.115 in sufficient detail to demonstrate compliance and performance of a substantive review(s)? The file must contain:

1. IRB application (original version and IRB-approved version).
2. Detailed protocol (if applicable).
3. Health and Human Services grant application (if applicable).
4. Informed consent/assent documents (if applicable).
5. Informed consent addenda (e.g., banking, DNA, and significant new findings).
6. Participant recruitment advertisements (e.g., newspapers, radio, television, posters, and letters) with IRB correspondence and IRB approval.
7. AE or unanticipated problem(s) reports.
8. Applications for Continuing Review.
9. Requests for Change in the Protocol and/or Consent/Assent
10. Noncompliance Investigations (if applicable).
11. Previous Quality Improvement Assessment records.
12. All correspondence between the IRB and the PI.

B. Are the IRB minutes pertaining to the protocol(s) in question sufficiently detailed per 45 CFR §46.115(a) (2)?

C. For example, the IRB meeting attendance is recorded; the vote on the protocol is recorded (number for, against, and abstaining); and nonparticipation of IRB members with a conflict of interest is documented. The basis for the Board's action(s) is recorded, where appropriate. Additional protections for vulnerable participants are documented in accordance with 45 CFR §46 subparts C and D. There is a reasonable detailed summary of the IRB's discussion of any controversial issues and their resolution.

D. Is the consent document approved by the IRB in compliance with 45 CFR §46.116(a, b)?

E. Were the IRB's initial review and subsequent reviews (e.g., amendments and AEs) and the IRB office's handling of the review timely and efficient?

F. Was continuing review substantive? Was the continuing review conducted within the IRB approval period, per the requirements of 45 CFR §46.109(e)?

G. Were AEs or other unanticipated problems involving risk to the participant or others promptly reported to the IRB, and if required, or the OHRP per the requirements of 45 CFR §46.103(b) (5)?

H. Was serious or continuing noncompliance promptly reported to OHRP per the requirements of 45 CFR §46.103(b) (5)?

I. Was the IRB review of initial proposals conducted under *expedited review* processes permissible under 45 CFR §46.110? Is the *expedited review* category documented?

J. Was research that was exempted permissible under 46 CFR §46.101(b)? Is the applicable *exemption* category documented?

4.5 Quality Improvement Assessment Report and Follow-Up

A. After the Quality Improvement Assessment is complete and all findings are analyzed and determined to be valid, a written report will be developed.

B. Report to PI

1. The report will be proactive and educational in nature by providing comments concerning strengths and recommendations on how deficiencies can best be corrected, with appropriate citations of federal regulations and institutional policies. The report will be completed in a timely manner, and a copy of the report will be provided to the IRB Chair and the Office of Research Compliance for review, approval, or initiation of additional action.

Section 6: General Requirements and Guidelines

RPP Policy: 6.01 Students as Researchers

1. Purpose

The purpose of this SOP is to describe requirements for research conducted by students.

2. Policy

It is the policy of the IRB that research conducted by students will adhere to the regulations set forth in 45 CFR §46, the ethical standards contained in the Belmont Report, and comply with all the policies and procedures of the ASU IRB.

3. Students as researchers

3.1 Student researchers may submit applications as a student researcher or study personnel.

3.2 All students conducting research requiring IRB review must complete CITI training prior to IRB approval of the research. This includes *research that qualifies for exemption*. (See RPP Policy # 3.10 for further information.)

4. Student research projects that require IRB review:

4.1 Any student project that recruits or includes a protected class of participants;

4.2 Any student project that may be disseminated outside the immediate classroom;
A. Or, if the results will be shared with more than the other students in the class or the instructor of record. If there is even a remote chance that the data or the report/manuscript will be used in the future for a conference presentation or a related research project, the research should go through IRB review.

4.3 Research that involves direct human interaction or a manipulation of their environment (e.g., in person, or via mail, email, web survey, or telephone), or data from human subjects for which the researchers will have access to identifiers;

4.4 Research that is limited to secondary analysis of data, records or specimens that are either publicly available, de-identified or otherwise impossible to be linked to personal identities;

- 4.5 Research activities using departmental subject pools (e.g., Psychology, Business, Political Science) even when the activity is conducted for educational purposes as a class requirement;
 - A. IRB approval is required if the intent is to develop new or expanded Knowledge.
- 4.6 Class projects or practica that involve direct interaction or an intervention or secondary analyses of private identifiable data and are undertaken as both an educational experience and as research (e.g., results of these activities will be presented publicly or otherwise disseminated or the data will be stored and used by the students or others as research data).

5. Procedure for seeking approval

- 5.1 Students with projects that include a protected class of participants (other than prisoners) must submit a protocol to IRB for review, which may be reviewed by the Full Board, expedited, or qualify for an exemption.
 - A. Research with participants who are prisoners must be submitted for Full Board Review.
- 5.2 Students with projects that may be disseminated outside the immediate classroom must submit a protocol to IRB for review, which may be reviewed by the Full Board, expedited, or qualify for an exemption.
- 5.3 Direct human interaction:
 - A. An IRB application form must be submitted with P.I. or faculty advisor's signature; or an existing approved study must be amended to add student to research personnel.
 - B. Student researcher, co-investigators (if a group) and faculty advisor are required to complete research ethics education and submit certificates of completion with the application, if not already on file.
- 5.4 Secondary analysis
 - A. If source data has identifiers that will not be disclosed to the researcher, then a data use agreement between the researcher and the data custodian may be required to verify that the researcher will not have access to identifying codes.
After receipt of the data use agreement, the IRB will issue a memo stating that no further IRB action is required.
- 5.5 Departmental Subject Pools:
 - A. An IRB application form must be submitted for each activity by an individual or small group.
 - B. Student researcher, co-investigators (if a group) and faculty advisor must have current CITI training.
- 5.6 Class projects or practica involving direct interaction:

6. Student activities that may not require IRB review

6.1 Class projects with the limited objective of teaching proficiency in performing certain tasks or using specific tools or methods do not require IRB approval.

A. Class projects or practica that involve direct interaction (e.g., in person, via mail, email, web surveys, or telephone), but where the purpose is training, an educational exercise or professional development, and is not intended for research purposes. The project or practicum is not “research” even if students ask people questions as part of learning how to conduct interviews or surveys, take histories, administer assessments, or perform “in-house” evaluations as requested by the practicum site.

1. Neither approval nor determination of human research status is required but may be requested if instructor or students are unsure, or if documentation is required by gatekeepers (e.g., schools, businesses) for access to participants.

2. Class instructor and department are responsible for providing the necessary training in respecting the privacy of the individuals and the confidentiality of any resulting information, along with training in the relevant professional ethics.

3. The Instructor should provide information about the assignment for the students to distribute to people who participate in these class projects. The information should list the instructor as the appropriate contact person should questions arise.

B. Class projects involving secondary data analyses that are assigned and conducted as educational exercises, and that use data sets that include private information and codes that link to identifiers, but the students do not have access to the identifiers or the code key. Note - activity must be limited to class project use only.

7. Faculty responsibility when IRB approval is not necessary

7.1 General

A. Faculty members are responsible to discuss the guidelines and ethics for the protection of research subjects with their students and incorporate these into their methodology. Particular emphasis should be placed on:

A. Developing an awareness of the types of risk subjects may be exposed to in various types of research projects, i.e., psychological, social, physical, economic, and legal.

B. Obtaining voluntary informed consent to participate in a way that honestly informs subjects of the purpose and potential risks and benefits of the research.

C. Management of potential risks to subjects.

D. A risk/benefit analysis for all populations, with special consideration of vulnerable populations (children, pregnant women, fetuses, mentally disabled, institutionalized persons, prisoners, etc.).

E. Protection of privacy and confidentiality of the subjects.

F. Identification of benefit to be derived from participation in the research.

7.2 Types of projects

1. Class projects with limited objective of teaching: Neither approval nor determination of human research status is required but may be requested if instructor or students are unsure, or if documentation is required by gatekeepers (e.g., schools, businesses) for access to participants.

1. Class instructor and department are responsible for providing the necessary training in respecting the privacy of the individuals and the confidentiality of any resulting information, along with training in the relevant professional ethics.

2. The Instructor should provide information about the assignment for the students to distribute to people who participate in these class projects. The information should list the instructor as the appropriate contact person should questions arise.

2. Class projects involving de-identified secondary data analyses that are assigned and conducted as educational exercises,

1. No IRB action required (neither approval nor determination of human research status)

2. Class instructor and department are responsible for providing the necessary training in respecting the confidentiality of the data.

3. Class projects involving secondary data analyses that are assigned and conducted as educational exercises, using data that is either publicly available, de-identified or otherwise impossible to be linked to personal identities.

1. No IRB action required (neither approval nor determination of human research status) because there are no identifiers and no interactions with people.

RPP Policy: 6.02 Epidemiological Research Guidelines

1. Purpose

The purpose of this SOP is to describe the guidelines required when conducting epidemiological research.

2. Policy

It is the policy of the IRB that all epidemiological research will be performed in accordance with the regulations set forth in 45 CFR §46.

2.1 Introduction

A. *Epidemiological research* is defined as the collection and analysis of medically relevant data about individuals or groups to determine the causes, distribution, and control of diseases in populations.

B. Some epidemiological research requires access to many sources of Protected Health Information (e.g., medical records, databases, disease registries, and hospital discharge records). As a result the greatest risk associated with this research is breach of confidentiality and privacy. While the HIPAA Privacy Rule is not intended to obstruct epidemiological research, the investigator must understand and follow specific rules in order to meet the HIPAA Privacy Rule regulations as well as minimize the risks.

2.2 Development of the Protocol

A. During the development of an epidemiological research protocol, the investigator must consider several questions and be prepared to justify the responses in the IRB Application. Consideration of these questions will aid the investigator in meeting the requirements of the Privacy Rule, Health and Human Services regulations at 45 CFR §46, as well as all applicable IRB requirements:

- 1.** What is the purpose of the research and what data is required to achieve the purpose of the research?
- 2.** Will retrospective (already existing) or prospective (collected in the future) data be used in the study?
- 3.** Where will the data come from (e.g., medical record review, databases, registries or clinical interaction with participants)?
- 4.** Will the research involve banking of data for future use or for purposes that are not integral to the current research?
- 5.** Does, or will, the collected data contain Protected Health Information or other information that can be directly, or indirectly, linked to a participant? If yes, why will the link to a participant be required and how long will the identifiers be retained?
- 6.** Does the investigator have ethical access to the data (e.g., through a treatment relationship with potential participants or through control of an existent database)?

7. Does the research have the potential to collect data on the participant (e.g., proband -- the family member through whom a family's medical history comes to light) and other related individuals (e.g., family members) identified by the participant or through other means (e.g., surveys and questionnaires)?

2.3 Protected Health Information

1. Identifiers

The Privacy Rule states that only the *minimum Protected Health Information necessary to achieve the research objective* can be used. Where it has been determined that participant identifiers are crucial to the research, the investigator must list the identifiers to be used and provide justification for their use (see RPP Policy # 10.01 for a list of the identifiers.)

2. Limited Data Set

1. In cases where the investigator provides justification for a need to maintain subject links to the data, the use of a Limited Data Set should be considered (see RPP Policy # 10.02 for further information.)

2. The investigator who is using the Limited Data Set *cannot* maintain the linked code. At ASU, the Office of Research Compliance will normally maintain such codes. To obtain a Limited Data Set the investigator must complete a ASU Data Use Agreement. This will identify the investigator as the recipient of the Limited Data Set, how the data may be used and disclosed by the investigator, and provide assurances that the data will be protected.

3. During consideration of the application, the IRB will determine if the use of the Limited Data Set meets the HIPAA and Health and Human Services requirements for waiver of informed consent.

3. De-Identified Data Set

1. If the data has been de-identified, the IRB will consider one of two (2) review options:

2. The IRB may determine that this qualifies for exemption under Health and Human Services regulations at 45 CFR §46.101(b) (see RPP Policy # 4.01 for a listing of the research categories that qualify for exemption.)

3. The research is not considered human participant research; therefore, it is not subject to Health and Human Services regulations at 45 CFR §46.

2.4 Informed Consent

A. Informed consent must be obtained from the participant, unless the IRB approves a waiver or alteration.

2.5 Waiver or Alterations of Informed Consent

1. While protection of patient privacy and confidentiality is the primary goal of the HIPAA regulations, it is understood that situations may arise where obtaining informed consent may be impractical (e.g., research conducted on existing databases or repositories where no contact information is available). In these cases, HIPAA and Health and Human Services regulations have provided for IRB waiver or alteration of informed consent, if approved by the full IRB.

2. The following criteria must be met (see RPP Policy #9.06):

3. The use or disclosure of Protected Health Information involves no more than minimal risk.

4. An adequate plan to protect participant identifiers from improper use and disclosure must be presented to the IRB (e.g., data is coded or linked and the codes are stored separately).

5. An adequate plan to destroy participant identifiers at the earliest opportunity must be presented to the IRB (unless there is a health or research justification for retaining the identifiers or required by law).

6. Using the “reasonable person standard”, the alteration of the waiver of informed consent will not adversely affect the rights and welfare of the individuals.

7. The research cannot practicably be conducted without the waiver or alteration of informed consent and justification is provided.

8. The research cannot be conducted without access to and use of the Protected Health Information. The objectives and validity of the study must provide justification for the use of specific Protected Health Information.

9. Whenever appropriate, the participants will be provided with additional pertinent information after participation.

2.6 Participant Recruitment

1. All participant recruitment activities must be approved by the IRB (see RPP Policy # 3.11).

2. IRB approval of the recruitment plan is particularly important in situations where the investigator requests that a participant identify family members (or other applicable individuals) that might qualify for the study. It is important to note that the investigator has ethical access only to the enrolled participant, not those individuals identified by the participant. The investigator, or specialist, may not directly contact the family members (or others) without permission of those individuals.

3. The IRB recommends where possible the following recruitment plan be utilized:

1. The participant may be asked if they have family members who might qualify for the study. Rather than request the names and contact information, the investigator should ask the participant to speak with family members about the project. The participant may be provided an IRB-approved informational brochure or letter to give to the family member. The brochure/letter should provide information on whom to contact for further information. Alternately, it would be appropriate to provide self-addressed stamped postcards to the participant to hand out to family members. Interested family members (or others) could indicate their interest by returning the card with names and contact numbers filled in. In both cases, contact would be initiated by individuals expressing an interest in the study.

2.7 Research Involving the Development of a Database

There are two separate activities to consider in the development of a database. Each is considered a separate research activity under the HIPAA regulations and will require IRB-approved informed consent (authorization), unless the IRB grants a waiver or alteration to the informed consent requirement:

1. Creation of a Research Database or Repository

The use or disclosure of Protected Health Information for *creating* a research database or repository.

1. During consideration of an IRB application to create a research database or repository, the IRB must consider:

- a) Will the database maintain Protected Health Information? If yes, what is the investigator's justification?
- b) Will informed consent (authorization) be required, or does the database meet the qualifications for waiver or alteration of informed consent? In most cases, if the database involves collection of data through direct intervention or interaction with the participant, the IRB will require informed consent.
- c) Has the investigator provided sufficient assurance that the Protected Health Information in the database will not be used or disclosed for future research without IRB approval prior to use?

2. Future Research Using a Database

The use or disclosure of Protected Health Information in the database for a *future* research purpose.

1. Creation of a database for the purposes of research *does not* mean the database can be used for any future research without specific IRB approval of the proposed study.

- a) Use of a database for research not pre-approved by the IRB for research requires review and approval by the IRB.
- b) Informed consent requirements will be based on:
 - 1) The Protected Health Information present in the database, 2) Prior informed consent of the subject to authorize the placement of Protected Health Information in the database, 3) The purpose of the research, and 4) Prior IRB waiver or alteration of informed consent.

RPP Policy: 6.03 Exercise Protocol Guidelines

1. Purpose

The purpose of this SOP is to describe the guidelines required when conducting studies that include exercise.

2. Policy

It is the policy of the IRB that all exercise studies will be conducted in accordance with regulations at Health and Human Services 45 CFR §46.

2.1 Introduction

A. The American College of Sports Medicine published guidelines in 2000 for use in studies involving exercise testing and prescriptions. These guidelines have been recognized as setting national standards. The guidelines, adopted by the IRB for research protocols involving exercise, reflect the American College of Sports Medicine 2000 guidelines and requirements of 45 CFR §46.

These guidelines are largely based upon the following criteria:

1. Intensity of exercise.
2. Age of participant.
3. Apparent health status of participant.
4. Apparent fitness/activity level of participant.

B. The aforementioned criteria, in turn, determine health screening, monitoring, physician oversight and the type of IRB review (e.g., *expedited continuing* vs. *Full Board*). The IRB reserves the right to rule in exception to the exercise guidelines if necessary.

2.2 Health Screening

A. Appropriate participant health screening is required prior to the initiation of any maximal or sub-maximal intensity exercise test or program. Physician approval is required for participants that are at higher risk. A questionnaire may be administered by qualified study personnel to participants that are at lower risk. This questionnaire should be submitted with the IRB Application.

2.3 Maximal Exercise Procedures

A. Cardiovascular Endurance

1. Cardiovascular endurance exercise procedures that are higher in intensity than 90% of maximal heart rate or 85% of maximal oxygen uptake or heart rate reserve maximum are regarded as maximal exercise and are considered in the category which requires review by the full IRB.

The following table should be used to determine how to classify a particular participant in maximal cardiovascular endurance protocols and which requirements must be met:

	Participant 1	Participant 2	Participant 3	Participant 4	Participant 5
Health Status	Apparently Healthy	Apparently Healthy	Apparently Healthy	Apparently Healthy	Unhealthy
Exercise Status	Active	Active	Sedentary	Sedentary	Active or Sedentary
Age, yr	<age 35	>age 35	<age 35	>age 35	<or> age 35
Review	<i>Full Board</i>	<i>Full Board</i>	<i>Full Board</i>	<i>Full Board</i>	<i>Full Board</i>
Health Professional Attendance	None	Physician, R.N. or P.A.	None	Physician, R.N. or P.A.	Physician, R.N. or P.A.
Health Screening	Questionnaire	Physician approval	Questionnaire	Physician approval	Physician approval
Subject Monitoring	Heart rate	Heart rate EKG	Heart rate	Heart rate EKG	Heart rate EKG

B. Muscular Strength/Endurance

1. Muscular strength/endurance exercise procedures using maximal (e.g., one-to-five) repetitions require full IRB approval regardless of participant health, activity level, and/or age.
2. Isokinetic exercise testing programs (e.g., Biodex) at slow movement speeds are considered in this category.
3. Scientific justification will be required to support the use of exercises that are considered high risk. These exercises include, but are not limited to:
 - a) Squat.
 - b) Dead Lift.
 - c) Clean and Jerk.
 - d) Overhead Press.
 - e) Any equivalent of the above.

The following table should be used to determine how to classify a particular participant in maximal muscular strength/endurance research and which requirements must be met:

	Participant 1	Participant 2	Participant 3	Participant 4	Participant 5
Health Status	Apparently Healthy	Apparently Healthy	Apparently Healthy	Apparently Healthy	Unhealthy
Exercise Status	Active	Active	Sedentary	Sedentary	Active or Sedentary
Age, yr	<age 35	>age 35	<age 35	>age 35	<or> age 35
Review	<i>Full Board</i>	<i>Full Board</i>	<i>Full Board</i>	<i>Full Board</i>	<i>Full Board</i>
Health Professional Attendance	None	Physician, R.N. or P.A.	None	Physician, R.N. or P.A.	Physician, R.N. or P.A.
Health Screening	Questionnaire	Questionnaire or IRB Ruling	Questionnaire	Questionnaire or IRB Ruling	Physician approval

2.4 Moderate Exercise Procedures

A. Cardiovascular Endurance

A. Cardiovascular endurance exercise procedures that are lower in intensity than 90% of maximal heart rate or 85% of maximal oxygen uptake or heart rate reserve maximum are regarded moderate exercise and are considered in this category.

The following table should be used to determine how to classify a particular participant in moderate cardiovascular endurance protocols and the requirements which must be met:

	Participant 1	Participant 2	Participant 3	Participant 4	Participant 5
Health Status	Apparently Healthy	Apparently Healthy	Apparently Healthy	Apparently Healthy	Unhealthy
Exercise Status	Active	Active	Sedentary	Sedentary	Active or Sedentary
Age, yr	<age 35	>age 35	<age 35	>age 35	<or> age 35
Review	<i>Expedited continuing</i>	<i>Full Board</i>	<i>Expedited continuing</i>	<i>Full Board</i>	<i>Full Board</i>
Health Professional Attendance	None	None	None	None	Physician, R.N. or P.A.
Health Screening	Questionnaire	Questionnaire	Questionnaire	Questionnaire or IRB Ruling	Physician approval
Subject Monitoring	Heart Rate	Heart Rate	Heart Rate	Heart Rate	Heart Rate EKG

2.5 Other Exercise Procedures

Investigators intending to use exercise procedures not addressed in these guidelines should compare the proposed exercise to the most closely related category and classification. Attention should be given to the intensity of the exercise, the age of the participant, the apparent health status of the participant, and the apparent fitness/activity level of the participant. Finally, the appropriateness of the exercise should be considered in relation to these factors.

RPP Policy: 6.04 Research Conducted in Foreign Countries

1. Purpose

The purpose of this SOP is to describe the guidelines for research conducted in foreign countries.

2. Policy

It is the policy of the IRB that all research in foreign countries will be conducted in accordance with the regulations at Health and Human Services 45 CFR §46.

2.1 Non-federally funded research

A. Non-federally funded research that is conducted in a foreign country is subject to all of the IRB requirements except that IRB requirements can be waived in consideration of the culture and local customs of the country in which the research is conducted. Investigators who seek a waiver of *any* IRB requirements must provide appropriate justification to the IRB.

2.2 Federally funded research

A. Federally funded research, which is conducted in a foreign country is subject to all of the IRB requirements with exceptions granted in accordance with the federal (model) policy and OHRP guidance.

B. According to the model policy for the protection of human participants and OHRP requirements, when federally funded research takes place in foreign countries, a FWA must be filed. However, procedures normally followed in the foreign countries to protect human participants may differ from those set forth in the model policy. In these circumstances, a department or agency head must determine that the procedures prescribed by the foreign institution afford protections that are at least equivalent to those provided in the model policy. If the procedures meet these criteria, the department or agency head may approve the substitution of the foreign procedures in lieu of the procedural requirements provided in the model policy.

2.3 IRB Requirements

A. The international institution must provide assurance to the IRB that all of its activities related to human participant research, regardless of funding source, will be guided by the ethical principles in one of the following documents:

1. The Declaration of Helsinki (as adopted in 1996 or 2000).

2. The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research of the U.S. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.

3. Other appropriate international ethical standards recognized by federal departments and agencies that have adopted the US Federal Policy for the Protection of Human Subjects. A copy of these standards must be provided by the institution.

B. In addition, the IRB requires confirmation of IRB approval (or equivalent) from the foreign site, a copy of the protocol, and a copy of the informed consent document.

Section 7: Informed Consent

RPP Policy: 7.01 Development of the Informed Consent or Assent Document

1. Purpose

The purpose of this SOP is to describe development of the informed consent or assent (hereafter “consent” this policy) document.

2. Policy

It is the policy of the IRB that the informed consent document will be developed in accordance with regulations at Health and Human Services 45 CFR §46.

2.1 Consent documents

A. All consent documents printed on paper should include the ASU letterhead, while all electronic consent forms should include the words “Alabama State University” in a prominent position.

2.2 Specific Layout Instructions

A. All consent documents submitted should be suitable for reproduction and easy readability by potential participants.

B. Lines requiring the participant, witness, or PI signatures should not be placed on a separate page without the presence of any of the preceding language required in that section of the informed consent.

C. Each page of the consent/assent document *must* include:

1. The IRB protocol number in the upper right corner as labeled by the IRB (“IRB #_____”), date of approval of current consent form, and “valid until” date. Commonly, there are many versions or amendments to the original consent throughout the course of a study. This requirement will help the investigator and IRB track the most current version of the consent/assent documents.

2. Page numbers (“Page _ of _”) at the bottom of each page.

3. “Participant’s Initials _____” at the bottom of each page.

2.3 Identification of Type of Consent and Assent

To easily identify the type of consent/assent document, one of the following labels should be placed at the top of the first page:

A. Adult Consent: Utilized when enrolling competent adults (in Alabama defined as individuals 18 years of age or older and individuals under 18 years of age who are legally emancipated or who are otherwise able to consent to the procedures involved in the research).

B. Parent or Legal Guardian Consent: Utilized when enrolling children (in Alabama defined as individuals under 18 years of age except those who are legally emancipated or who are otherwise able to consent to the procedures involved in the research) in a research study.

1. *Youth Assent:* To be used for children aged 13-18 years
2. *Child Assent:* To be used for children aged 7-12 years

C. Proxy, Legally Authorized Representative, or Durable Power of Attorney

Consent: Utilized when enrolling decisionally-impaired adults.

D. Adult Assent: Used when enrolling decisionally-impaired adults.

E. Screening Consent: Used to obtain participant consent to allow study-related screening tests for potential enrollment in a study. Full study consent will follow.

F. Addendum Consent: Commonly used to obtain additional consent from participants for auxiliary studies (e.g., tissue banking). Also may be used to inform currently enrolled participants of new information pertaining to the research.

2.4 Identification of Study Personnel

A. The PIs listed in the IRB Application must be listed on the last page of the informed consent/assent document in accordance with Health and Human Services regulations at 45 CFR §46.111(a) (4) and §46.116(a) (7).

B. The following subheadings must be used (as appropriate):

1. Principal Investigator
2. Supervising Investigators
3. A contact phone number for the PI and the Supervising Investigator must be provided.

2.5 General Style of Consent Documents

A. The informed consent form should be written in the **second** person throughout (e.g., “you are invited to participate”; “you will be assigned,” etc.). When combined with conditional language and the invitation to participate, utilization of the second person communicates that the investigator believes there is a choice to be made by the prospective participant. Utilization of the first person may be interpreted as presumption of participant consent before consent has been legally obtained.

2.6 Parental, Legal Guardian, Proxy, Legally Authorized Representative, and Durable Power of Attorney Consent Documents

A. Proxy consent documents should reflect that it is the minor, or other vulnerable participant, who is the participant in the study. The individual giving consent (parent or legally authorized representative) is providing permission to allow the participant to participate in the study.

2.7 Adult, Youth, and Child Assent Documents

A. Assent documents should reflect the age, maturity and cognitive ability of the decisionally-impaired adults, youth, and children that will be the participants of the research.

B. Please refer to the appropriate section for further information about:

1. Parental/legal guardian consent and youth/child assent, see RPP Policy # 8.04.
2. Proxy/DP consent and adult assent, see RPP Policy # 8.04.

2.8 Readability

A. The consent form must be written in simple enough language so that it is readily understood by the least educated of the participants to be involved. Generally, the level of language in the adult consent document should be around an eighth grade standard. Youth and child assent documents should be written in an age-appropriate style.

B. Medical and scientific terms should be avoided where possible. If medical jargon is used the lay terms should be used first and then the medical term included in parentheses.

C. Common units of measure should be used appropriate to the procedure or content.

D. It is recommended that the language consist of short, concise sentences arranged in relatively short simple paragraphs. Headers should be used to separate sections of the document for easier reading, particularly when describing what will happen during the study. Generally, abbreviations should not be used in the consent document that is, all words should be spelled out. The IRB may approve limited use of abbreviations where appropriate, as long as the acronym is spelled out the first time it is used.

2.9 Length

A. There are no restrictions on the length of the informed consent/assent documents. The informed consent form should be lengthy enough to explain the elements of consent adequately, but not so lengthy or detailed as to lose the attention of the participant or to cause confusion.

2.10 Format

A. *Exempt Research:* If the research is *exempt*, but requires written informed consent (e.g., an educational study requiring parental consent), a narrative consent form format may be used at the discretion of the investigator. In the narrative consent form, all necessary elements of consent should be present on the consent form, but the elements need not be identified by subheadings.

B. *Research Involving Greater than Minimal Risk:* If the research involves procedures, which are *greater than minimal risk*, the legalistic consent document format must be used (see RPP Policy# 3.04 for a definition of minimal risk). The IRB has developed an informed consent document template that is designed to provide investigators guidance in the development of this form. The template is available on the ORSP website.

C. *Exculpatory Language*

The consent document must not contain any exculpatory language through which the participant or the participant's representative is made to waive, or appear to waive, any of the participant's legal rights. Additionally the consent document must not release, or appear to release, the research investigator, the sponsor, the Institution, or its agents from liability for negligence.

RPP Policy: 7.02 Required Elements for Informed Consent Documents

1. Purpose

The purpose of this SOP is to describe the required elements for informed consent documents.

2. Policy

It is the policy of the IRB that the IRB shall ensure that informed consent is documented in accordance with and to the extent required by Health and Human Services 45 CFR §46.116, unless documentation is waived by the IRB as provided in Health and Human Services 45 CFR §46.109(c) and §46.117.

2.1 Informed Consent

A. The prospective participant has sufficient knowledge and comprehension of the elements of informed consent (see RPP policy # 9.01) prior to enrollment and during participation in research. This is accomplished through the initial and on-going process of informed consent.

2.2 IRB Responsibility

A. The IRB shall require that information given to participants as part of informed consent is in accordance with Health and Human Services regulations at 45 CFR §46.116.

B. The IRB may require that information, in addition to that required by regulations, be given to participants when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of participants in accordance with Health and Human Services 45 CFR 46.109(b). The IRB has authority to observe or have a third party observe the consent process and/or the conduct of research [45 CFR §46.109(e)].

2.3 Investigator Responsibilities

A. The investigator has a legal and ethical obligation to ensure that the prospective research participant has sufficient knowledge and comprehension of the elements of informed consent, meaning that the prospective research participant must be able to make an informed decision whether or not to participate in research. Obtaining informed consent should be seen as a communication process of explanation and not as an act of signing a form. As part of the process of obtaining informed consent, each element of consent should be explained carefully and simply to the prospective participant. In addition, the investigator should assess periodically the prospective participant's comprehension by asking appropriate questions. Ultimately, the investigator bears full responsibility for obtaining valid informed consent from the participant.

B. Investigators should be sensitive to the possible needs of an interpreter or translator for participants who do not speak English as a first language or who are hearing impaired.

2.4 Mail/Telephone and On-Line Surveys

A. Mailed surveys that are completely anonymous can meet the informed consent requirement in one of two ways:

1. They can be sent out with an accompanying cover letter and an informed consent form, or

2. They can be sent out with an accompanying informed consent form but written in a cover letter format.

a) If the second option is chosen, the return of the survey implies consent, which can be approved if the IRB grants an exemption determination or waives the requirement for documentation of the consent process.

b) The letter would have to include notification of use of data, assurance of confidentiality, and phone numbers to contact in case of questions about participant's rights. similar requirements exist for on-line and email surveys.

B. Some anonymous telephone interviews with adults can be handled in a similar way. It is preferred for the participant to receive a copy of the informed consent letter or form before the interview; however, in situations when that is not possible, information typically given on an informed consent form (notification of use of the data, assurance of confidentiality, phone numbers to contact in case of questions, etc.) can be included in an oral script that is read to participants to obtain oral consent. Oral scripts must be submitted to the IRB for review and approval before the study is conducted.

2.5 Informed consent documents

The consent form must be:

A. Appropriate to the research and participant population being studied.

B. Approved by the IRB and include the elements of informed consent required by Health and Human Services 45 CFR §46.117 and 46.117(b)(1);

C. Signed by the participant or the participant's legally authorized representative [Health and Human Services 45 CFR §46.117(a)]; unless the IRB has waived the requirement for document of the consent process in, which case a cover letter may be used as an informed consent document; and

D. Provided to the participant or legally authorized representative [Health and Human Services 45 CFR §46.117(a)].

2.6 Required Elements for Informed Consent Documents

The following are the required elements that must be present in all consent documents.

A. Informed consent shall include the following elements:

A. A statement that the study involves research [Health and Human Services 45 CFR §46.116(a)(1)];

B. An explanation of the purposes of the research [Health and Human Services 45 CFR §46.116(a)(1)];

C. The expected duration of the participant's participation in the research [Health and Human Services 45 CFR §46.116(a)(1)];

D. A description of the procedures to be followed [Health and Human Services 45 CFR §46.116(a)(1)];

E. Identification of any procedures which are experimental [Health and Human Services 45 CFR §46.116(a)(1)];

F. A description of any reasonably foreseeable risks or discomforts to the participants [Health and Human Services 45 CFR §46.116(a)(2)];

a) The agreement, written or oral, entered into by the participant, may not include language through which the participant is made to waive, or to appear to waive, any legal rights, or to release, or appear to release the investigator, the sponsor, ASU, or its agents from liability for negligence.

G. A description of any benefits to the participant or to others which may reasonably be expected from the research [Health and Human Services 45 CFR §46.116(a)(3)];

H. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant [Health and Human Services 45 CFR §46.116(a)(4)];

I. A statement describing the extent, if any, to which confidentiality or anonymity of records identifying the participant will be maintained [Health and Human Services 45 CFR §46.116(a)(5)];

a) Confidentiality, as defined in the 1993 Office for Protection from Research Risks IRB Guidebook, "pertains to the treatment of information that an individual has disclosed in a relationship of trust and with the expectation that it will not be divulged to others in ways that are inconsistent with the understanding of the original disclosure without permission." Anonymity indicates that there will be no way in which the data could be connected to the respondent, including by the researcher.

J. For research involving more than minimal risk, an explanation as to whether any compensation is available if injury occurs; whether any medical treatments are available if injury occurs; and,

if so, what they consist of, or where further information can be obtained [Health and Human Services 45 CFR §46.116(a)(6)];

K. Information regarding whom to contact for answers to pertinent questions about the research and who to contact in the event of a research related injury to the participant. [Health and Human Services 45 CFR §46.116(a) (7)]. A contact phone number for the PI and the Supervising Investigator must be provided;

L. Information regarding whom to contact regarding participants rights, for example, “Sometimes study participants have questions or concerns about their rights. If you have such questions, you should call Alabama State University Institutional Review Board at (334) 229-5053.” [Health and Human Services 45 CFR §46.116(a)(7)]; and

M. A statement that participation is voluntary that refusal to participate involves no penalty or loss of benefits to which the participant is otherwise entitled. That the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled: for example “You are free to decide not to participate in this study. You can also withdraw at any time without harming your relationship with the researchers or Alabama State University or other agent.” [Health and Human Services 45 CFR §46.116(a) (8)].

N. The IRB may require additional information to that required by Health and Human Services 45 CFR §46 be provided to participants when, in its judgment, the information would meaningfully add to the protection of the rights and welfare of participants (Health and Human Services 45 CFR 109). Such information may be:

1. Why the participant was selected.
2. Where research will take takes place.
3. The age of participants (under 18 require parental informed consent in Alabama except those who are legally emancipated or who are otherwise able to consent to the procedures involved in the research).

2.7 Documentation of Consent Process

The consent process must be appropriately documented in accordance with Health and Human Services regulations at 45 CFR §46.117. (seeRPP Policy # 9.02):

A. The participant must initial the bottom of each page of the consent, or the consent form should say “page ___ of ___” and formally provide for full signature and date at the end of the consent.

B. For studies involving greater than minimal risk, a witness must also provide signature and date.

C. The investigator's name and phone number must be listed at the end of the consent form.

D. The IRB may require additional protections in the consent process when, in its judgment, these procedures would meaningfully add to the protection of the rights and welfare of the participants. These may include:

a) The IRB may require the consent process be monitored or observed when individuals with decisional impairments are involved.

b) The IRB may require waiting periods prior to consenting.

c) The IRB may require an advocate or ombudsman oversee the consent process for individuals with decisional impairments

d) The IRB may require procedural changes or additional protections for individuals with decisional impairments.

e) When individuals with decisional impairments are potential research participants, the IRB may require the investigator to use techniques that would confirm that individuals did understand the consent process.

2.8 Observation of the Consent Process

A. The IRB may choose to observe the consent process where it determines that such observation will meaningfully contribute to the reduction of risk to the research participant. For example, the IRB may observe in situations with vulnerable populations where such observation of the consent might minimize coercion or undue influence, or situations involving non-compliance with the consent process.

B. If the IRB decides that the consent should be observed, the investigator will be notified before such observation. The PI will be consulted collegially so that appropriate arrangements can be made for the observation to take place in a manner that is as unobtrusive as possible. ORC staff will conduct the observation.

RPP Policy: 7.03 Consent by Telephone

1. Purpose

The purpose of this SOP is to describe the guidelines governing consent by telephone to a study.

2. Policy

It is the policy of the IRB that telephone consent will be gained in accordance with the regulations at Health and Human Services 45 CFR §46.

2.1 Introduction

Whenever possible, consent should be obtained in person by an authorized investigator. However, the IRB recognizes that an alternative informed consent process may, at times, be necessary. Therefore, under extenuating circumstances, the IRB may approve an alternative informed consent process(es) via telephone.

A. IRB approval of a telephone consent process for research requires a waiver of the requirement for written documentation of consent. In lieu of written consent documentation, consent will be acquired orally.

B. The consent discussion needs to include all required elements of consent disclosure (see RPP Policy # 7.02) unless the IRB approves a waiver or alteration of the consent process.

2.2 IRB Requirements for Use of a Telephone Consent Process

A. The IRB will review the proposed method of consent based upon:

- 1.** The nature of the study,
- 2.** The risk level, and
- 3.** Participant population needs.

B. The proposed method of consent must be fully explained and justified in the IRB protocol.

2.3 Re-consent by Telephone for Significant Changes or Disclosure of Significant Additional Risks

The following describes IRB requirements for the use of telephone consent for re-consent for significant changes or disclosure of significant additional risks and re-consent for minor changes or disclosure of additional minor risks:

A. With appropriate scientific rationale and justification, the IRB may approve a telephone consent procedure to allow the participant to be notified of significant new risks.

B. The IRB may determine what procedure and documentation are required in order to ensure the maximum protection to the participant.

C. Procedures that may be adopted include, but are not limited to:

- 1.** A consent document (revised consent form or addendum) that is to be provided to the participant for review prior to the telephone consent process.
- 2.** It is preferred that this be done by mail; however, fax is acceptable when necessary.
- 3.** A signed copy (fax or original) of the consent form has been received by the investigator before research interventions are conducted.
- 4.** An extra copy to be provided for the participant to keep for his or her records.
- 5.** A telephone call that will be scheduled. The minimum required participants in the consent process are:
 - a)** The participant.
 - b)** The authorized investigator.
- 6.** Each element of the consent document, which has been changed, should be explained to the participant, and the participant's comprehension may be assessed.
 - a)** The participant may be given the opportunity to ask questions.
 - b)** It may be necessary to extend the process over several days and include other individuals such as the participant's family members.
 - c)** The participant may need to be instructed in the signing of the consent form and may need to return the original signed document to the investigator by mail.
 - d)** The participant may need to be re-consented in the presence of the investigator when he/she returns to research site for follow-up.

D. In all cases, the alternative process of consent must be documented in the research record by indicating the reason for the alternative method used, date, time, and personnel involved in obtaining and documenting consent.

2.4 Telephone Re-Consent for Minor Changes or Disclosure of Additional Minor Risks

- A.** The IRB may approve a telephone consent procedure to allow the participant to be notified of minor changes or of additional minor risks.
- B.** The IRB may determine what procedure and documentation are required in order to ensure the maximum protection to the participant.

RPP Policy: 7.04 Re-Consent/Assent Research Participants

1. Purpose

The purpose of this SOP is to describe the process of re-consent/assent of research participants.

2. Policy

It is the policy of the IRB that the process of re-consent/assent of research participants will be conducted in accordance with the regulations at Health and Human Services 45 CFR §46.

2.1 The initial informed consent/assent document(s) signed by the participant at enrollment remains in effect for the duration of the participant's participation in the study.

A. *Or* until the IRB approves a change in the consent/assent document(s), which requires re-consent/assent of participants.

2.2 In order to validate the voluntary nature of participation in research and exhibit respect for the individual, participants must be provided with any new formation, which may affect their willingness to continue to participate in the research. Health and Human Services regulations at 45 CFR §46.116(b) (5), require investigators to inform participants of any important new information that is germane to the participant's willingness to continue participating in the study.

2.3 Each year, during the continuing review process, original consent/assent document(s) are submitted for review.

A. Upon IRB re-approval of the study, the consent/assent documents are stamped with the "date approved" and "valid until" dates.

B. The IRB does not require re-consent of previously enrolled participants at this time, unless the IRB approves a request for change during the continuing review process or identifies new information which requires re-consent of the participants.

2.4 Commonly, minor information (e.g., changes in personnel or administrative changes in the consent document) is provided to participants through verbal exchanges between the investigator and participant, without undergoing a formal re-consent procedure. Minor information is unlikely to affect a participant's willingness to continue participation in a study.

A. Significant new information which requires re-consent/assent of participants must be acquired through use of IRB-approved, revised consent/assent document(s) or an addendum to the consent/assent form. Significant new information may include:

A. Changes in the duration of the study

B. Major changes in the methods of the study.

3. Changes in investigator or investigative team

RPP Policy: 7.05 Absence of Valid Consent: Re-Consent and Use of Data

1. Purpose

The purpose of this SOP is to describe the guidelines governing the re-consent and the use of data in the absence of valid consent.

2. Policy

It is the policy of the IRB that, in the absence of valid consent, re-consent and the use of data will adhere to the regulations at Health and Human Services 45 CFR §46.

2.1 The investigator has a legal and an ethical obligation to ensure that the prospective participant has sufficient knowledge and comprehension of the elements of informed consent prior to enrollment and during participation in research.

A. This is accomplished through the initial and on-going process of informed consent.

2.2 If a participant enrolls and begins participation in a study without the presence of a valid informed consent document (e.g., the participant signed a wrong or outdated consent form), participant comprehension of the elements of informed consent and true informed decision-making is called into question. The ethical principal of respect for persons demands that participants enter into research voluntarily and with adequate information.

2.3 If a participant enrolls in a study without valid informed consent, the principal investigator must immediately notify the IRB Chair and the participant and explain the situation.

A. The PI should request that the participant re-consent to participate.

B. If the participant agrees, the complete informed consent process is repeated, including:

- 1.** Signatures on the consent document,
- 2.** Documentation of consent in the research record,
- 3.** Data obtained during the period of invalid consent may be used with approval of the IRB.

C. If the participant refuses to consent, participation in the study must be halted immediately and the collected data cannot be used.

RPP Policy: 7.06 Waiver or Alteration of Consent

1. Purpose

The purpose of this SOP is to describe the situations in which the IRB may waive or alter the informed consent process and/or waive consent documentation.

2. Policy

It is the policy of the IRB that all requests for waiver or alteration of the informed consent process or consent documentation must undergo appropriate IRB review, and when waivers or alterations are granted, they are given based on Health and Human Services regulatory criteria at 45 CFR §46.111(a) (4) and (5), 45 CFR §46.116(a) to (e), 45 CFR §46.117(a) to (c).

2.1 Waiver of Documentation of Informed Consent

A. The IRB may waive the requirement that the participant or the participant's representative sign a written consent documentation per 45 CFR § 46.117 (c) if it finds:

- 1.** That the signed consent is the only link that could result in potential harm to the participant if a breach of confidentiality occurred. Each participant will be asked whether he or she wants documentation linking the participant with the research, and the participant's wishes will govern;
- 2.** That the research presents no more than the minimal risk of harm to the participants, and involves no procedure for which written consent is normally required outside of the research context (e.g., as a part of a routine exercise in the classroom and the material (data) would have been collected in any case.

B. In cases in which the documentation requirement is waived, the IRB may require the investigator to provide participants a written statement regarding the research.

C. When the IRB considers waiving the requirement to obtain documentation of the consent process, the IRB should review a description of the information that will be provided to participants.

2.2 Waiver or Alteration of Consent

A. The Board may waive the requirement for informed consent per 45 CFR §46.116(d) (or allow an alteration of some or all of the elements of informed consent) only if the Board finds that each of the following four elements are met (This is different from waiving the requirement of documentation of informed consent):

- 1.** The research involves no more than minimal risk to participants; and
- 2.** The waiver or alteration will not adversely affect the rights and welfare of the participants; and
- 3.** The research could not practicably be carried out without the waiver or alteration; and
- 4.** Whenever appropriate, the participants will be provided with additional pertinent information after participation (45 CFR 46.116(d)).

B. The investigator must complete the form for IRB Waiver of Informed Consent.

Section 8: Vulnerable Populations and Special Classes of Participants

RPP Policy: 8.01 Additional Protections for Vulnerable Populations

1. Purpose

The purpose of this SOP is to describe additional protections for vulnerable populations.

2. Policy

It is the policy of the IRB that the vulnerability of a potential participant population will be evaluated to ensure that appropriate protections are in place for any participant who may be vulnerable in accordance with Health and Human Services regulations at 45 CFR §46.111(a)(3).

Health and Human Services regulations at 45 CFR §46 provide special protections for prisoners (Subpart C) and children (Subpart D). Regulations 45 CFR §46 does not, however, include *specific* requirements for the protection of other vulnerable participant populations, such as persons who are decisionally-impaired, terminally ill, economically or educationally disadvantaged, or other vulnerable populations.

In these situations, the IRB, in consultation with the investigator, will determine the appropriate means to protect the rights and welfare of the individuals.

2.1 Definition

A. Vulnerable population is defined as an individual or group of individuals with limited autonomy (e.g., lacks independence in decision making for a variety of reasons) or is otherwise at increased risk compared to nonvulnerable individuals. Within any population of vulnerable participants, individuals will have different levels of vulnerability based on the level of capacity, circumstance, or condition affecting independent decision-making.

2.2 Categories of Vulnerable Populations

Vulnerable populations may be categorized according to the following groups:

- A.** Prisoners (see RPP Policy # 5.03)
- B.** Children (see RPP Policy # 5.04)
- C.** Pregnant women (see RPP Policy # 5.02)
- D.** Fetuses and neonates (see RPP Policy # 5.02)
- E.** Decisionally impaired (see RPP Policy # 5.05)
- F.** Comatose
- G.** Terminally ill
- H.** Economically disadvantaged
- I.** Educationally disadvantaged
- J.** Socially disadvantaged
- K.** Employees and students (See RPP Policy # 5.06)
- L.** Others, as determined by the IRB and investigator.

2.3 Factors Determining Vulnerability

- A. The nature of the research.
- B. The risks of the research.
- C. An increased probability of risk occurrence in the proposed population.
- D. Degree of autonomy, or limited autonomy, present in the proposed population.
- E. The clinical status of the proposed population.
- F. The educational status of the proposed population.
- G. The economic status of the proposed population.
- H. The presence of a support system (e.g., family and friends) for the proposed population.
- I. Cultural or social factors associated with the proposed population.

2.4 Additional Protections for Vulnerable Populations

A. Upon determining the vulnerability of an individual or population, the IRB and investigator will provide special protections against risk. These additional protections will include those specified by RPP policies for research involving pregnant women, prisoners, children, or decisionally impaired participants.

B. Other additional protections, as deemed necessary by the IRB, may also include:

1. The use of an extended consent process.
2. The use of a consent monitor.
3. Appointment of a participant advocate.
4. Involvement of the participant's family and/or friends.
5. Limits placed on risk.
6. Exclusion from participating in the research.
7. Increased safeguards to protect privacy and confidentiality.
8. Increased monitoring of the research by the IRB or other mechanisms.
9. More stringent withdrawal criteria (i.e., easier to withdraw from study).
10. Longer study follow-up.

RPP Policy: 8.02 Research Involving Pregnant Women, Human Fetuses, and Neonates

1. Purpose

The purpose of this SOP is to describe the IRB requirements for research involving pregnant women, fetuses, and neonates.

2. Policy

ASU RPP policies provide for additional protections for pregnant women, fetuses, and neonates involved in research. These policies are described below.

Research which is funded by DHHS must satisfy the additional protections described in 45 CFR §46 subpart B. For all other research, additional protections are identical to those found in 45 CFR §46 subpart B, except as indicated in 2.2 (A) (2) (b)

2.1 Definitions

A. *Pregnancy*: Period from confirmation of implantation of a fertilized egg within the uterus until the fetus has been delivered. Implantation is confirmed through a presumptive sign of pregnancy (e.g., missed periods or a positive pregnancy test). While confirmation may be in error, investigators must presume that a living fetus was present until evidence is presented to the contrary.

B. *Fetus*: The product of conception from implantation until delivery.

C. *Viable neonate*: A neonate, after delivery who can survive to the point of independently maintaining heartbeat and respiration. (A viable neonate is covered by Health and Human Services regulations at 45 CFR §46, Subparts A and D.)

D. *Nonviable neonate*: A neonate after delivery who, although living, is not viable.

2.2 RB Review

A. In addition to review of research under Health and Human Services regulations at 45 CFR §46 (Subpart A), the IRB must provide special review of all behavioral/social science research where pregnant women, fetuses and/or neonates are involved.

2.3 Research involving pregnant women or fetuses

A. Pregnant women may be involved in research funded by DHHS if all of the following conditions are met:

- 1.* Appropriate preclinical studies, including studies on pregnant animals and clinical studies involving non-pregnant women, have been conducted and provide data for assessing potential risks of pregnant women and fetuses.
- 2.* Any risk to the fetus is caused solely by interventions that offer direct benefit for the woman or fetus, or if there is no prospect of direct benefit: The risk to the fetus must not be greater than minimal, and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means.
- 3.* Any risk to the pregnant woman or the fetus is the least possible to achieve the research objectives.
- 4.* Consent of the pregnant woman alone is required for research which:
 - a)** Offers direct benefit to the pregnant woman only, or
 - b)** Will not directly benefit the woman or fetus but: a) there is no more than minimal risk to the fetus, and b) the purpose of the research is to develop important knowledge and the data cannot be obtained by any other means.
- 5.* Consent of the pregnant woman and father is required if the research offers direct benefit to only the fetus. However, the father's consent is not required if he is unavailable, decisionally impaired, or temporarily incapacitated or if the pregnancy resulted from rape or incest.
- 6.* The consent must fully disclose the reasonable foreseeable impact of the research on the fetus (e.g., risk).
- 7.* Assent and parental permission for pregnant children participation in research must be obtained in accordance with Health and Human Services regulations 45 CFR §46, Subpart D (see RPP Policy # 5.04).
- 8.* No inducements, monetary or otherwise, will be offered to terminate a pregnancy.
- 9.* Individuals engaged in research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy.
- 10.* Individuals engaged in research will have no part in determining the viability of a neonate.

B. Pregnant women may be involved in research if all of the following conditions are met:

- 1.* Appropriate preclinical studies, including studies on pregnant animals and clinical studies involving non-pregnant women, have been conducted and provide data for assessing potential risks of pregnant women and fetuses.
- 2.* If any risk to the fetus is caused solely by interventions that offer direct benefit for the woman or fetus, or if there is no prospect of direct benefit, the risk to the fetus must not be greater than minimal.

3. Any risk to the pregnant woman or the fetus is the least possible to achieve the research objectives.
4. Consent of the pregnant woman alone is required for research, which:
 - a) Offers direct benefit to the pregnant woman only, **OR**
 - b) Offers direct benefit to the woman *and* fetus, **OR**
 - c) Will not directly benefit the woman or fetus but there is no more than minimal risk to the fetus.
5. Consent of the pregnant woman *and* father is required if the research offers direct benefit to *only* the fetus. However, the father's consent is not required if he is unavailable, decisionally impaired, temporarily incapacitated, or if the pregnancy resulted from rape or incest.
6. The consent must fully disclose the reasonable foreseeable impact of the research on the fetus (e.g., risk).
7. Assent and parental permission for pregnant children participation in research must be obtained in accordance with Health and Human Services regulations 45 CFR §46, Subpart D (see RPP Policy # 5.04).
8. No inducements, monetary or otherwise, will be offered to terminate a pregnancy.
9. Individuals engaged in research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy.
10. Individuals engaged in research will have no part in determining the viability of a neonate.

2.4 Research involving placenta, dead fetus(es) or fetal material

A. Research involving the placenta, dead fetus, or fetal material after delivery may occur if all federal, state, or local laws and regulations are met. If any information associated with the material used in the research can be linked in any way to a living person, Health and Human Services regulations view the living person as a research participant and the research is subject to the regulations discussed in this policy.

B. The State of Alabama has no applicable local or state laws or regulations.

2.5 Research not otherwise approvable

A. The Health and Human Services Secretary may conduct or fund research that the IRB does not feel meets the above policy if the following conditions are met:

I. The IRB finds that the research, which will be funded by Health and Human Services, presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses or neonates, *and* the Secretary has determined through consultation with a panel of experts that the research does, in fact, meet the requirements of 45 CFR 46.204; **OR**

2. The Secretary determined that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health and welfare of pregnant women, fetuses or neonates; is conducted in accord with sound ethical principles; and informed consent will be obtained.

B. Note: For non-Health and Human Services funded research, involving pregnant women, fetuses, or neonates, the ASU IRB will convene an equivalent panel of experts to advise the IRB.

2.6 Non-pregnant participants who become pregnant during research

A. If a participant becomes pregnant while actively participating in a research protocol, and this contingency was not addressed *a priori*, the investigator must:

A. Determine if it is in the best interest of the pregnant participant to continue participating in the study or terminate participation in the study by completing the report on unanticipated problems or AEs involving risks to research participants or others, as described in RPP Policy # 13.01.

a) If it is in the best interest of the pregnant participant to remain in the study, adequate justification must be provided to receive IRB Chair approval for the participant to continue participation. If it is not in the best interest of the participant to continue, the participant's participation must be terminated.

B. Submit the study for re-review by the full IRB, as soon as possible, in consideration of this policy.

2.7 Documentation of IRB findings under Subpart B

A. The IRB will fully document compliance with Subpart B in the minutes of the IRB meeting by documenting the required determinations and protocol-specific findings justifying those determinations.

RPP Policy: 8.03 Research Involving Prisoners

1. Purpose

The purpose of this SOP is to describe the procedure for research involving prisoners.

2. Policy

It is the policy of the IRB that the IRB will adhere to Health and Human Services regulations at 45 CFR §46, Subpart C which provides for additional protections for prisoners involved in social/behavioral and biomedical research. These special protections include individuals who are prisoners at the time of enrollment in the study, as well as participants that become incarcerated after enrollment in a study. The IRB will apply Subpart C to all research involving prisoners regardless of funding, with one exception described under “Special Circumstances” (See section 2.3 below).

2.1 Definitions

A. Prisoner is defined by Health and Human Services regulations as any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.

B. Minimal risk in prisoner research is defined by Health and Human Services regulations as “the probability and magnitude of *physical or psychological* harm that is normally encountered in the daily lives or in the routine medical, dental, or psychological examination of *healthy persons*.”

2.2 Permitted Research Involving Prisoners.

A. Social/behavioral and biomedical research may involve prisoners as participants only if:

1. The IRB has reviewed, approved, and determined that the research falls under one of the categories listed below in Section 2.7. In the case of DHHS-funded research, the IRB also must certify the approval to OHRP as described in 2.9.

2. The proposed research falls within one of the following categories of permissible forms of research:

a) Study of the possible causes, effects, and processes of incarceration and of criminal behavior, provided that the study presents *no more than minimal risk, and no more than inconvenience* to the participants.

b) Study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents *no more than minimal risk, and no more than inconvenience* to the participants.

For the remaining two categories, it should be noted that final approval, as indicated below, rests with the Secretary of Health and Human Services, with OHRP acting on behalf of the Secretary. Following IRB

approval, the entire research proposal (including the IRB- approved protocol, any relevant Health and Human Services grant application or proposal, consent documents, any IRB application forms, and any other information requested or required by the IRB for initial review) will be submitted to OHRP. OHRP will consult with appropriate experts, including experts in penology, medicine and ethics, and publish notice, in the Federal Register, of intent to approve such research. Health and Human Services, through OHRP, will issue its approval in writing to the IRB.

c) Research on conditions particularly affecting prisoners as a class (for example, research on social and psychological problems, such as alcoholism, drug addiction and sexual assault).

d) Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the participant. In cases in which those studies require the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups, which may not benefit from the research, the study may proceed only after the proposal is reviewed by OHRP (as discussed above).

B. For research which is not funded by Health and Human Services, neither certification to OHRP nor expert review for categories c) and d) above is required. The IRB will only approve research which fits one or more of the designated categories. In addition, the IRB will, at its discretion, convene an equivalent expert review body to review studies classified as 3 or 4.

2.3 Special Circumstances

A. When a previously enrolled participant becomes a prisoner

When a previously enrolled research participant becomes a prisoner and the relevant research was *not* reviewed and approved by the IRB in accordance with the requirements of Health and Human Services regulations at 45 CFR §46, Subpart C, the principal investigator must report the situation to the IRB immediately.

1. Upon notification that a previously enrolled research participant has become a prisoner and the principal investigator wishes to have the prisoner continue to participate in the research, the IRB will promptly re-review the protocol in accordance with the requirements of Subpart C (as applicable).

2. All research activities and interventions for the now incarcerated prisoner participant must stop until the protocol is reviewed under the requirements of Subpart C, except where the PI can justify that it is in the best interest of the participant to remain in the Health and Human Services-funded research study while incarcerated. The IRB Chair may determine that the participant may continue to participate until all the requirements of Subpart C are satisfied.

B. When a potential participant is an adolescent detained in a juvenile detention facility

If a potential participant is an adolescent detained in a juvenile detention facility, the individual is both a child and a prisoner. In such a case, Health and Human Services regulations at 45 CFR §46 Subpart C (prisoners involved in research) and 45 CFR §46 Subpart D (children involved in research) apply and will be satisfied.

A. When the proposed participant population may have high risk of incarceration during the course of the study

The IRB may choose to review the proposal under Health and Human Services regulations at 45 CFR §46 Subpart C. However, it should be noted that predetermination of a participant population's potential for incarceration carries additional risks of violating the rights of justice and respect for persons. The definitions of minimal risk and the risk/benefit analysis may not truly be applicable to the participant population.

2.4 Expedited review of research involving prisoners

Health and Human Services regulations allow *expedited review*; however, OHRP recommends that the convened IRB review all research involving prisoners. Therefore, the IRB will normally not use *expedited review* for protocols, changes, or continuing review of research involving prisoners.

2.5 Research involving prisoners and exemption under 45 CFR §46.301(a).

Health and Human Services regulations do not allow exemption of research involving prisoners (see 45 CFR §46.101(i), footnote 1).

2.6 IRB Membership Requirements for review of research involving prisoners

In addition to federal requirement regarding any research involving human participants, the IRB will satisfy the following additional requirements when the research involves prisoners, regardless of funding source:

A. The majority of the members of the IRB will not have an association with the prison(s) involved in the study (excluding the prisoner attending the IRB meeting).

B. At least one member of the IRB present at the IRB meeting and involved in the review will be a prisoner or a prisoner representative. The prisoner representative will have a close working knowledge, understanding, and appreciation of prison conditions from the perspective of the prisoner.

C. The IRB will notify the ORC of any change in the IRB roster by the addition or change of a prisoner representative, as required by Health and Human Services regulations at 45 CFR §46.103(b) (3). The IRB will be aware of the impact of roster changes on quorum requirements under Health and Human Services regulations at 45 CFR §46.108(b).

D. The IRB is aware that the special composition requirement for research involving prisoners involves not only the initial review of the protocol, but also continuing review, protocol/consent amendments, review of reports of unanticipated problems involving risks to participants, and all other IRB matters pertaining to the protocol.

2.7 IRB Findings

The IRB will follow all pertinent federal regulations pertaining to human participant research, as well as make seven additional findings for research involving prisoners regardless of funding source:

A. The research represents one of the categories permissible under Health and Human Services regulations pertaining to research involving prisoners.

B. Any possible benefits to the prisoner through his/her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his/her ability to weigh the risks of the research against the value of such advantages in the limited-choice environment of the prison is impaired.

C. The risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers.

D. Procedures for the selection of participants within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the principal investigator provides to the IRB justification in writing for following some other procedures, control participants will be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project.

E. The information is presented in language which is understandable to the participant population.

F. Adequate assurance exists that parole boards will not take into account a prisoner's participation in research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole.

G. If the IRB finds there may be a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoner's sentences and ensuring that participants are informed of this fact.

2.8 Documentation of IRB Findings

Per federal regulations, the IRB will prepare and maintain adequate documentation of IRB activities. For the purposes of Subpart C, the IRB activities include making the specific findings required under Health and Human Services regulations along with protocol-specific findings justifying those determinations. OHRP accepts documentation of protocol-specific information justifying each IRB finding required under 45 CFR §46.305(a) to be one way of adequately documenting the IRB activities required under Subpart C. The IRB will follow the aforementioned OHRP guidance.

2.9 Health and Human Services-Funded Research - Notification to OHRP

The IRB is responsible for providing certification to OHRP that the IRB has made the seven findings applicable to Health and Human Services funded research involving prisoners. The IRB will send OHRP a certification letter to this effect, which includes:

1. The name and address of the Institution
2. Identification of the research protocol and the relevant Health and Human Services grant application or protocol.
3. A copy of all paperwork necessary for IRB initial review (IRB-approved protocol, relevant Health and Human Services grant application or proposal, IRB application, consent(s), etc.).
4. Verification of the presence of a prisoner representative during consideration of the study.
5. Verification of the seven required findings (listed above).
6. Determination that the research meets one of the above categories of research permissible by federal regulations.

H. Prisoner research certification letters should be mailed to the OHRP Prisoner Research Contact person in the Office for Human Research Protections at the Department of Health and Human Services.

RPP Policy: 8.04 Research Involving Children

1. Purpose

The purpose of this SOP is to describe the procedures for research involving children.

2. Policy

It is the policy of the IRB that the board will review all research proposals involving participation of children in accordance with Health and Human Services regulations at 45 CFR §46 Subpart D and applicable state law. The IRB will classify the research in accordance with Subpart D and document how and why the proposal meets the requirements.

2.1 Definitions

A. *Age of majority* is defined according to Alabama Code §26-1-1. It states that any person in this state, at the arrival at the age of 18 years, shall be relieved of his disabilities of minority and thereafter shall have the same legal rights and abilities as persons over 21 years of age. No law of this state shall discriminate for or against any person between and including the ages of 19 and 21 years solely on the basis of age.

(a) This section shall also apply to any person who arrived at the age of 19 and 20 years before July 22, 1975, but shall not abrogate any defense or abridge any remedy available to him prior to such date.

(b) All laws or parts of laws which read "under the age of 21 years" hereafter shall read "under the age of 19 years." Wherever the words "under the age of 21 years" appear in any law limiting the legal rights and abilities of persons under such age, such words shall be construed to mean under the age of 19 years.

(c) Notwithstanding the provisions of subsection (c) of this section, nothing in this section shall be deemed to repeal any provision of Chapter 19 of Title 15 of this Code.

B. *Assent* is defined as a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.

C. *Children* are defined as persons who have not attained the legal age for consent to treatments or procedures involved in the research under the applicable law of the jurisdiction in which the research will be conducted.

1. In Alabama, individuals under the age of 18 years, with the exceptions noted below, are considered to be "children" as defined by DHHS regulations because they have not attained the legal age to consent to treatments or procedures involved in some research and the additional protections of Subpart D are required.

a) The exceptions to this rule are the following individuals who are able to consent to treatments or procedures involved in the research, so that they do not meet the DHHS definition of "children," and the additional protections of Subpart D are not required:

- 1) Emancipated minors.
- 2) Individuals of any age where the research procedures are limited to:
 - **Use of contraceptives.**
 - **Treatment for venereal disease.**
 - **Treatment for drug abuse.**

D. *Commensurate* is defined as the requirement that children and/or their guardians are familiar with procedures that are reasonably similar in nature and risk proportionally to those the child has experienced, or is expected to experience, and not restricted to specific situations the child has experienced or will likely experience in the future.

E. *Disorder or condition* is defined as a specific (or set of specific) physical, psychological, neuro developmental, or social characteristic(s) that an established body of scientific evidence or clinical knowledge has shown to negatively affect children's health and wellbeing or to increase their risk of developing a health problem in the future.

F. *Dissent* is defined as a child's decision to decline participation in research.

G. *Emancipated minor* is defined as a legal status conferred upon persons at least 18 years old who have not yet attained the age of legal competency as defined by Alabama state law (18) (§26-13-1), but who are entitled to treatment as if they had.

H. *Guardian* is defined as an individual who is authorized under applicable state or local law to consent on behalf of a child to general medical care. ORC staff, in consultation with the IRB chair, will decide which individuals meet the DHHS definition of "Guardian" when research is conducted in Alabama and when research is conducted outside Alabama.

I. *Minimal risk* is defined as the risks that normal, average, healthy children

encounter while living in safe environments or the risks associated with routine physical or psychological examinations or tests. The determination of minimal risk should take into account that:

1. Children face differing risks at different ages,
2. Risks associated with repetitive tests may increase,
3. Special/unique characteristics may make a certain population more vulnerable than average children (e.g., hemophilia), and
4. The risks associated with routine examinations or tests are equivalent to a routine well-child examination.

J. *Minor increase over minimal risk* is defined as the determination whether the research procedures or interventions present a minor increase over minimal risk. The IRB will consider the following five criteria in determining inherent risk:

1. Magnitude,
2. Probability,
3. Duration,
4. Cumulative characteristics, and
5. Irreversibility of risk to the child.

K. *Parent* is defined as a child's biological or adoptive parent.

L. *Permission* is defined as the agreement of parent(s) or guardian(s) to the participation of his/her (their) child or ward in research.

M. *Vital importance* is defined as the extent to which the research is:

1. Essential for the scientific understanding or evaluation of procedures to alleviate the disorder or condition, and
2. Perceived as essential by practitioners and family stakeholders for the understanding or amelioration of the child's disorder.

2.2 Categories of Research

Health and Human Services regulations specify that research involving children must be approvable under one or more of the following four (4) categories:

- A. Research not involving greater than minimal risk** (e.g. most educational studies, studies in which behavior is not manipulated) (45 CFR §46.404)
1. The potential risks must be outweighed or balanced by the potential benefits to the participants and/or society.
 2. Adequate provisions must be made for soliciting assent of the children and permission of the parent(s) or guardian(s).

B. Research involving greater than minimal risk, but presenting the prospect of direct benefit to the individual participants (45CFR §46.405)

1. The risk is justified by the anticipated benefit to the participants.
2. The relation of the anticipated benefit to the risk is at least as favorable to the participants as that presented by available alternative approaches.
3. Adequate provisions are made for soliciting the assent of the children and permission of their parent(s) or guardian(s).

C. Research involving greater than minimal risk and no prospect of direct benefit to individual participants, but likely to yield generalizable knowledge about the participant's disorder or condition (45 CFR §46.406).

1. The risk represents a minor increase over minimal risk.
2. The intervention or procedure presents experiences to participants that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations.
3. The intervention or procedure is likely to yield generalized knowledge about the participant's disorder or condition which is of vital importance for the understanding or amelioration of the disorder or condition.
4. Adequate provisions are made for soliciting assent of the children and permission of their parent(s) or guardian(s).

D. Research, not otherwise approvable, which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children (45 CFR §46.407).

1. The IRB will submit this category of research to Health and Human Services for approval *if* the research is funded by Health and Human Services. If the research is not Health and Human Services-funded, the IRB will, at the board's discretion, convene an equivalent expert review panel.

2.3 Process of Consent/Assent

A. Children cannot legally give consent on their own behalf. The consent (permission) of one or both of their parent(s) or legal guardian(s) is, therefore, required before they can participate in any *non-exempt* (and some *exempt*) research projects unless waived by the IRB under the provisions of Health and Human Services regulations at 45 CFR §46.116(d)

1. The IRB will make a determination whether permission of one or both parents is required for research approvable under 45 CFR §46.404 or §46.405.

- a) If the research involves activities that are *no more than minimal risk*, consent of only one parent must be obtained.
- b) If the research involves *greater than minimal risk but presents the prospect of direct benefit* to the individual participants, consent of only one parent may be obtained.
- c) If the research involves *greater than minimal risk and no prospect of direct benefit to individual participants*, consent of both parents must be obtained unless one parent is deceased, unknown, incompetent, or not reasonably available. Consent of both parents is not required, however, when only one parent has the legal responsibility for the care and custody of the child.

B. Consent of a Mature Minor

A minor may, with IRB approval, legally consent on his/her own behalf when he/she does not meet the DHHS definition of "child." In Alabama, if a participant over the age of 18 is legally declared emancipated, he/she may consent to participate in research because the individual no longer meets the DHHS definition of a child; therefore, Subpart D does not apply.

C. Assent of Children

1. In addition to obtaining of parental/legal guardian consent (permission), the investigator must also solicit assent of minor participant age 7 years or older, unless the participant displays intellectual or emotional development below that of the average 7-year-old child.
2. Obtainment of assent shows respect for a child's developing autonomy. In most circumstances (non-therapeutic research), a child's deliberate objection should be regarded as a veto to his/her involvement in the research.
3. For research conducted in educational settings the IRB may approve a waiver of consent for children as old as 12 years old.
 - a) Assent may be waived if its pursuit may require comprehension of fine distinctions between the required behaviors. For example, data is collected in the classroom. The behavior/work/participation is required and assent is being sought to use the data above and beyond its original purpose (for research not just for as an educational practice).
 - The PI must request the waiver and justify the request
 - The waiver is associated with a protocol that involves no more than minimal risk
4. Purpose of Assent
 - a) Assent serves to provide information to the child and to allow the child to dissent. With these purposes in mind, the following points should be considered when writing the *Youth or Child Assent Form*.
 - 1) In deciding whether to seek assent, the minor's age is an important criterion, but intellectual and emotional development also need be considered. The child must be able to identify the benefits and risks of the research, and to be able to reason about the consequences of participation as well as a typical 12 year old;
 - 2) A valuable function of seeking assent from the minor is to provide information that the minor and his/her parents may use in their decisions concerning the research.
 - a) In seeking assent, undue advantage should not be taken of the child's developmental limitations related to his/her voluntariness (acquiescence to authority figures and any lack of ability to express his/her rights).
 - b) When there is uncertainty as to whether assent should be sought from the child or adolescent, an independent psychological examiner should be employed to help evaluate the minor's decision-making capacities.

D. Dissent of Children

Dissent from participation or withdrawal from research is always to be honored unless the protocol affords access to a therapeutic intervention that is not otherwise available. In that case, parental consent for therapeutic intervention may override a child's dissent. However that information must be provided to the child prior to the intervention procedure.

E. Waiver of Assent

Parents or guardians may, with IRB approval, override a young child's objections to interventions that hold the prospect of direct benefit to the child in accordance with 45 CFR §46.408(a). Assent may also be waived by the IRB under 45 CFR §46.116(d).

F. Waiver of Parental Consent

1. Situations may be encountered where, with appropriate scientific rationale and justification, the IRB may approve a waiver of the requirements for parental consent.
2. If the IRB determines that a research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (example, neglected or abused children), it may waive the consent requirements noted in RPP Policy #9.01 provided an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted, and provided further that the waiver is not inconsistent with federal, state, or local law.
3. The choice of an appropriate mechanism will depend upon the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and their age, maturity, status and condition.
4. With IRB approval, the following conditions **may** qualify for a waiver of parental consent:
 - a) If the research involves a treatment for, which a minor's consent is permissible under applicable law (e.g., use of contraceptives, treatment for venereal disease or substance use).
 - b) If a participant under the age of 18 is legally declared emancipated, he/she may consent to participate in research.
 - c) If the study involved administration of a sensitive survey that deals with a minor's personal/private behavior such as substance use, sexual activity, or criminal activity providing all of the following conditions are met as prescribed by 45 CFR §46.116(d) and the IRB determines that:
 - 1) *The research involves no more than minimal risk.*
 - 2) *The lower end of the age range of the participants is no less than 13 years.*
 - 3) *The nature of the survey is such that it is unlikely that the adolescent who is experiencing emerging maturity and developing autonomy would be prepared to discuss participation in a research project with his/her parents that involves what the adolescent considers to be his/her personal and private behavior.*

- 4) *The research could not practicably be carried out without a waiver of parental consent (e.g., inadequate sample size).*
 - 5) *The value of the data to be derived from the research is significant and the waiver in the judgment of the IRB will not adversely affect parental rights using the "prudent or careful parent standard."*
 - 6) *The policy of the involved school or organization does not require parental consent for the research project.*
5. If the study involves the administration of interventions that are less than minimal risks (e.g., innocuous surveys about food, clothing, social preferences/non-sensitive dating behavior, etc.), the IRB may approve use of an unsigned parental consent form providing the involved educational entity (e.g., school, school district, etc) also approves.
 6. Waiver of Parental Consent must be approved by the *Full Board*.

G. Wards

Health and Human Services regulations at 45 CFR §46.408 set specific requirements for children who have been declared wards of the state or any other agency, institution, or entity.

1. Wards can participate in research approved under §46.406 or § 46.407 if:
 - a) The research is related to their status as a ward.
 - b) The research is conducted in schools, camps, hospitals, institutions, or similar settings where the majority of children involved in research are not wards.
2. The IRB will require appointment of an advocate for each child who is a ward.
 - a) The advocate serves in addition to any other individual acting on behalf of the child as a guardian or in the absence of the parent(s).
 - b) The advocate may represent more than one child.
 - c) The advocate must have the background and experience to act in the best interest of the child for the duration of the child's participation in research.
 - d) The advocate must not be associated in any way with the research, the investigator(s), or the guardian organization. The federal regulations do not specifically exclude IRB members from serving as a child advocate if the other conditions are met.

H. Re-consent of participants reaching the age of majority

1. All minor participants actively participating in an IRB-approved study must be consented using the adult IRB-approved informed consent document *at the first visit after reaching the legal age of majority*. If the minor participated in a study that is completed, except for data analysis, re-consent is not required.

2. The now adult participant has the right to refuse to continue participation in the study. This is to be respected and undue pressure or coercion to continue may not be applied. While new data may not be collected on participants refusing participation, existing prior data collected under the assent/proxy consent process can be used.
3. If, upon reaching the age of majority, the now adult participant is found decisionally impaired or is of diminished capacity, the participant remains vulnerable and the proxy/parental consent remains in effect. This must be documented in the study records and the **IRB** must be notified.

2.4 Consent and Assent Documents

A. Parental/Guardian Consent Form

If the participant is under the age of 7 years, only a *Parental/Guardian Consent Form* is required. The *Parental/Guardian Consent Form* should include all relevant elements of informed consent as outlined previously and be written in a *proxy* consent style that indicates it is the parent or legal representative, who is consenting to allow the minor to participate in the study. The standard statements must be modified for the Parent Consent form (e.g., *all references to "you" must be changed to "your child"*).

B. Youth Assent Form

If the participant is 7-18 years of age, a *Youth Assent Form* is required. The *Youth Assent Form* is based on the adult consent form, but should be revised to meet the cognitive and educational level of an average youth. The assent form must contain *simple* language written at the appropriate educational level of the youngest prospective participant in the youth age range. In some research projects, it may be necessary to utilize two assent forms written to accommodate participants at either end of the age range. The *Youth Assent Form* must contain all of the required elements of consent previously outlined in the **IRB** Guidelines except instructions about emergency care and rights of research participants, and should follow the general format of the adult consent form.

C. Child Assent Form

1. If the participant is under the age of 7 years, only a *Parental/Guardian Consent Form* is required. However, verbal assent should be obtained as appropriate.
2. If the participant is 7 through 12 years of age, a *Child Assent Form* is required. The *Child Assent Form* must be *brief*, without subheadings, and contain *extremely simple* language arranged in brief paragraphs. The assent form must contain the following elements: title of the research study; opportunity to ask questions; basis for participant selection; purpose of the study; explanation of procedures; potential risks/discomforts; potential benefits; statement concerning consultation with parents; freedom to withdraw; and confidentiality statement.

2.5 Documentation of IRB Findings

Per federal regulations, the IRB will prepare and maintain adequate documentation of IRB activities. For the purposes of Subpart D, the IRB activities include making the specific findings required under Health and Human Services regulations along with protocol-specific findings justifying those determinations. ORC accepts documentation of protocol-specific information justifying the IRB finding identified under Health and Human Services regulations at 45 CFR §46.404, §405, or §406. IRB actions will be documented in the approval letter.

RPP Policy: 8.05 Research Involving Participants who are Decisionally-Impaired

1. Purpose

The purpose of this SOP is to describe additional protections for participants who are decisionally impaired.

2. Policy

It is the policy of the IRB that research involving participants who are decisionally-impaired and cannot provide voluntary informed consent, must include appropriate additional protections in accordance with the requirements of Health and Human Services regulations at 45 CFR §46.111(b).

2.1 Definitions

A. Participants who are decisionally-impaired

A person that lacks the ability to reason, exhibit sound judgment and provide voluntary consent to participate in research. The impairment may fluctuate (e.g., mental disorders), decline with time (e.g., Alzheimer's), or result from health conditions (e.g., coma or other infirmity).

B. Legally Authorized Representative

1. The parent or parents having legal custody of a participant;
2. The legal guardian of a participant; or
3. The individual authorized to consent on behalf of a participant pursuant to Durable Power of Attorney.
4. *Note: ORC staff, in consultation with the IRB Chair, will decide which individuals meet the DHHS definition of "legally authorized representative" when research is conducted in Alabama and when research is conducted outside of Alabama.*

C. Institutionally Authorized Surrogate

In the absence of a legally authorized representative, as described in 2.1(B), no one can provide legally effective consent on behalf of a potential participant who is decisionally-impaired. Under federal regulations Institutionally Authorized Surrogates who do not meet the DHHS definition of Legally Authorized Representatives may not provide consent on behalf of another individual unless the IRB has waived the requirement for informed consent.

2.2 Acceptable Research

A. A participant who is decisionally impaired may participate in research involving *greater than minimal risk* only if the research potentially offers an acceptable level of *direct therapeutic benefit* to that participant.

B. A participant who is decisionally-impaired may participate in research involving *minimal or slightly above minimal risk* without direct participant benefit if a Legally Authorized Representative is available and provides proxy consent.

2.3 Use of Proxy Consent

A. If the prospective participant is decisionally impaired, the participant's Legally Authorized Representative must provide written proxy consent.

B. If the prospective participant is decisionally impaired, but is capable of executing a Durable Power of Attorney, the prospective participant may grant authority to the holder of the Durable Power of Attorney to give written informed consent to participate in research on his or her behalf. The Durable Power of Attorney in this case is a Legally Authorized Representative.

1. The Durable Power of Attorney may already be in effect or one may be appointed to grant proxy consent for research participation.

2. The Durable Power of Attorney is to be used only with prior approval of the IRB.

3. The Durable Power of Attorney cannot be used if the prospective participant has a Legally Authorized Representative.

4. The prospective participant must understand the meaning of a Durable Power of Attorney and appoint someone of their choice.

5. The person appointed as a Durable Power of Attorney must be willing to do so and understand the responsibilities involved.

6. Employees of ASU are *not* eligible for appointment as holder of a Durable Power of Attorney for a prospective participant unless they are the spouse, adult child, parent, or relative of the prospective participant.

7. A nursing home (e.g., owner, part-owner, manager, administrator, or employee, as well as spouses of these individuals) providing residential care to a participant or a community-based program is *not* eligible for appointment as holder of a Durable Power of Attorney for prospective participants.

8. Signed copies of the Durable Power of Attorney form should be maintained by the investigator.

9. The ORC must be contacted prior to appointing a Durable Power of Attorney.

C. If the potential human participant does *not* have a Legally Authorized Representative and is judged by the investigator to both lack the capacity to give consent *and* execute a Durable Power of Attorney, the research may only be conducted if the IRB waives the requirement for consent.

2.4 Proxy Consent Form

A. The *Proxy Consent Form* must include all required elements of the informed consent and be written in the proxy consent style that indicates that the Legally Authorized Representative is providing permission to allow the participant who is decisionally impaired to participate in the study.

2.5 Adult Assent Form

A. The *Adult Assent Form* is based on the adult consent form, but should be written in *simple* language aimed at the appropriate cognitive level of the decisionally-impaired participants to be enrolled in the study. The *Adult Assent Form* must contain all required elements of consent.

2.6 Application of Laws

A. IRB and/or investigators must apply State and local laws that reach beyond Federal laws relevant to research involving humans as participants. Examples of such laws are reporting of child abuse and educational privacy laws. University counsel is available for advice in all cases as needed and requested. ASU's ORC staff and members of the IRB have access at all times to university legal counsel for assistance in applying laws to research involving human participants.

RPP Policy: 8.06 Research Involving Employees and/or Students
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1. Purpose

The purpose of this policy is to describe additional requirements for research that involves employees of and/or students enrolled at ASU.

2. Policy

It is policy of the IRB that recruitment of employees or students in the laboratory, office, or class of an investigator is generally discouraged, particularly in research involving more than minimal risk to the participant. This participant population is considered potentially vulnerable because of the subordinate position to the investigator and the potential for coercion or undue pressure. However, research conducted with ASU employees or students must follow the same guidelines as research with any other participants and must be reviewed by the IRB if it is intended to be generalized.

2.1 Students as Research Participants

- A. The parental informed consent form that covers studies with no more than minimal risk may be used by departments with research participation requirements when participants are under 19 years of age, except those who are legally emancipated or otherwise able to consent to the procedures involved in the research.
- B. If course requirements or extra credit options involve research participation, alternative activities must be available to students so they do not feel coerced into research participation.
- C. The student's ASU campus-wide identification number (CWID), social security number, telephone number or initials are not acceptable as identification codes for tracking confidential data.
- D. The IRB recommends a coding system that adequately protects confidentiality.

2.2 Requirements

If an investigator wishes to recruit participants from within their laboratory, office, or class, the IRB application must clearly address:

- A. The nature of the professional relationship between the investigator and the prospective participants.
- B. Justification of the need to recruit participants from the investigator's laboratory, office, or class. This justification must be particularly strong for any study that involves greater than minimal risk procedures.
- C. Description of the method of participant recruitment and how situational coercion will be minimized to the greatest extent possible. The investigator should consider (a) the use of a general bulletin board posting and not engage in one-on-one solicitation and (b) the use of an individual to obtain consent that does NOT have any supervisory or instructional role relative to the prospective participant.

2.3 IRB Review

The IRB will carefully examine the proposed inclusion of this participant population and must ensure that special protections for this population are in place to minimize the potential for coercion or undue influence.

Section 9: Funding Agencies

Policy: 9.01 Certification of Review to Funding Agencies

1. Purpose

The purpose of this SOP is to describe the process of certification of review to funding agencies.

2. Policy

It is the policy of the IRB that certification of review will be sent to funding agencies in full accordance with regulations at Health and Human Services 45 CFR §46.

2.1 Grant Application Covered by one IRB Protocol

A. When an investigator submits either a grant application involving human participants to the Office of Research and Sponsored Programs (ORSP) or receives notification from the National Institutes of Health of a fundablescore, the investigator must identify the IRB protocol number, which will cover the human participants activities described in the grant application.

B. If the title on the IRB protocol on file does *not* match the title of the project listed on the grant application, the investigator should submit to the IRB a “Request for Change” in protocol with either of the following:

- 1.** Addition of a second title (the title on the grant application) to the IRB protocol, **OR**
- 2.** Substitution of the new title.

C. Regardless of which option is selected by the investigator, ORSP will not process a funded grant unless the titles match and there is an IRB protocol number. (Under special circumstances, ORSP may waive this requirement with appropriate justification). ORSP is required to ensure that IRB review and approval of the grant application’s human participant activities have been obtained by the investigator prior to any protocol activity. The IRB, in turn, will compare the grant application with the IRB application.

D. It is acceptable for consent document(s) to have a lay title rather than scientific title. However, this should be documented for the record in the IRB application.

2.2 Grant Application Covered by Two or More IRB Protocols

A. In a situation where the human participant activities portion of a grant application is covered by two or more IRB numbers, ORSP and the IRB will not require matching titles. However, the submission must specifically identify the IRB protocol which covers each section of the grant application.

2.3 Commercially Sponsored Contracts

A. When research is commercially sponsored, it is preferable that titles match between all documents (i.e., contract, protocol, consent document(s), and IRB application). The sponsor's protocol number may be included in the protocol title; however, the IRB discourages inclusion of sponsor names in protocol titles.

Section 10: Protected Health Information and Research

RPP Policy: 10.01 Definition and Description of Protected Health Information Identifiers

1. Purpose

The purpose of this SOP is to define and describe Protected Health Information identifiers.

2. Policy

It is the policy of the IRB that the use of Protected Health Information will be in full accordance with regulations at Health and Human Services 45 CFR §46 and other applicable federal, state and local laws.

2.1 The Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule was issued August 13, 2002, with a compliance date of April 14, 2003. The purpose of this rule is to provide additional protections of the privacy rights of participants involved in research. The HIPAA Privacy Rule contains requirements designed to ensure that the Protected Health Information of research participants is appropriately used and/or disclosed during the conduct of research. ASU Student Health Services is a “covered entity” and, therefore, complies with HIPAA.

2.2 Protected Health Information is defined as any *individually identifiable health information*. Protected Health Information obtained by any means that is used or disclosed during the course of any research project at this Institution is subject to HIPAA. Only the minimum Protected Health Information necessary to achieve the research objectives can be used.

2.3 The individually identifiable Protected Health Information list contains *18 identifiers*. If **any** of the 18 identifiers are associated with the health information, then the information is considered “protected”. De-identification of Protected Health Information requires either:

A. Removal of all 18 identifiers, *or*

B. Documentation by an expert statistician of how he/she determined that the risk of participant identification using a subset of identifiers present is very small.

C. The 18 identifiers are:

1. Names.
2. Postal address information: street address, city, county, precinct, ZIP code (except specified combinations).
3. All elements of dates (except year) related to an individual (e.g. birth, admission, discharge). For participants over 89 years of age, all elements of dates (including year) must be removed.
4. Telephone numbers.
5. Fax numbers.
6. Electronic mail addresses.
7. Social Security numbers.
8. Medical Record numbers.
9. Health plan beneficiary numbers.
10. Account numbers.
11. Certificate/license numbers.
12. Vehicle identifiers and serial numbers, including license plate numbers.
13. Device identifiers and serial numbers.
14. Web Universal Resource Locators.
15. Internet protocols address numbers.
16. Biometric identifiers, including finger and voice prints.
17. Full face photographic images [and any comparable images].
18. Any other unique identifying number, characteristic, or code.

RPP Policy: 10.02 Limited Data Set

1. Purpose

The purpose of this SOP is to describe the use of Limited Data Sets.

2. Policy

It is the policy of the IRB that the use of Limited Data Sets will be in full accordance with regulations at Health and Human Services 45 CFR §46.

2.1 A researcher with IRB approval and a Data Use Agreement between the researcher and the covered entity can use and disclose Protected Health Information that contains a Limited Data Set without a HIPAA authorization or a waiver of consent granted by the IRB.

A. The Limited Data Sets must have all the identifiers removed, except the following:

- 1.** A unique identifying number, characteristic or code (e.g., a registry or study number).
- 2.** Elements of dates (e.g., birth).
- 3.** Town, city, state, and ZIP code.

2.2 One of the advantages associated with the use of a Limited Data Set is that it is not subject to the HIPAA requirements of accounting for disclosure of Protected Health Information. Additionally, the Limited Data Set also allows the maintenance of a linked code, which permits re-identification of an individual in the future should the need arise. However, the investigator who is using the Limited Data Set cannot maintain the linked code. The RCO will maintain such codes.

RPP Policy: 10.03 Medical Records

1. Purpose

The purpose of this SOP is to describe the research use of medical records which contain Protected Health Information.

2. Policy

It is the policy of the IRB to use and disclose Protected Health Information in accordance with the HIPAA requirements and federal regulations pertaining to research found at Health and Human Services 45 CFR §46.

2.1 Definitions

A. Protected Health Information is individually identifiable health information. Health information means any information, whether oral or recorded in any medium that:

1. Relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual.

B. De-Identified Protected Health Information is the removal of all 18 identifiers from the health information (see RPP Policy # 10.001 for a definition of the identifiers) or obtainment of a bio-statistical consult indicating there is only a “small risk” of re-identification of a participant.

C. Designated Record Set means the medical records and billing records about individuals and records used to make decisions about individuals.

D. Authorized Investigators:

1. Any faculty member, student or staff member who is working with a person having ethical/legal access to Protected Health Information materials in a non-research context and who will assume responsibility for maintaining confidentiality safeguards as certified in writing.

E. Existing Medical Records: are defined as medical records existing at the time of initial submission of the IRB application (e.g., date of the PI signature on the IRB application) and *not* when the IRB grants final approval and release of the study.

F. Non-Authorized Investigators: are person(s) that do not fall within the definition of an authorized investigator.

2.2 Access to Medical Records

A. Only authorized investigators listed by name in the IRB application shall have access to confidential records to be used for research purposes where participant identifiers are present.

B. Non-authorized investigators shall have access to confidential records to be used for research purposes with IRB and covered entity approval *only* when the following conditions are met:

1. Approval is obtained to use the records from the covered entity (e.g., medical records department) **OR**

2. The investigator has obtained informed consent/HIPAA authorization from the participant, **OR**

3. *All* Protected Health Information has been de-identified in accordance with the requirements of HIPAA.

C. In all cases, the non-authorized investigator shall have received CIT training especially as it regards confidentiality and privacy.

2.3 Research that qualifies for exemption

A. Research involving medical records qualifies for *exemption* if the records utilized in the research are existing and the data are recorded in such a manner that participants cannot be identified (e.g., either all 18 HIPAA specified identifiers are removed or a biostatistical consult indicated there is only a “small risk” of re-identification of a participant).

2.4 Research that does not qualify for exemption

A. Research involving the study of medical records may not qualify for *exemption* if the investigator records the data in such a manner that participants can be identified either directly or through identifiers linked to the participant or if the study involves prospective collection of records.

B. If participant identifiers must be temporarily maintained in order to permit the investigator to identify additional records for inclusion in the study, informed consent/authorization is required unless the IRB may grant a waiver of informed consent in accordance with the following specific requirements of HIPAA and 45 CFR §46.116(d):

C. Only the minimum amount of participant identifier data is recorded.

D. The use or disclosure of Protected Health Information or data which is not Protected Health Information involves no more than minimal risk.

E. The alteration or waiver of informed consent will not adversely affect the rights and welfare of the participants.

F. The research cannot practicably be carried out without the alteration or waiver.

G. There is an adequate plan to protect participant identifiers from improper use and disclosure.

H. There is an adequate plan to destroy the identifiers associated with Protected Health Information at the earliest opportunity, unless there is a health or research justification for retaining the identifiers or retention is required by law.

I. Whenever appropriate, the participants will be provided with additional pertinent information after participation.

J. If identifiers are recorded for the purpose of selecting a prospective participant population and the investigator intends to subsequently solicit informed consent to participate in a prospective study, specific guidelines must be followed regarding initial contact with potential participants. Contact with potential participants should originate with an individual who has the appropriate professional relationship with the potential participant (e.g., primary care physician, counselor, teacher, etc). If an investigator does not have such a relationship, they should obtain assistance from someone who does. Once the appropriate professional has originated the contact, negotiation for informed consent can begin as with any other research protocol.

RPP Policy: 10.04 Review of Protected Health Information in Preparation for Research

1. Purpose

The purpose of this SOP is to describe the process of review of Protected Health Information in preparation for research.

2. Policy

It is the policy of the IRB that the review of Protected Health Information in preparation for research will be conducted in full accordance with regulations at Health and Human Services 45 CFR §46.

2.1 The HIPAA permits an investigator to review medical records containing Protected Health Information in preparation for a research project without obtaining an authorization or a waiver of consent from the IRB.

A. In order to qualify as being engaged in preparatory research, the investigator, or other study personnel, must have an ethical-professional access to the Protected Health Information in the medical setting.

B. The investigator must file a request for access with the pertinent institution (e.g., ASU Student Health Center, local hospital or clinic). If the Protected Health Information is not contained within the medical record, the request should be filed with the IRB.

C. The investigator must certify:

1. The review of Protected Health Information will be conducted solely to determine the feasibility of a research project or for similar purposes in preparation for research.

2. The Protected Health Information may not be recorded, copied, or removed from the records repository in the course of review.

3. The Protected Health Information that is accessed is solely for research purposes.

D. If an investigator intends to record any Protected Health Information for the express purpose of contacting prospective research participants, the appropriate IRB application and associated informed consent documents must be submitted and approved by the IRB prior to the review of the medical records.

Section 11: Continuing Review

RPP Policy: 11.01 Continuing Review

1. Purpose

The purpose of this SOP is to describe the IRB's process for conducting continuing review.

2. Policy

It is the policy of the IRB that continuing review will be conducted in accordance with Health and Human Services regulations at 45 CFR §46.109(e) and OHRP guidance on continuing review (July 11, 2002)

2.1 *Full Board, expedited and research qualifying for exemption* protocols are approved for one year at a time and must be renewed annually by completion of an Application for Continuing Review form.

A. In order for a study to continue without interruption, the IRB must re-review and approve the protocol *prior* to the IRB approval expiration date.

Continuing Review has to occur as long as the research remains active for long-term follow-up of subjects, even when the research is permanently closed to the enrollment of new participants and all participants have completed all research-related interventions. Continuing review of research has to occur when the remaining activities are limited to collection of private identifiable information. If an investigator does not provide continuing review information to the IRB, or the IRB has not approved the protocol by the expiration date, the investigator will be instructed to stop all research activities, including recruitment, enrollment, interventions, interactions, and collection of private identifiable data, and to stop all interventions and interactions on current participants, unless the IRB finds an over-riding safety concern or ethical issue involved such that it is in the best interests of individual participants to continue participating.

B. New enrollment of participants is not allowed after the expiration of IRB approval.

2.2 Risk Level

A. All human participant studies are subject to continuing review based on the level of risk as assessed by the IRB. Research approved previously by *expedited review* is considered eligible for *expedited review* at the time of its regular continuing review, if, during the course of the study, the risks of the study have not increased. Projects that were initially reviewed by the *full board* continue to receive *Full Board* review unless the IRB determined at the initial review during the *Full Board* meeting that the study meets the specific criteria for *expedited review*.

2.3 Continuing Review Submission Requirements

A. It is the responsibility of the PI to submit the IRB Application for Continuing Review which must include informed consent/assent forms (updated as necessary) in sufficient time to allow the IRB to complete a substantive and meaningful review of the research, as well as provide the PI with a timely, written response prior to the expiration date indicated on the current IRB approval letter.

B. The PI will receive three (3) IRB notifications (approximately 60 days prior to expiration of IRB approval, 30 days prior to expiration of IRB approval, and 20 days prior to expiration of IRB approval) if the Application for Continuing Review has not been submitted.

C. If the designated IRB reviewers, determine that a project requires review more often than annually, the investigator will be so notified at the time of initial review and/or at the time of continuing review. Factors which determine the frequency of continuing review are described in RPP Policy #3.10.

2.4 Pre-Review

A. The IRB staff is responsible for pre-review of all protocols undergoing continuing review. At any time, the individual staff person may seek guidance and/or assistance from either the ORC staff during the pre-review process.

B. The protocol file is pulled and IRB number, title(s) and study personnel listing are checked for accuracy and training for personnel is verified. The current application for continuing review will be compared with the previous year's application, as well as other documents found in the protocol file as necessary, with particular attention paid to the types of consent documents. The primary and secondary reviewers are provided with the complete protocol. When conducting review using the expedited procedure, the reviewers receives and reviews all submitted information including at a minimum all information that the convened IRB would have received. It is expected that primary and secondary reviewers perform an in-depth review of all pertinent documentation.

C. The copy of the most recent consent document will be reviewed to determine if it was the appropriate version and used within the correct approval dates indicated in the IRB approval stamp.

D. The new consent form(s) to be used during the next IRB approval period will be compared with the version last approved by the IRB to determine if the correct version of the consent form(s) has (have) been provided. In addition, the consent document will be closely checked for typographical or formatting errors and to determine if any changes have been made to the consent document (without accompanying Request for Change in Protocol form).

E. Discrepancies or omissions in the Application for Continuing Review will result in an email to the PI and/or study coordinator requesting clarification and/or correction to appropriate forms. If the number of problems in the application are of such magnitude that IRB review is not possible, the full application and supporting documents will be sent back to the PI for revision and resubmission of the revised application and/or consent document(s).

F. In situations of suspected non-compliance, the PI will be notified. A complete review of the IRB study file will be performed by the RCO and the IRB Chair to determine what further action should be taken in accordance with RPP Policy # 13.01.

G. For *Full Board* continuing reviews, copies of all correspondence (emails or letters) resulting from the pre-review process will be provided in the meeting packet mailed to all IRB members. In addition, the IRB staff will contact the assigned reviewers to inform them of unresolved problems or concerns.

2.5 Expedited IRB Continuing Review Procedure

A. Applications for continuing review, which qualify for *expedited review* will be assigned to IRB members for review.

B. The reviewers will determine whether or not increased monitoring and/or more frequent continuing review is required in accordance with RPP policy #3.010.

C. IRB approval periods for protocols reviewed by the *expedited* method begin as of the date of the initial approval letter.

1. Approval periods cannot exceed one year. IRB approval therefore expires one year later, or sooner if the reviewer sets a more frequent continuing review date.

2. For example, if the review was completed on February 17, 2005, and the reviewer set an approval period of one year, IRB approval is valid until February 17, 2006. This means that IRB approval is in force until 11:59 pm February 16, 2006. As of midnight all research activity must cease unless IRB re-approval and full release has been granted.

2.6 Expedited Review Actions

A. Re-approval and full release

1. No modifications or clarifications are required. All of the criteria for IRB approval specified in Human and Health Services regulations at 45 CFR §46.111 are satisfied. The investigator will be notified of the re-approval in writing and is authorized to continue the study.

B. Re-approval and full release (with minor clarifications)

1. Minor clarification(s) or information concerning the protocol is necessary for completion of the record. This action is only taken when the clarification(s) is (are) minor and does not impact protection of human participants and/or the approvability of the consent document(s). The investigator will be notified of the re-approval in writing and asked to make the necessary modifications and return the materials before final approval for continuing review can be granted.
2. Failure to respond to the IRB continuing review clarification letter may result in the IRB revoking approval of the study. In such a case, all research related activities must immediately cease, unless an extension is granted by the IRB Chair in consideration of a written request from the PI. The IRB will be notified of all extensions granted by the IRB Chair.
3. The ORC may be empowered by the IRB to review the Investigator's response in consultation with the IRB Chair as necessary and grant re-approval and full release.

C. Conditional approval, contingent upon IRB reviewers acceptance of specific modifications/clarification

1. After the review of the request for continuation, the PI will be notified in writing as to the nature of the required modifications/clarifications. During the remaining IRB approval period, the investigator is authorized to continue the research. When the investigator complies, in writing, with all requirements as determined by the IRB reviewers, re-approval and full release will be granted.
2. If the PI fails to respond to the IRB's continuing review request letter within the remaining IRB approval period, the protocol has, or will be, classified as "closed-out". If IRB approval expires, all research-related activities must immediately cease, unless an exception is granted by the IRB Chair in consideration of a written request. The IRB will be notified of all exceptions granted by the IRB Chair.

D. Referred for full IRB review

1. IRB members assigned to perform an *expedited review* can refer the protocol for review by the full board.

2.7 Full IRB Review Procedure

A. If the research initially required full board approval, the Application for Continuing Review must also be approved by the full IRB.

1. If the initial protocol was determined to involve no greater than minimal risk and no additional risks have been identified then the application for continuing review can be reviewed as *expedited continuing*.

B. Applications for continuing review are scheduled for full board consideration at the monthly IRB meeting. Each attending member will receive, one week in advance, all continuing review applications and associated consent/assent documents to be considered at the meeting and a complete copy of the protocol file. IRB members are asked to review the complete IRB protocol files.

C. The primary reviewer will present to the full board the results of his/her review and any remaining concerns will be discussed by the members who are also expected to have reviewed the application and the consent/assent documents. Each protocol will be voted on separately in accordance with IRB policy (see RPP Policy # 2.11).

D. The IRB will determine whether or not increased monitoring or whether more frequent continuing review is required in accordance with RPP Policy #3.10.

E. IRB approval periods for protocols reviewed by the *full board* begin as of the date of initial or continuing review. Approval periods cannot exceed one year which is defined as one year from the date of the initial or continuing approval letter. IRB approval, therefore, expires one year later, or sooner if the IRB sets a more frequent continuing review date. For example, if the IRB reviewed a protocol on February 17, 2005, and set an approval period of one year, IRB approval would be valid until February 17, 2006. This means that IRB approval is in force until 11:59 pm February 16, 2006. As of midnight all research activity must cease unless IRB re-approval and full release has been granted.

2.8 Full Board Actions

A. Re-approval and full release

No modifications or clarifications are required. All of the criteria for IRB approval specified in Health and Human Services regulations at 45 CFR §46.111 are satisfied. The investigator will be notified of the re-approval in writing and is authorized to continue the study.

B. Re-approval and full release (with minor clarifications)

Minor clarification(s) or information concerning the protocol is necessary for completion of the record. This action is only taken when the clarification(s) is (are) minor and does not impact protection of human participants and/or the approvability of the consent document(s). The investigator will be notified of the re-approval in writing and asked to make the necessary modifications and return the materials before final approval of continuing review can be granted.

1. Failure to respond to the IRB continuing review clarification letter may result in the full IRB revoking approval of the study. In such a case, all research related activities must immediately cease, unless an extension is granted by the IRB Chair in consideration of a written request from the PI. The IRB will be notified of all extensions granted by the IRB Chair.

2. The ORC is empowered by the IRB to review the Investigator's response in consultation with the IRB Chair as necessary and grant re-approval and full release.

C. Conditional approval, contingent upon IRB Chair acceptance of specific modifications/clarifications

This category is restricted to modifications/clarifications, which are not considered to be substantive in nature.

1. The investigator will be notified in writing as to the nature of the required modifications/clarifications. During the remaining IRB approval period, the investigator is authorized to continue the research. When the investigator complies, in writing with all requirements as determined by the IRB Chair, re-approval and full release will be granted.
2. If the PI fails to respond to the IRB's continuing review letter within the remaining IRB approval period, the protocol has, or will be, classified as "closed-out". If IRB approval expires, all research-related activities must immediately cease, unless an exception is granted by the IRB Chair in consideration of a written request. The IRB will be notified of all exceptions granted by the IRB Chair.

D. Conditional approval, contingent upon full board re-review of specific modifications/clarifications.

This category is restricted to modifications/clarifications which are considered substantive in nature, but are not of sufficient magnitude to require a hold be placed on participant accrual.

1. The PI will be notified in writing as to the nature of the required modifications/clarifications. During the remaining IRB approval period, the investigator is authorized to continue the research. When the investigator complies in writing with all requirements as determined by the full IRB at a convened meeting, re-approval and full release will be granted.
2. If the PI fails to respond to the IRB's continuing review letter within the remaining IRB approval period, the protocol has, or will be, classified as "approval expired". If IRB approval expires, all research-related activities must immediately cease, unless an exception is granted by the IRB Chair in consideration of a written request. The IRB will be notified of all exceptions granted by the IRB Chair.

E. Tabled with re-review by the full board

This action is taken when the IRB has identified significant concerns related to participant safety and/or conduct of the study.

1. All research-related activities must immediately cease unless an exception is granted by the IRB Chair in consideration of a written request. The IRB will be notified of all exceptions granted by the IRB Chair.
2. The IRB must receive a satisfactory response from the PI regarding any necessary modifications and/or clarifications of the protocol and/or consent document(s) within *thirty (30) business days*. Failure to respond to the IRB continuing review letter within the designated time period may result in termination of the study.

F. Decline to Complete Review

This category is restricted to applications which are deficient and precluded the IRB from performing a substantive and meaningful review.

1. The investigator will be instructed in writing to revise the application in accordance with IRB requirements. During the remaining IRB approval period, the investigator is authorized to continue the research.
2. If the PI fails to respond within the remaining IRB approval period, the protocol will be classified as “approval expired”. If IRB approval expires, all research-related activities must immediately cease unless an exception is granted by the IRB Chair in consideration of a written request. The IRB will be notified of all exceptions granted by the IRB Chair.

G. Disapproved

The IRB will “Disapprove” a protocol where there is a serious concern regarding participant safety and/or compliance. The protocol will be suspended or possibly terminated and a report submitted to OHRP in accordance with RPP Policy # 13.02. No new participants can be accrued. All research-related activities must cease and the full IRB will make a determination if currently enrolled participants may continue participation in the study. The Research Integrity Officer will be notified.

2.9 IRB Re-Approval Notification and Release

A. Upon IRB re-approval of a research project, the PI will be sent a letter of re-approval and stamped/dated IRB-approved consent/assent forms. The stamp indicates the date of IRB re-approval and the “valid until” date. The “valid until” date is the last date that IRB approval is in effect. The letter provides a summary of investigator responsibilities and also reminds investigators that changes in research activity may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to participants.

B. The re-approved consent/assent forms should be kept on file as the master copy(ies) and all outdated consent/assent forms must be destroyed as they are no longer valid.

C. Initial and amended informed consent documents signed by the participant remain in effect for the duration of the participant's participation in the study. Therefore, previously enrolled participants are *not* required to be re-consented each year following continuing review, *unless* the IRB approves a change during the continuing review process which requires re-consent of participants (e.g., participant notification of new risks or changes in protocol.)

2.10 IRB approval terminated

A. If a PI fails to submit the IRB Application for Continuing Review orrespond to the IRB review letter in sufficient time to allow the IRB to complete its review and grant re-approval and full release before the end of the current IRB approval period, the protocol will be classified as "IRB approval terminated."

B. Notification of imminent IRB approval termination is sent by email to thePI and any designated research personnel at least one day before the date of expiration. If the date of expiration falls on a weekend or holiday, the notification is sent out sooner.

RPP Policy: 11.02 Suspension and Termination of IRB Approval

1. Purpose

The purpose of this SOP is to describe the conditions under which suspension and termination apply and the process thereof.

2. Policy

2.1 Suspension of IRB approval is a directive of the convened IRB, IRB Chair or RCO to either temporarily or permanently stop some, or all, previously approved research activities. Suspended protocols remain open and require continuing review.

A. The IRB Chair or RCO may suspend research to ensure protection of the rights and welfare of participants. Suspension directives made by the IRB Chair or RCO must be reported to a meeting of the convened IRB.

B. When study approval is suspended by the convened IRB or an authorized individual, in addition to stopping all research activities, the convened IRB or individual ordering the suspension will notify any subjects currently participating that the study has been suspended. The convened IRB or individual ordering the suspension will consider whether procedures for withdrawal of enrolled subjects are necessary to protect their rights and welfare of subjects, such as: transferring participants to another investigator; making arrangements for care or follow-up outside the research; allowing continuation of some research activities under the supervision of an independent monitor; or requiring or permitting follow-up of participants for safety reasons.

C. If follow-up of subjects for safety reasons is permitted/required by the convened IRB or individual ordering the suspension, the convened IRB or individual ordering the suspension will require the participants be so informed and that any AEs/outcomes be reported to the IRB and the sponsor.

2.2 Termination of IRB approval is a directive of the convened IRB to stop permanently all activities in a previously approved research protocol. Terminated protocols are considered closed and no longer require continuing review.

A. Research may only be terminated by the convened IRB. Terminations of protocols approved under expedited review must be made by the convened IRB.

B. When study approval is terminated by the convened IRB in addition to stopping all research activities, the convened IRB ordering the termination will notify any subjects currently participating that the study has been terminated. The convened IRB ordering the termination will consider whether procedures for withdrawal of enrolled subjects are necessary to protect their

rights and welfare of subjects, such as: transferring participants to another investigator; making arrangements for care or follow-up outside the research; allowing continuation of some research activities under the supervision of an independent monitor; or requiring or permitting follow-up of participants for safety reasons

C. If follow-up of subjects for safety reasons is permitted/required by the convened IRB ordering the termination, the convened IRB will require the participants be so informed and that any AEs/outcomes be reported to the IRB and the sponsor.

Section 12: Amendments to Approved Protocols

RPP Policy: 12.01 Request for Change

1. Purpose

The purpose of this SOP is to describe the process for requesting change to an approved protocol.

2. Policy

It is the policy of the IRB that review of all requests for changes in approved protocols will be conducted in full accordance with regulations at Health and Human Services 45 CFR §46.

2.1 Introduction

A. Any proposed change in a protocol which affects the human participants must be reviewed and approved by the IRB *prior* to implementation except when an immediate change is necessary to eliminate a hazard to the participants or to provide participants with new information on AEs or research results considered essential to a participant's decision whether to continue participating.

2.2 Submission Requirements

Investigators must submit:

A. IRB Request for Change in Protocol form.

B. Complete description of the changes requested.

C. Revised protocol (as appropriate).

D. Revised consent/assent document(s) (as appropriate).

1. The IRB files must contain a complete and accurate description of the research. Therefore, changes indicated in the Request for Change in Protocol must be described clearly.

E. When a change in protocol is the result of a new or revised grant application, a copy of the complete grant narrative must accompany the Request for Change form.

2.3 IRB Review

A. As a Request for Change in Protocol form is received in the ORC, the staff will pre-review and document the requests to determine whether the requested change is:

1. *Minor* in nature and the risk to the participant is minimal. Examples of minor changes include: changes in telephone numbers, addition or deletion of staff, correction of typographical errors, and addition of procedures found on the *expedited review* list (e.g., minor change in eligibility requirements, deletion of an intervention, and change in follow up schedules).

a) Minor changes are approvable under an expedited review. While re-consent of current participants utilizing the revised IRB-approved consent document is normally not required by the IRB, the PI must

provide a plan, as necessary, for notification of current participants.

2. Major, but does not require immediate implementation in order to reduce a hazard to participants. Examples of major changes include: changing the treatment or revising eligibility requirements.

a) The changes cannot be implemented until reviewed by the *Full Board*. Re-consent of current participants utilizing the revised IRB-approved consent document or addendum is normally required.

3. Significant and requires **immediate implementation** in order to decrease risk to participants and requires full disclosure to the participants immediately. These changes may include: addition of a major risk resulting from a reported AE or other major changes enacted to reduce risk to participants. Re-consent of current participants utilizing the revised IRB-approved consent document or addendum is required. A witness is required during the re-consent process.

B. If the *Request for Change* requires immediate implementation, the RCO will notify the IRB Chair for formal determination that there is significant risk to the participant, which requires immediate implementation of the amendment prior to *full board* approval. In the event that an immediate approval for the request for change occurs, the full IRB will be notified of the action at the next convened meeting. At that time the IRB will review the request for change and may: A) formally approve the action taken by the IRB Chair; and/or B) determine that additional information or modifications are necessary to decrease risk to the participants.

C. All IRB members are provided all submitted materials for the review of modifications to previously approved research by the convened IRB. It is expected that primary and secondary reviewers will perform an in-depth review of all pertinent documentation. All other IRB members will review all provided materials in enough depth to discuss the information at the convened meeting.

D. When conducting review using the expedited procedure, the reviewers receives and review all submitted information including at a minimum all information that the convened IRB would have received.

2.4 Change to Eliminate Immediate Risk Prior to IRB Approval

A. If a change is initiated without any IRB approval in order to eliminate immediate hazards to the participants or to provide essential information to the participants, the IRB must be notified as soon as possible, but no later than two (2) business days from the time the change was initiated. If the change was initiated for all participants, the IRB form, Request for Change in Protocol, must be completed.

B. The investigator is authorized to implement changes without IRB approval in order to eliminate apparent immediate hazards to participants.

C. The IRB chair or designate has no authority to approve more than minor changes even if needed to eliminate immediate hazards to participants.

Section 13: Unanticipated Problems and Adverse Events

RPP Policy: 13.01 Unanticipated Problems Involving Risk and Adverse Events

1. Purpose

The purpose of this SOP is to describe the procedure to ensure prompt reporting to the IRB, appropriate institutional officials, sponsor, coordinating center, and the appropriate regulatory agencies of unanticipated problems involving risks to participants or others.

2. Definitions

2.1 *An Unanticipated Problem Involving Risk to Participants or Others* may be: a) an AE, which caused harm to an individual, b) a problem, which placed individuals at increased risk of harm, or c) new information that indicates a previously unknown risk. (The event, problem, or new information was related or possibly related to the research procedures. The individual might be a participant or a non-participant.)

A. Example: Events that could lead to a breach of confidentiality or privacy provisions such as the unanticipated loss or theft of files or that in any way might subject the research participant to a higher degree of risk than anticipated in the research protocol.

B. An unanticipated problem involving risks to participants or others is defined as any problem that was unforeseen and indicates that research procedures caused harm to participants or others or indicates that participants or others are at increased risk of harm.

3. Policy

It is the IRB's policy to comply with Health and Human Services regulations at 45 CFR §46.103(b) (5) (1) (i) and to have policies and procedures that ensure reporting of all unanticipated problems involving risk to participants or others to the IRB, regulatory agencies, and institutional officials.

3.1 The following problems must be reported to the IRB within 2 business days:

A. Any physical or psychological harm experienced by a participant, which in the opinion of the principal investigator, is both unexpected and related.

1. Harm is "unexpected" when its specificity and severity are not accurately reflected in the consent document.

2. Harm is "related to the research procedures" if, in the opinion of the principal investigator, it is more likely than not:

a) to be caused by the research procedures

b) the event affects the rights and welfare of current participants.

B. Information that indicates a change to the risks or potential benefits of the research. For example: An interim analysis or safety monitoring report indicates that the frequency or magnitude of harms or benefits might be different from those initially presented to the IRB.

- C. A breach of confidentiality.
- D. Change to the protocol taken without prior IRB review to eliminate an apparent immediate hazard to a research participant.
- E. Incarceration of a participant in a protocol not approved to enroll prisoners.
- F. An event that requires reporting to the sponsor.
- G. Sponsor-imposed suspension.
- H. Complaint of a participant.
- I. Protocol deviation.

3.2 IRB review of externally reported problems.

A. In the case of an externally reported problem, the RCO advises the IRB Chair and they review the problem reports and determine whether each is an unanticipated problem involving risks to participants or others. If the report is an unanticipated problem involving risks to participants and others, it is referred to the convened IRB for review. The IRB Chair also considers whether each report involves noncompliance. If so, the noncompliance policy is followed. If the IRB chair determines that the report is neither an unanticipated problem involving risks to participants or others nor noncompliance, it is filed and no further action is taken.

B. The IRB Chair will take all actions necessary to protect human participants including suspension or termination of the study (RPP Policy # 14.01). Investigators may also make changes to the research without prior approval by the IRB when necessary to eliminate apparent immediate hazards.

C. If referred for full board review, reviewers are assigned to review the Report of Unanticipated Problem(s) or AEs Involving Risk. These members are provided and review, in depth, copies of:

1. The report of unanticipated problem involving risk and all submitted supporting materials.
2. The current consent document.
3. The protocol application.
4. The industry protocol (if one exists).
5. The investigator's brochure (if one exists).

D. The primary reviewer presents the event or problem to the convened Board and leads the discussion. The IRB discusses and votes on whether the event or problem represents an unanticipated problem involving risks to participants or others as defined above. If the IRB determines by majority vote that the event or problem represents an unanticipated problem involving risks to participants or others, the SOP on Reporting to Regulatory Agencies and Institutional Officials will be followed (see RPP Policy #13.02).

E. The IRB chooses from the following actions on all reportable events or problems:

- 1.** No action.
- 2.** Modification of the research protocol.
- 3.** Modification of the information disclosed during the consent process.
- 4.** Additional information provided to past participants.
- 5.** Notification of current participants (required when such information may relate to participants' willingness to continue to take part in the research).
- 6.** Requirement that current participants re-consent to participation.
- 7.** Modification of the continuing review schedule.
- 8.** Monitoring of the research.
- 9.** Monitoring of the consent.
- 10.** Suspension of the research.
- 11.** Termination of the research.
- 12.** More information sought pending a final decision.
- 13.** Referral to other organizational entities (e.g., legal counsel, risk management).

RPP Policy: 13.02 Non-Compliance

1. Purpose

The purpose of this SOP is to: 1) define noncompliance, 2) describe categories of noncompliance, 3) describe procedures for reporting noncompliance to the IRB, 4) address IRB actions, and 5) outline procedures for reporting noncompliance to OHRP and Department or Agency heads.

2. Definitions

2.1 Noncompliance is defined as the failure to comply with any Health and Human Services regulations, and/or IRB requirements. Noncompliance may be assessed as non-serious, serious, or continuing.

2.2 Incident of noncompliance is defined as a proven assertion of non-compliance.

2.3 Serious noncompliance is defined as failure to comply with Health and Human Services regulations and/or IRB requirements, which in the judgment of the convened IRB, places human participants at unacceptable risk, decreases potential benefits to participants, compromises the integrity of the RPP, or results in non-disclosure of pertinent information to all participants thereby compromising informed consent.

A. Example 1: Use of an outdated consent document where the changes are material to the participant's consent and, therefore the participant was unable to make an informed decision (e.g., new information about risks).

B. Example 2: Failure to have the participant sign a required consent form.

C. Example 3: Failure to submit a Request for Change prior to implementing a change and the change has impact on the risk/benefit relationship of the research and/or the signed informed consent, if required in the study (e.g., addition of blood draws.)

D. Example 4: Conduct of a study after IRB approval expiration.

E. Example 5: Failure to obtain IRB approval of research.

F. Example 6: Failure to report to the IRB an unanticipated problem involving risk to the participant or others, which impacts the risk/benefit relationship of the study and/or informed consent (e.g., a participant develops depression after a particularly psychological technique is implemented and that is not described in the informed consent form).

2.4 Continuing noncompliance is defined as a pattern of noncompliance that, in the judgment of the convened IRB, suggests a likelihood that instances of noncompliance will continue without intervention. “Continuing noncompliance” also includes failure to respond to a request to resolve an episode of noncompliance. “Continuing noncompliance” includes:

A. Multiple incidents of serious or non-serious noncompliance in a twelve (12) month period, which occurs in any one research protocol. The incidents of noncompliance may involve one specific issue or different issues.

B. Example: During a routine audit of the PI’s research records, ten of fifty consent forms obtained during the last twelve months did not have a signed and dated investigator’s signature.

C. Multiple incidents of serious or non-serious noncompliance in a twelve month period carried out by the same individual in multiple research protocols. The incidents of noncompliance may involve one specific issue or different issues.

D. Example: During a routine audit of the PI’s research records for six studies, multiple protocol violations were identified , which included failure to record lab values, participants signing outdated consent forms, and lack of re-consent of participants in a timely manner.

E. The IRB reserves the right to judge noncompliance as continuing in circumstances that do not meet the above definition.

2.5 Allegation of noncompliance is defined as an unproven assertion of noncompliance.

3. Policy

All members of the University community involved in human participant research are expected to comply with the ethical standards of professional conduct in accordance with federal and state regulations and ASU and IRB policies governing the conduct of research involving human participants. Therefore, it is the policy of the IRB that investigators and research staff must immediately report to the ORC any allegations or incidents of noncompliance.

All allegations or incidents of noncompliance will be promptly investigated in order to ensure ongoing adequate protection of the rights and welfare of research participants. Confidentiality will be preserved and due process observed.

Serious or continuing noncompliance and suspensions or terminations of IRB approval must also be promptly reported to OHRP, and department or agency heads in accordance with RPP Policy # 13.02.

3.1 Reporting Noncompliance

A. Investigators and research staff must report all allegations or incidents of noncompliance *immediately* to the ORC (334-229-5053).

B. A report of an allegation or incident of noncompliance can be submitted to the ORC office or any IRB member via a letter, email, or telephone call from any source.

C. Whistleblowers will be offered all protection they are entitled to by Federal law under the Inspector General Act of 1978.

1. A whistleblower may maintain his or her anonymity by not signing the communication.

a) Such a communication will be investigated with the same rigor as a signed communiqué.

b) The RCO or IRB shall not, after receipt of a complaint or information from an employee, disclose the identity of the employee without the consent of the employee, unless the full board of the IRB determines such disclosure is unavoidable during the course of the investigation.

3.2 Procedure for Handling an Allegation of Noncompliance

A. The RCO will document in writing the receipt of the allegation of noncompliance.

B. Within 72 hours of receipt of the allegation, the PI will be informed of all allegations of noncompliance.

C. If deemed appropriate, the IRB will engage in the following actions:

1. The department head of the ASU Computing Services will be notified.

a) Computing Services will ensure that any records on the PI's account will be preserved until further notice.

b) If the protocol in question receives funding of any sort, the head of ORSP will be notified to freeze all funds associated with said (and only said) protocol or grant.

c) Confidentiality and compliance with policies and procedures will be maintained at all times.

D. The Chair and the RCO will investigate the allegation of noncompliance to determine whether it has basis in fact.

1. If the Chair and RCO are unable to conduct the investigation on their own, others may be requested to assist.

E. If the Chair and RCO determine that the allegation of noncompliance has no basis in fact, this determination is communicated to the investigator and no other action is taken.

F. If the Chair and RCO determine that the allegation of noncompliance is true, it is handled below as an incident of noncompliance.

3.3 Procedure for Handling an Incident of Noncompliance

A. The RCO will document the incidence of noncompliance.

B. If the RCO is notified by anyone other than the PI, then:

1. Within 72 hours of the documentation of noncompliance, the PI will be informed of the noncompliance.

a) The RCO will hand deliver the letter to the PI. Delivery will be confirmed by PI signature.

2. If deemed appropriate, the IRB will engage in the following actions:

a) The department head of the ASU Computing Services will be notified.

b) Computing Services will ensure that any records on the PI's account will be preserved until further notice.

c) If the protocol in question receives funding of any sort, the head of ORSP will be notified to freeze all funds associated with said (and only said) protocol or grant.

d) Confidentiality and compliance with policies and procedures will be maintained at all times.

C. The Chair and RCO will conduct a preliminary investigation to identify the nature and scope of the noncompliance.

1. If the Chair and RCO are unable to conduct the investigation on their own, others may be requested to assist.

2. Determination as to the nature of the noncompliance must occur within 10 business days of initial notification of the allegation or incidence of noncompliance.

3. If preliminary investigation by the Chair and the RCO indicate an incidence of serious or continuing noncompliance has occurred then they will take all actions necessary to protect human participants, including suspension of the study.

D. Within 8 business days the IRB will convene to review the incidence of noncompliance. The members are provided with and review, in depth, copies of:

1. The report of unanticipated problem.
2. The current consent.
3. The protocol application.

E. The IRB may determine the incident to be **neither serious nor continuing**:

1. The PI will be informed of the determination by letter. It will be filed and no further action taken.
 - a) Computing services is informed and the account status returns to normal.
 - b) ORSP is informed and the funds unfrozen.

F. The IRB may determine the incident to be **serious or continuing**.

1. The IRB considers the following actions on all incidences of serious or continuing non-compliance:
 - a) Increased monitoring of the study by the RCO
 - b) Required interim reports from PI.
 - c) Reported internal audits be conducted by the PI and/or study personnel.
 - d) Monitoring of the consent process by the RCO or IRB members.
 - e) More frequent continuing review.
 - f) Disclosure to the participant information, which may affect the participant's willingness to continue in the study.
 - g) Required additional training of the principle investigator and or/study personnel in the protection of human participants.
 - h) Suspension of the study.
 - i) Termination of the study.
 - j) Suspension of all principal investigator's studies pending a full audit of said studies
2. The PI will receive a written determination from the IRB.
 - a) The letter will be hand-delivered by the RCO, and a signature as proof of delivery will be required.
 - b) The letter will inform the PI of:
 - c) the determination
 - d) IRB actions regarding the current study and others not associated with the noncompliance
 - e) the forwarding of the matter to the Research Integrity Officer (RIO).
3. Additional actions by the IRB include:
 - a) Reporting of all noncompliance to be serious or continuing to OHRP, and Federal Department or Agency Heads in accordance with RPP Policy# 13.002. Recommendations to the RIO that may include:

- b)** That a letter of reprimand be placed in the principal investigator's personnel file or the file of other study personnel.
- c)** That the principal investigator's privilege to conduct research be suspended for a specific period of time or terminated.
- d)** That the principal investigator's employment or the employment of specific study personnel be terminated.
- e)** That the case be referred for further action or investigation by the Research Integrity Officer.

G. Noncompliance in student research

- 1.** The PI may be the student, but the Faculty Advisor is the focus of the IRB investigation.
 - a)** All correspondence and communication will go to the Faculty Advisor.
 - b)** It is the Faculty Member's responsibility to advise and inform the student of the IRB's communications and the information contained therein.
- 2.** If deemed appropriate the IRB may engage in the following actions:
 - a)** The head of Computing Services will be instructed to protect the computers of both the faculty advisor and the student.
 - b)** The head of ORSP will be instructed to freeze all funds associated with the incidence of non-compliance.
 - c)** The matter will be investigated as described in policy #13.02.

RPP Policy: 13.03 Reporting Incidents to OHRP or Department and Agency Heads

1. Purpose

The purpose of this SOP is to describe the procedure to ensure prompt reporting to OHRP or Department and Agency Heads: 1) unanticipated problems involving risk to the participants or others, 2) serious or continuing noncompliance, and 3) suspensions or terminations of approved research by the IRB.

2. Definitions

- 2.1 An unanticipated problem involving risks to participants or others** is defined as any problems that (1) was unforeseen and (2) indicates that the research procedures caused harm to participants or others or indicates that participants or others are at increased risk of harm.
- 2.2 Serious noncompliance** is defined as failure to comply with any Health and Human Services regulations, and/or IRB requirements that places human participants at unacceptable risk or results in non-disclosure of pertinent information to all participants thereby compromising informed consent.
- 2.3 Continuing noncompliance** is defined as: 1) multiple incidents of serious or non-serious noncompliance in a twelve (12) month period, which occurs in any one research protocol, or 2) multiple incidents of serious or non-serious noncompliance in a twelve (12) month period carried out by the same individual in multiple research protocols. The incidents of continuing noncompliance may involve one specific issue or different issues.
- 2.4 Suspension or termination of IRB approval of research** is defined as a mandatory directive to the investigator in writing to suspend or terminate some or all research activities conducted under an IRB-approved protocol. Such directives may be issued as a result of decisions made by either the full IRB at a convened meeting or by the IRB Chair in order to eliminate apparent immediate hazards to the participants or others.
- 2.5 Internal study hold** is defined as a mandatory directive by the IRB to the investigator in writing to suspend further participant accrual on an IRB-approved protocol. Such directives may be issued when the IRB has a concern about unresolved AE or serious problem reports or other issues which impact participant safety.
- 2.6 External Study Hold** is defined as a mandatory directive by the sponsor or cooperative group to the investigator in writing to suspend further participant accrual on an IRB-approved protocol. Such directives are usually issued for planned study holds to evaluate reported problematic therapeutic techniques.

3. Policy

It is the policy of the IRB that the following incidents will be promptly reported to OHRP and Department or Agency heads (if applicable) in accordance with Health and Human Services regulations at 45 CFR §46.103(b) (5): 1) any unanticipated problem involving risk to the participant or others, 2) any serious noncompliance, 3) any continuing noncompliance, 4) any suspension or termination of IRB approval, and 5) any internal or external holds placed on IRB approved protocols. Reporting to OHRP unanticipated problems involving risk to the participant or others which occur at institutions not under the jurisdiction of the IRB are the responsibility of the external institution.

3.1 The IRB Chair or designate is responsible for the prompt submission of all required written reports to OHRP, and Department or Agency heads.

A. The IRB Chair or designate may notify OHRP verbally in advance of a written report when the incident is particularly serious.

B. All required reports will be submitted no later than five (5) business days from the time the full IRB makes a final determination concerning the incident.

C. Information to be included in written reports:

D. Name of the institution.

E. Protocol number.

3.2 Notification of Institutional Officials

A. Copies of the letter sent to the OHRP and any necessary supporting documents must be provided to:

1. The individual(s) directly responsible for the noncompliance or adverse or unanticipated event.

2. The PI.

3. The IO.

4. The Federal sponsor.

5. Other Institutional officials as determined by the IRB, to include the RIO.

3.3 Notification of Health and Human Services Office of Human Research Protection (OHRP)

A. Within five (5) business days of the *full board* decision, the IRB Chair will send a formal letter to the OHRP Director of Compliance Oversight. The letter must include the following:

1. Identification of the protocol.
2. Funding of the protocol (federally or non-federally funded, commercially sponsored).
3. Timeline and description of the noncompliance.
4. Copy of the IRB application and applicable consent document(s).
5. Applicable reports from IRB consultants.
6. Other documentation pertaining to the event.
7. Corrective action plan approved by the full IRB.

B. The OHRP mailing address is as follows: Division of Compliance Oversight, Office for Human Research Protections, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852 Phone: (301) 435-8072, Fax: (301) 402-0527.,

RPP Policy: 13.04 Audits by Outside Agencies

1. Purpose

The purpose of this SOP is to describe audits by outside agencies.

2. Policy

It is the policy of the IRB that the IRB will cooperate with audits by outside agencies in full accordance with regulations at Health and Human Services 45 CFR §46.

2.1 Audit of the IRB by the Food and Drug Administration, OHRP, Department of Defense, or National Institutes of Health Cooperative Group

When an ORC member or IRB officer is contacted by a representative from a federal agency or a National Institutes of Health cooperative group for an audit of the IRB, the following actions must be taken:

A. Ask for the reason for the visit, if this has not already been provided.

B. Inquire what documents and information will be required during the investigation.

C. Immediately contact the RCO and the IRB Chair.

D. An email confirming the visit will be sent to the RCO, the IRB Chair, ORC staff, the IO and his designate.

E. When the auditor(s) arrives, ask to see the auditor's identification and business card for name and agency affiliation. Additionally, if the investigation is being conducted by a federal agency, the auditor may provide a copy of the memo from headquarters detailing the reason for the visit.

F. During the visit, the RCO and Chair should be available to the auditor. A written record of the study files that are reviewed and documents photocopied must be kept.

G. During the closing interview it is preferable that the IRB Chair, and the RCO be present. If the IRB Chair and/or the RCO are not available, then a staff member from the ORC may participate alone or request an IRB member join the interview. The ORC staff member will note all issues identified by the investigation and the action proposed by the auditor (if applicable).

H. If the RCO is unable to attend the exit interview, then a staff member from the ORC will provide a summary of the results of the interview and required actions resulting from the investigation. If necessary, all individuals involved in the investigation will meet with the RCO for debriefing.

I. Following the discussion with the RCO, the ORC staff member will immediately send an email to the RCO, the IRB Chair, ORC staff, the IO and his designate above providing a synopsis of the investigation and the preliminary results presented at the closing interview. Special emphasis will be placed on those areas where deficiencies were found that require attention.

J. The IRB Chair the RCO and the ORC staff member will meet within five(5) calendar days following the investigation to propose a corrective action plan to address deficiencies found during the investigation. The full IRB will be notified of the investigation and action plan. The full IRB may modify the plan as necessary.

K. The RCO will notify by email all principal investigators whose study files were examined during the investigation. Results from the audit that are pertinent to the specific study will be discussed. Following receipt of the official letter from the regulatory agency, the Principal Investigator will also be notified of areas of concern related to his/her study.

L. The IRB will normally receive a report of the results of an audit. Where there are identified areas of concern or sanctions placed, the IRB Chair, Director and other appropriate ASU officials will respond to the agency.

2.2 OHRP For-Cause Investigation of Noncompliance and Not-For-Cause Compliance Oversight Evaluation

A. For-Cause Investigation of Noncompliance For-cause evaluations occur in response to OHRP's receipt of substantive written allegations or indications of non-compliance with the HHS regulations. Sources of such allegations or indications of noncompliance include, but are not limited to, research subjects and their family members, individuals involved in the conduct of research such as investigators and study coordinators, institutional officials, and research publications.

B. Not-For-Cause Compliance Oversight Evaluation Not-for-cause compliance oversight evaluations are conducted in the absence of substantive allegations or indications of non-compliance. Institutions are selected for not for- cause evaluation based on a range of considerations, including: (a) volume of HHS- supported research, (b) relatively low level of reporting under the requirements of HHS regulations at 45 CFR 46.103(b)(5); (c) lingering concerns following a previous for-cause compliance oversight evaluation, (d) complaints about a human subject protection program that indicate dysfunction without clearly implicating particularly regulatory requirements, (e) geographic location, (f) status of accreditation by professionally recognized human subject protection program accreditation groups, and (g) status of recent human subject protection evaluation or audit by other regulatory agencies (such as the Food and Drug Administration) or recent participation in quality improvement programs (such as OHRP's Quality Improvement program).

C. If the IO receives notification from OHRP that OHRP has initiated a for-cause investigation of noncompliance or a not-for-cause compliance oversight evaluation, the IO, together with the IRB Chair, RCO, and other appropriate institutional officials will respond immediately and appropriately with an action plan to address the matter.

2.3 Audits of Investigator's Records by Outside Agencies

A. When a PI is contacted by a representative from any federal agency, sponsor, or other entity for an investigation or audit of a research protocol, the IRB must be notified of the visit. If the visit is pre-planned, an email may be sent to the RCO. If it is a no-notice investigation or audit, the IRB Administrator should be called as soon as possible. The following information must be provided to the IRB:

1. The IRB # and protocol title.
2. The name of the governmental agency, sponsor, or other entity.
3. Name of the investigator.
4. The dates of the visit.
5. The type of visit:
 - a) routine surveillance/monitoring visit,
 - b) "for cause" investigation, or
 - c) other:_____.

B. Following the investigation or audit, the IRB must be notified by the Principal Investigator of any compliance issues identified during the exit interview. If the investigation or audit revealed conditions or practices that are of significant departure from the federal regulations with potential for sanctions, the IRB Chair must be immediately notified by telephone. If the IRB Chair is not available, the RCO should be informed. This information will be relayed to other appropriate ASU officials as soon as possible and RPP Policy # 13.03 will be implemented as necessary.

C. A copy of the official letter detailing the results of the investigation must be provided to the IRB. If the investigation or audit revealed areas of concern, the Principal Investigator must provide the IRB with a copy of the response with particular ASU emphasis on the corrective action plan.

D. The full IRB will be given all information and will determine what action is necessary, including reporting noncompliance to OHRP and Food and Drug Administration.