UNIVERSITY AT ALBANY
State University of New York

Institutional Review Board (IRB) Procedures Manual

PREFACE

The policies and procedures set forth in this manual adhere to the ethical principles and guidelines for the protection of research participants summarized in the Belmont Report, and comply with applicable federal regulations and state laws related to human subjects protections. Both the membership of the Institutional Review Board (IRB) and any prospective researchers who intend to use human subjects in their research projects are reminded that this document establishes the basic minimum of policies and procedures and does not include every possibility for the variation in research protocols involving human subjects.

Note on regulatory flexibilities:
The review of human subjects research at the University at Albany is a collaborative process intended to result in mutually acceptable research procedures that aid investigators in accomplishing their scientific objectives while protecting the rights and welfare of research participants. Every effort is made to adopt creative administrative and other means to reduce administrative burdens and maximize attention to the most important ethical issues. The IRB applies commensurate protections for research projects that fall out of the scope of the FWA. As noted in the preamble of the revised Common Rule (45 CFR Part 46), institutions are allowed a wide degree of flexibility with regard to making determinations related to ethical oversight of research not regulated by the Common Rule. To this end, the IRB tries to be as flexible as possible in its interpretation of regulatory requirements ,and reviews each study protocol based on the facts specific to the individual study rather than simply imposing rigid requirements. Every attempt is made consider all factors in determining the outcome of the review. This approach does not create a two-tiered application of ethical principles or protections; rather, it allows for an appropriate level of flexibility without compromising human subjects protections. The IRB encourages consultation at all stages of the research process.

I. GENERAL PROCEDURES

A. Authority

The University at Albany ensures that the rights and welfare of human research subjects are adequately protected in research activities conducted under its auspices. In order for the university to fulfill its responsibilities and to comply with federal and state law and regulations, all human-subjects research, including student research, conducted under the auspices of the University at Albany must receive appropriate review and approval. In its Federal Wide Assurance, on file with the Office for Human Research Protections (OHRP), U.S. Department of Health and Human Services, the university assures compliance with all requirements of Title 45, Part 46 of the Code of Federal Regulations (45 CFR 46), including subparts B, C and D. No distinctions in the monitoring of research will be drawn between funded and nonfunded research, or between research conducted by faculty, students, other university personnel or affiliated researchers.

The university is guided by the ethical principles set forth in the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, "Ethical Principles and Guidelines for the Protection of Human Subjects of Research" (The Belmont Report).

The University has authorized a Human Subjects Protection Board (aka the “Institutional Review Board” or “IRB”) to review and approve human subjects research. The IRB committee is an administrative body established to protect the rights and welfare of human research subjects enrolled in research. It is comprised of University at Albany faculty, staff, graduate students, and administrators, with at least one unaffiliated member and one member whose primary interests are non-scientific.

The IRB has the authority to approve, require modifications to, defer, or disapprove all research activities that fall within its jurisdiction as specified by both the federal regulations and local institutional policies. Research that has been reviewed and approved by the IRB may be subject to further review and may be disapproved by officials of the institution. However, those officials may not approve research that has been disapproved by the IRB.

The performance of research involving human subjects without IRB approval or exemption is considered noncompliance with human subjects protection requirements and will be handled as described in this policy and/or the University’s Policy and Procedures on Misconduct in Research and Scholarship.

B. IRB Membership Composition

The requirements for the composition of the IRB are described in the Common Rule. The IRB complies with these requirements.

The IRB must be appropriately constituted for the volume and types of human research to be reviewed, in accordance with federal regulations. The IRB will include members with diverse experience and expertise to assure the professional competence necessary to review the university’s research, as well as knowledge of community attitudes and training in protecting the rights and welfare of human subjects.

In appointing IRB members, the Institutional Official (IO) and/or the Assistant Vice President for Research/Research Compliance Officer will ensure that all of the following conditions are met for the university IRB:

- IRB members will have varying backgrounds, experience, expertise, and professional competence as necessary to promote complete and adequate review of research activities

commonly conducted by the University at Albany.

- The IRB will be sufficiently qualified through the experience, expertise, and diversity of its members, including considerations of race, gender, cultural backgrounds, and sensitivity to issues such as community attitudes, to promote the respect for the IRB and its advice and counsel in safeguarding the rights and welfare of human subjects.

- The IRB will include persons knowledgeable about institutional commitments and regulations, applicable laws, and standards of professional conduct and practices.

- The IRB will consist of at least five members.

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

- When the IRB reviews research that involves a category of subjects that is vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these categories of subjects.

- IRB will include at least one member whose primary concerns are in nonscientific areas and at least one member who is not otherwise affiliated with the University at Albany and who is not part of the immediate family of a person affiliated with the University at Albany. The nonaffiliated members of the IRB should be drawn from the local community at large, and may include: ministers, teachers, attorneys, business-people, prisoner representatives, or individuals who are members of advocacy groups. The nonaffiliated member(s) should be knowledgeable about the local community and be willing and able to discuss issues and research from that perspective. When selecting the nonaffiliated member(s), consideration should be given to the type of community from which the institution will draw its research subjects. **Note**: In many cases, the same member will satisfy both roles. The IRB may, on occasion, meet without representation of the unaffiliated member; however, this should be the exception. Attendance of the unaffiliated member and the member who represents the perspective of subjects at convened meetings will be monitored and assessed through documentation in the minutes (e.g., minutes indicate attendance at greater than 50% of meetings).

- The IRB will invite individuals with expertise in specific areas to assist in the review of issues that require expertise or perspective beyond or in addition to that available on the IRB. Although these individuals may attend meetings and take part in the discussion of research protocols, they may not vote.

- The IRB Chair/Vice Chair should be a highly respected individual from within or outside the institution, fully capable of managing the IRB and the matters brought before it with fairness and impartiality. The task of ensuring that the IRB is a respected part of the institutional community will fall primarily to this/these individual(s). The IRB must be, and must be perceived as, fair and impartial, immune from pressure either by the institution's administration, investigators whose protocols are brought before it, or other sources.

C. Duties of IRB Members

The IRB is appointed as an Institutional Committee. As such, the IRB members serve the institution as a whole, rather than a particular school or department. Therefore, members must not allow their own interests or those of their department to supersede their duty to protect the rights, safety, and welfare of research subjects.

In general, IRB members are expected to read study applications and research protocols and to attend and participate in full committee meeting reviews and discussions. IRB members will vote on each proposed research protocol at convened full board meetings. In addition, IRB members are expected to participate on special subcommittees as assigned by the IRB Chair and contribute to discussions of regulations and interpretations that lead to policies and investigator guidance.

D. Delegation of Responsibilities

The Chair is responsible for managing committee discussion and deliberation and ensuring that all members who may wish to comment, do so. The Vice Chair is expected to participate on a regular basis and assist the Chair with their IRB duties.

The Chair may appoint an IRB member to assist or act on IRB matters on a case-by-case basis (e.g., if the Chair must recuse from the review and vote on a particular protocol and a Vice Chair is not present to lead the meeting. This action would be noted in the minutes of a convened meeting). The Chair may also delegate any responsibilities as appropriate to other qualified (i.e., experienced) IRB member(s).

E. Conflict of Interest (COI)

A conflict of interest is defined as a conflict between the private interests and the official responsibilities of a person.

Investigator COI - The Principal Investigator is responsible for disclosure to the IRB at the time a protocol is submitted if any research personnel involved in the protocol have any conflicts of interest that are or could be perceived to be related to the proposed research protocol. If there is a known or potential conflict of interest at the time of IRB submission, a separate letter of disclosure should be included with the submission detailing the nature of the conflict. Any change to this status as related to a protocol should also be brought to the attention of the IRB.

IRB Member COI - No IRB member may participate in the review of any project in which the member has a conflicting interest or in which the appearance of a conflict exists, except to provide information as requested by the IRB. In the case of such a conflict, this should immediately be reported to the IRB Chair. Except to provide requested information, members must absent (recuse) themselves at a fully convened meeting of the IRB in which they have conflicting interests and their absence is recorded in the minutes.

F. Record Keeping and Retention

IRB:
The IRB staff prepares and maintains adequate documentation of the IRB's activities. In addition to written IRB procedures and membership rosters, such documentation includes electronic copies of all research proposals (including informed consent documents) reviewed, minutes of IRB meetings, records of continuing review activities, copies of correspondence between the IRB and investigators, and statements of significant new findings provided to subjects. IRB-related records are retained for at least three years.

For non-exempt research involving human subjects covered by the Common Rule (or exempt research for which limited IRB review is required) that takes place at an institution in which IRB oversight is conducted by an IRB that is not operated by the institution, the institution and the organization operating the IRB shall document the institution's reliance on the IRB for oversight of the research and the responsibilities that each entity will undertake to ensure compliance with the requirements of this policy (e.g., in a written agreement between the institution and the IRB, by implementation of an institution-wide policy directive providing the allocation of responsibilities

between the institution and an IRB that is not affiliated with the institution, or as set forth in a research protocol).

Investigators:
Records pertaining to research that is conducted must be retained for at least three years after completion of the research. All records must be accessible for inspection and copying by authorized representatives of the department or agency supporting or conducting the research at reasonable times and in a reasonable manner. In addition, investigators are responsible for maintain records beyond three years when required by other laws, university policies, agreements, etc.

G. Human Subjects Protection Training

The IRB requires human subjects protection training for the individual(s) responsible for the overall design and/or conduct of the study (e.g., the PI), as well as any research study personnel considered engaged in human subjects research activities (e.g., recruiting, obtaining consent, collecting data, interacting or intervening with human subjects, analyzing identifiable data, etc.). Individuals conducting both exempt and non-exempt human subjects research are subject to this requirement. The University at Albany offers research ethics and compliance training to faculty, staff and students through the online CITI Training Program. ALL investigators, key personnel, and faculty advisors involved in research with human subjects must complete and provide documentation for the required training(s). "Key Personnel" means any person who interacts with human subjects or accesses their research data. Training certification is effective for five (5) years after completion. Training requirements are outlined below. Refer to the Research Ethics and Compliance Training page to create and manage your CITI account. Investigators, Key Personnel and Faculty Advisors must complete the following course: *IRB: Human Subject Research (Investigators, Advisors).* IRB Members and IRB Staff are required to complete the following course: *IRB: Human Subject Research (IRB Members, IRB Staff).*

ALL investigators, key personnel, and student advisors involved in research with human subjects must complete and provide documentation for the required training(s) at time of IRB study protocol submissions. The IRB may accept other sources of training on a case-by-case basis.

The IRB staff is also available to provide workshops/presentations on a variety of topics related to ethical issues in human subjects research. The staff will design an educational program to meet researchers' particular needs upon request.

H. Principal Investigator (PI) Status (PI Eligibility)

University faculty, staff, and students* are eligible to serve as Principal Investigator on an IRB protocol for activities that meet the definition of human subjects research AND are being carried out under the auspices of the University at Albany (i.e., in fulfillment of their university at Albany institutional obligations (faculty employment, student academic degree program, etc.)

**Addition requirement for students – students may only serve as principal investigator (PI) on IRB protocol with a UAlbany Faculty member Co-Investigator who serves as the study sponsor/Faculty Advisor.*

I. IRB Review of Grant Applications

The IRB staff is responsible for conducting congruency review of IRB study protocol and the grant proposal/award funding that supports the study.

II. Review and Approval Process

Types of IRB Review
There are three types (or levels) of IRB Review — **full board**, **expedited**, and **exempt** — determined by the nature of the project, the make-up of the subject population, and the degree of potential risk to human subjects. *The IRB determines the applicable level of review, upon receipt of the submission.*

Exempt or Expedited Review
The IRB may conduct an exempt or expedited review if it is determined that the research places subjects at no more than minimal risk, i.e., the risk one experiences in daily living. These reviews are done on a rolling, ongoing basis by a single IRB member.

Full Board Review
Full board review (i.e., review conducted by a convened IRB board) is required for studies that involve greater than minimal risk or vulnerable subjects who require special protection by the IRB. Full board reviews are conducted at the next available board meeting, and must be scheduled in advance

A. Administrative Pre-Screening by IRB Staff

All submissions undergo administrative pre-screening by the IRB Staff. The IRB Staff may request additional information and/or request clarifications or modifications of the study application documents prior to the IRB's review by a member of the IRB. The pre-review includes consideration of:

- Key personnel
- Specific aims/protocol objectives
- Study procedures
- General scope of work – participant population, intervention, etc.

B. Exempt Determinations and Limited IRB Review

The Common Rule specifies the categories of research that are exempt from the human subjects protection regulatory requirements (see Appendix 2.)

"Exempt" human subjects research is a sub-set of research involving human subjects that does not require comprehensive IRB review and approval because the only research activity involving the human subjects falls into one or more specific exemption categories as defined by the Common Rule.

Limited IRB Review is a new provision under the revised Common Rule that allows certain research to be considered Exempt from IRB review even when the identifiable information might be sensitive or potentially harmful if disclosed. In order to qualify for the exemption, the study must meet the standards of Limited IRB review.

For Exempt categories 2 and 3, the requirement for Limited IRB Review is triggered when:

1) The information obtained is recorded by the investigator in such a manner that the identity of the participants can be readily ascertained, directly or through identifiers linked to the subjects, AND

2) Any disclosure of the participants' responses outside the research would reasonably place the subjects at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, educational advancement, or reputation.

When changes to research are proposed that fall within the scope of the Limited IRB Review requirement (e.g., storage or maintenance, privacy and confidentiality), the changes must undergo Limited IRB Review and be approved before implementation (except when necessary to eliminate apparent immediate hazard to participants).

Continuing review is generally not required for research determined to be exempt, even when that research is subject to limited IRB review. However, the IRB may determine that continuing review is required for a particular study subject to limited IRB review, in which case it shall document the reasons for its determination in the IRB record and communicate the requirement to the investigator in the IRB determination letter.

Limitations on Exemptions:

Children:

- Exemption #2 (i) and (ii) for research involving survey or interview procedures or observations of public behavior does NOT apply to research in children, except for research involving observations of public behavior when the investigator does not participate in the activities being observed.
- Exemption #2 (iii), where identifiable information is obtained and the IRB conducts a limited IRB review, is NOT applicable to research in children.
- Exemption #3 does NOT apply to research involving children.

Prisoners:

- Exemptions do not apply EXCEPT for research aimed at involving a broader subject population that only incidentally includes prisoners.

C. <u>Research that is Eligible for Expedited Review Procedures</u>

The Common Rule specifies conditions under which research may be reviewed by the IRB under expedited review procedures. The standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review--expedited review or full board review--utilized by the IRB.

Expedited does not mean that the review is less rigorous or happens more quickly than convened review. It refers, instead, to certain types of research considered to involve minimal risk.

Research activities that meet both of the following conditions may be reviewed under expedited review procedures:

(1) The research presents no more than minimal risk to human subjects, and
(2) The research involves only procedures listed in one or more of the allowed expedited review categories.

The IRB shall apply the most current list of categories of research published in the Federal Register that may be reviewed using expedited review procedures.

HHS regulations define "minimal risk" as “the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.”

Research that falls within the list of categories is presumed to be minimal risk unless the IRB determines and documents that the research involves more than minimal risk. If the reviewer determines that the research involves more than minimal risk, it will be referred for review by the convened IRB.

The expedited review procedure may not be used for:

- Research where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' 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.

The expedited review procedure may also be used to review minor changes in previously approved research during the period for which approval is authorized. The limited IRB review that is required for certain exempt research may be conducted using expedited review procedures.

Continuing review of research is not required for research that qualifies for expedited review unless the IRB determines that it is required for a specific project and documents the rationale within the IRB record. IRB staff who are designated as alternate members of the IRB and have sufficient training and experience may review and approve submissions that qualify for expedited review (including new studies, modifications, and continuing reviews).

D. Research Requiring Review by the Full Board

All research that does not meet exemption requirements and is not eligible for expedited review procedures will be scheduled for review by the full board at a convened IRB meeting for which there is a quorum. A quorum is the minimum number and type of IRB members that must be present at a convened meeting. A quorum for a convened University at Albany IRB meeting is 50% of the voting primary membership (including alternate members who may replace voting members) plus one. A quorum must be maintained for each vote to occur. If a quorum is not maintained, the meeting shall end or be suspended and the study shall be tabled. Full board procedures are discussed in detail below in Section III of this Manual.

E. Continuing Review

The 2018 Requirements at Section 46.109(f)(1)(i) eliminate the continuing review requirement for research eligible for expedited review unless an IRB determines otherwise. The 2018 Requirements also include a commitment by the Secretary, HHS, to evaluate the list of research activities eligible for expedited review at least every 8 years, and to amend it, as appropriate, after consultation with other federal departments and agencies and after publication in the Federal Register for public comment (§46.110).

Unless the IRB determines otherwise, continuing review of research is **not** required for research subject to the revised Common Rule in the following circumstances:

1. Research eligible for expedited review in accordance with §46.110;
2. Research reviewed by the IRB in accordance with limited IRB review;
3. Research that has progressed to the point that it involves only data analysis, including analysis of identifiable private information or identifiable biospecimens,

Please note that the IRB may determine that continuing review is required for any research protocol that falls within the above criteria. For example, the IRB may determine that continuing review is required when:

1. Required by other applicable regulations or funding agencies (e.g., the Department of Defense);
2. The research involves topics, procedures, or data that may be considered sensitive or controversial where additional oversight may be warranted;

3. The research involves particularly vulnerable subjects or circumstances that increase subjects' vulnerability;
4. An investigator has minimal experience in research or the research type, topic, or procedures; and/or
5. An investigator has a history of noncompliance.

When the IRB determines that continuing review is required for such research, it will document the rationale in the IRB record and communicate the requirement to the investigator in the IRB determination letter.

The University at Albany has an Addendum to its Federalwide Assurance (FWA) that it will apply Department of Defense (DoD) regulations and policies for the protection of human research subjects when conducting, reviewing, approving, overseeing, supporting or managing human subjects research involving the DoD. Responsibility for upholding DoD requirements for human subjects research is shared between researchers and their teams, the University administration and the DoD.

For research not requiring continuing review, the IRB may send yearly, automated messages to investigators with open protocols, reminding them of the requirements for open studies and prompting them to close projects when applicable.

For research requiring continuing review, the IRB sends courtesy reminders to researchers prior to the expiration date of IRB approval to remind the research team that a continuing review request should be submitted if the research is ongoing.

Continuing review must be substantive and meaningful, and must be conducted by the convened IRB, unless the research is appropriate for expedited review. Ordinarily, if research did not qualify for expedited review at the time of initial review, it does not qualify for expedited review at the time of continuing review. Continuing review must include determinations by the IRB regarding risks, potential benefits, informed consent, and safeguards for human subjects. In conducting continuing review, the IRB will review, at a minimum, the protocol and any modifications as well as a status report on the progress of the research, including (a) the number of subjects accrued; (b) a description of any unanticipated problems involving risks to subjects or others, withdrawal of subjects from the research, or complaints about the research; a summary of any recent literature, findings, or other relevant information, especially information about risks associated with the research; and (d) a copy of the current informed consent document. Review of the currently approved consent document must ensure that the information is still accurate and complete. Any significant new findings that may relate to the subject's willingness to continue participation should be provided to the subject.

F. Post Approval Monitoring

The goals of the Regulatory and Research Compliance Office (ORRC) are to enhance the caliber of research performed at the University at Albany and to increase the effectiveness of the university's Human Research Protection Program through program oversight, education, and outreach. One way in which the ORRC meets these goals is through post-approval monitoring. During the evaluation, ORRC will assess research activities, identify areas of concern, provide guidance in implementing corrective actions or best practice recommendations, and prepare a monitoring observations report.

The ORRC performs various post-approval monitoring activities to ensure the rights and welfare of research participants are protected. The Principal Investigator (PI) and their research personnel must fully cooperate with all routine monitoring conducted by the IRB, regulatory agencies, funding agencies, or study sponsors. In addition, the PI must implement the appropriate corrective and preventative actions to resolve any observations and ensure that their research aligns with applicable federal regulations, state laws, and institutional policies.

Self-Assessments and Visits

Post-approval monitoring is a routine compliance review of IRB approved studies. The review is an educational process that bolsters best research practices. ORRC performs the review. Monitoring typically consists of a self-assessment or in-person review of adherence to the IRB approved protocol, assessment of study records and participant files, evaluation of other research activities, and may include or be limited to an observation of the consent process. All active human research studies, including those where the University at Albany IRB ceded IRB review to an external IRB, are subject to routine monitoring, except those determined to qualify for exempt status. The ORRC randomly selects studies for monitoring; however, the ORRC, Institutional Official, or IRB staff may request a study undergo monitoring, often based on the following criteria:

- Risk level of the study
- Studies enrolling vulnerable populations
- Studies requiring more frequent than annual review by the IRB
- Randomly selected from open non-exempt studies

Post-Approval Monitoring (Self-Assessment)

ORRC will contact the Principal Investigator (PI) and primary study contact via email to inform them that they have been selected to undergo post-approval monitoring. The PI will be asked to review their own study within 30 days of initial notification and return their findings to the ORRC, in the form of completed post-approval monitoring checklist.

If the study identified for post-approval monitoring is ready to be closed with the IRB, the PI is still required to engage in the post-approval monitoring activity and complete the checklists. The PI may submit the study for closure once the PI has completed the post-approval monitoring activity and the close-out notification has been issued.

Post-Approval Monitoring (In-Person Visit)

For post-approval monitoring visits, the ORRC will provide the PI and their designee with a selection of days to choose from to schedule the visit. The ORRC will ask the PI to review their own study and return their findings to the ORRC a week before the visit. ORRC will ask the PI to provide the following information when scheduling the activity:

- PI and study staff availability
- Access to study files and regulatory documentation
- Access to participant records
- Space in which to review study documents
- Time to discuss with the PI or designated team member

G. Modifications

All amendments to currently approved research must be approved by the IRB prior to implementation, except when necessary to eliminate apparent immediate hazards to the human subjects (see below). Amendments or changes to the protocol are sometimes referred to as “modifications” or “addenda.”

Full Committee Review: Amendments that do not meet the criteria for expedited review must be reviewed by the Full Committee at a convened meeting. Expedited Review: Amendments that meet the criteria for expedited review will be reviewed by a Chair or Chair designee according to the Expedited Review procedures.

Amendments to protocols that were initially reviewed using the Expedited procedures or by Full Committee may be reviewed by Expedited Review if the amendment fulfills the criteria below:

Protocols Initially Approved by Expedited Review Process that May Be Reviewed as Expedited	Protocols Initially Approved by Full Committee Review that May Be Reviewed as Expedited
• The amendment continues to pose no more than minimal risk to subjects. • The amendments do not involve any procedures that do not meet Expedited categories 1 through 7.	• Amendments do not pose an increased risk to subjects; AND • Amendments constitute a minor change to previously approved research (see examples below). • Any added procedures must fall within Categories (1)-(7) of research that maybe reviewed using the expedited procedure.

Amendments that do not fulfill the above criteria may require Full Committee review
The following table provides examples of *minor* changes (generally can be reviewed via Expedited Review) and *significant* changes (may require review by Full Committee depending upon the overall risk level) to previously approved protocols:

Minor Changes	Significant Changes
• Administrative changes • Minor changes to recruitment procedures, recruitment materials or submission of new recruitment materials to be used in accordance with approved recruitment methods • Minor changes to study documents such as surveys, questionnaires, or brochures • New study documents to be distributed to or seen by subjects that are similar in substance to those previously approved • Changes in payment to subjects or the amount subjects are paid or compensated that are not significant enough to affect considerations of coercion/undue influence • Decrease in the number and volume of sample collections as long as they do not negatively alter the risk/benefit ratio of the study • Editorial changes that clarify but do not alter the existing meaning of a document • Addition of or changes in study personnel • Addition of a new study site (in many but not all cases) • Translations of materials already reviewed and approved by an IRB	• Changes that adversely affect the risk/benefit ratio of the study or specifically increase the risk to subjects • Changes in inclusion/exclusion criteria that impact the risk/benefit ratio of the study Significant changes in study design, such as the addition of a new subject population or the elimination of a study arm • New risk information that is substantial or adversely affects the risk/benefit ratio of the study • Significant changes to the study documents to be distributed to or seen by subjects • New study documents to be distributed to or seen by subjects that include information or questions that are substantively different from materials already approved by the IRB. • New or revised financial conflict of interest management plans (e.g., change in PI or change to study design)

H. Categories of IRB Actions at Convened Meeting

As a result of its review, the IRB may decide to approve or disapprove the proposed research activity, or specify modifications required to secure IRB approval of the research activity.

When the research is reviewed by the convened IRB, these actions will be taken by a vote from a majority of voting members. The following are actions that the IRB may take at meeting:

- *Approval*: The IRB has identified no revisions or questions about the research and the

application is approved as submitted. The study has been found to meet the requisite criteria for approval and the research may be carried out as described.

- *Conditional Approval*: The IRB has identified specific minor revisions or clarifications and has determined that research will meet the requisite criteria for approval once these revisions and/or clarifications are addressed. This means that the study is approved in principle; however, no research activities may take place until an appropriately qualified group or individual appointed by the IRB has determined that the investigator has satisfied the conditions for approval (i.e., IRB Member, IRB staff member.)

  The following revisions or clarifications may be required as conditions of approval:

  (1) Confirmation of specific assumptions or understandings on the part of the IRB regarding how the research will be conducted (e.g., confirmation that the research excludes children);
  (2) Submission of additional documentation (e.g., certificate of ethics training);
  (3) Precise language changes to the protocol or informed consent documents; or
  (4) Substantive changes to the protocol or informed consent documents which conform to clearly stated parameters.

  • *Table/Deferral*: The IRB has identified substantive clarifications and/or modifications such that the research study does not qualify for Approval or Conditional Approval. The study will be eligible for reconsideration by the convened IRB once the investigator has addressed the clarifications and/or modifications.

  • *Disapproval*: The IRB disapproves the study in principle and the research may not take place. This is decided when the research raises significant scientific or ethical concerns and/or fails to meet one or more of the requisite approval criteria. This action must be taken at a convened meeting.

Risk Level: For each new application the IRB will determine whether the research presents minimal risk or greater than minimal risk of harm to subjects. For modifications and continuing research, the IRB will determine whether the risk level has increased, decreased, or remains unchanged.

Approval Period and Additional Monitoring: The IRB will determine the interval for continuing review. In general, exempt research, exempt research with limited IRB review, and research eligible for expedited IRB review will not be subject to continuing review. For research requiring continuing review, the approval period may not exceed 365 days. The IRB will also determine whether additional monitoring of the research is necessary. Methods of monitoring ongoing research may include, but are not limited to, site visits and observation of the research procedures and/or consent process.

I. Categories of IRB Action for Exempt or Expedited Reviews

When reviewing research by expedited procedures, the IRB member reviewing the study application may take any of the following actions except to disapprove a study.

- *Approval*: The IRB member has identified no revisions or questions about the research and the application is approved as submitted. The study has been found to meet the requisite criteria for approval and the research may be carried out as described.

- *Conditional Approval*: The IRB member has identified specific minor revisions or clarifications and has determined that research will meet the requisite criteria for approval once these

revisions and/or clarifications are addressed. This means that the study is approved in principle; however, no research activities may take place until an appropriately qualified group or individual appointed by the IRB has determined that the investigator has satisfied the conditions for approval (i.e., IRB Member, IRB staff member.)

The following revisions or clarifications may be required as conditions of approval:

(1) Confirmation of specific assumptions or understandings on the part of the IRB regarding how the research will be conducted (e.g., confirmation that the research excludes children);
(2) Submission of additional documentation (e.g., certificate of ethics training);
(3) Precise language changes to the protocol or informed consent documents; or
(4) Substantive changes to the protocol or informed consent documents which conform to clearly stated parameters.

- *Referral to Full Committee*: The Designated IRB reviewer has identified substantive clarifications and/or modifications such that the research study does not qualify for Approval or Conditional Approval. The study will be referred to the full committee for review. The Principal Investigator will be notified and the study will be added to agenda for review at the next full committee meeting.

The investigator will be notified of such actions in writing.

J. Investigator Appeal of IRB Action

Investigators may appeal an IRB decision regarding the revisions required by the IRB to the protocol and/or informed consent form and/or other components of the IRB Application or the disapproval of a study. Appeals must be submitted in writing within 30 days of IRB notification of actions and should provide ***new*** information that would aid in evaluating the request for re- consideration. In addition, the IRB, IRB Chair or Designee may invite the investigator to appear before the IRB to supply information or answer questions. The appeal will be reviewed at a regularly scheduled convened meeting, usually within 30 days of receipt.

III. PROCEDURES FOR CONDUCTING FULL BOARD MEETING

A. Quorum

A quorum is “the minimum number of members required to be present at an assembly or meeting before it can validly proceed to transact business.” To achieve quorum at meetings, at least one more than half the number of roster members (i.e., a majority), including the nonscientist, must be present. The IRB cannot review research if a quorum is not present. The board may lose quorum if members recuse due to a conflict, or if the nonscientist has to leave the room.

In order to meet quorum requirements, a member’s alternate may attend in the member’s place. A member may participate electronically or remotely via telephone or video conference (e.g., Microsoft Teams, Zoom, etc.) to satisfy or establish a quorum. A special consultant(s) cannot be used to establish a quorum.

Should the quorum fail during a meeting (e.g., due to recusal of those with conflicts, loss of a non-scientist, early departures), discussions may proceed; votes, however, may not be taken.

Prior to the meeting, the IRB Staff and/or IRB Chair will designate a primary reviewer for each submission item (including new studies, modifications, and continuing reviews) included on the full board's agenda. A secondary reviewer may also be assigned.

The IRB may invite individuals with competence in special areas to act as consultants in the review of issues that require expertise beyond or in addition to that available on the IRB.

B. Meeting Materials Sent Prior to IRB Meetings

A meeting agenda, application materials and other documentation required for review are prepared by the IRB Staff and are made available to IRB members prior to each full board meeting. Meeting materials will be issued at least one week in advance. The meeting agenda, reports and the meeting minutes are maintained electronically on the UAlbany SharePoint of the ORRC.

C. Virtual Meetings

The regulatory requirements (e.g., quorum, representation, etc.) for a virtual IRB meeting are the same as for a live meeting. Use of an electronic submission and review process supports the virtual review process and ensures compliance with IRB policies.

Meetings Conducted Virtually:

All IRB members must receive access to all protocols and documents to be reviewed in advance of the meeting providing as much time as possible for member review.

IRB members must be told to clearly announce when they are arriving or leaving the meeting for any reason, so that quorum can be maintained, and accurate attendance and vote counts can be assured. (Note that the reason for leaving does not need to be announced or recorded in the minutes unless the reason is due to a conflict of interest.)

The IRB meeting minutes will clearly document that the meeting was held virtually, that all members were individually called for attendance and voting, announced their departures and returns throughout the meeting, and that all members received their agenda and supporting documents with enough time to properly review the materials prior to the IRB meeting. The minutes will document the member by name and the times in and out so that quorum is counted accurately for each submission reviewed. Members who are neither present at the convened meeting, nor participating in the conference call may vote on an issue discussed during a convened meeting (i.e., no voting by proxy).

The IRB Chair will ensure that all members present have an opportunity to speak. IRB staff will provide the Chair with a list of members in attendance. The Chair should address each member by name for further comment or questions before summation of discussion, motions, calling of the vote, etc.

When voting, the Chair will either:

- call each member individually by name for their decision, to ensure all members' votes are accounted for and no mistake is made on what their vote is; or.

- call for members to vote via "raise your hand" function (if this function is available on virtual meeting platform used.)

D. Recusal of IRB Members with a conflict of interest

When an IRB member has a conflict of interest that requires them to recuse themselves from discussion of and voting on a particular protocol or protocol request, that member may not participate in the discussion unless asked to address questions raised by other members. If the member's recusal causes a loss of quorum, the vote must be deferred to another meeting. For this reason, IRB

members should notify the Chair or IRB staff prior to the meeting if they have a conflict of interest related to a specific protocol slated for review at the meeting, and every effort should be made to ensure adequate members in attendance. The IRB minutes will reflect such recusals as they occur during meetings.

E. Discussion and Vote

Robert's Rules of Order is the standard used to guide IRB interactions and decisions. At a minimum, the Chair conducts the meeting, there is a pre-determined agenda, the minutes of the prior meeting are voted upon, and all actions and resolutions require a vote by voice (if a member is participating through teleconferencing or videoconferencing) or show-of-hands vote of the members present following discussion and the making and seconding of a motion.

The IRB Chair and Vice Chair are voting members of the IRB and their presence counts towards the quorum. The official meeting minutes record shall define the number of votes to approve, disapprove, defer or table without identifying the IRB member who cast that vote. The official meeting minutes shall also define the number of votes cast as abstentions. In the event an IRB member elects to abstain, the minutes shall record the abstention.

At the meeting, the primary reviewer introduces the research study protocol request to be reviewed and provides the first comments resulting from their in-depth review. After the primary reviewer has provided their comments, if a secondary reviewer has also been assigned, the IRB Chair will ask the secondary reviewer for their comments. Next, any special consultants will be asked to provide their comments.

The discussion of each new research proposal, continuing review progress report, modification, adverse/unanticipated event, protocol deviation or non-compliance on the agenda is led by the Chair and any designated reviewer(s). Discussion by all members present at the convened meeting is conducted on the necessary ethical and regulatory questions, controverted issues, determinations of scientific/scholarly validity, risk, benefit, and additional safeguards for vulnerable populations.

At the end of the discussion of an application, the Chair looks for a motion on an action. The Chair then calls for a vote on the motion and the members may vote by voice as well as by raising their hands. The Chair asks for votes for the motion, then against, and finally for abstentions. A simple majority carries the vote. The Chair will strive to build consensus as much as possible and may take a straw vote before a binding vote in order to assess whether additional discussion is needed. A deeply divided vote may indicate that further discussion or deferral is appropriate. IRB Staff will count the final vote and the vote is recorded in the minutes.

Members with a COI will recuse themselves from participating in the deliberation and vote for protocols or matters with which they have a conflict. In addition, recused members will leave the meeting room during the review and vote, unless requested by the IRB to remain to answer specific questions.

F. Minutes

Recording:

IRB Staff will take minutes of each meeting. Minutes will be written in sufficient detail to show at least the following:

- Meeting attendance; including status of each attendee (member, consultant, etc.), and conflicts of interest, if any;
- Actions taken by the IRB on each agenda item requiring full IRB action, including, the basis for requiring changes in or disapproving the research;
- Summary of the discussion of controverted issues and resolution;

- Determination of the level of risk and the duration of approval;
- Voting results, including number for, against, members abstaining (listed by name), and members who recused themselves and reason for recusal.
- Consideration of the requisite criteria for approval as well as any additional criteria for the protection of vulnerable populations.

Approval:
Draft minutes will be distributed to members prior to the next IRB meeting for review, typically as part of the agenda packet that is distributed to IRB members before each IRB meeting. Minutes will be approved by a vote of IRB members – a simple majority vote is needed to approve the minutes. The minutes are stored in a UAlbany SharePoint folder accessible to the IRB staff.

G. Guests

Investigators and co-investigators may be invited into the IRB meeting if needed to provide information about a study being reviewed. He or she will come only for that purpose and will leave before the final discussion and vote on the study.

Any guest at an IRB meeting may be asked to leave, at any time, at the discretion of the IRB Chair or Research Compliance Officer (or designee.)

IV. Considerations in Ethical Review of Research and Minimizing Risks for Participants

A. Selection of Subjects

Defining the appropriate population of subjects for a research project involves a variety of factors, including scientific design, susceptibility to risk, likelihood of benefit, practicability, and considerations of fairness. The requirement of the IRB to make a specific determination that the selection of subjects is equitable is based on the principle of justice and helps ensure that the burdens and benefits of research will be fairly distributed. The Belmont Report recommends that, as a matter of social justice, there should be an order of preference in the selection of classes of subjects: adults before children, competent individuals before incompetent individuals, and non-institutionalized persons before institutionalized persons. In addition, those individuals who may already be burdened (e.g., by disabilities or institutionalization) should not be asked to accept the burdens of research unless there is the possibility of direct benefit, or if other appropriate subjects cannot be found (i.e., if the research concerns their particular disability or circumstance). The IRB will consider the extent to which a proposed subject population may already be burdened by poverty, illness, or chronic disabilities in deciding whether they are a suitable subject population.

B. Remuneration

In making its determination about the appropriateness of a given remuneration, the IRB will consider who the subjects will be, what remuneration is being offered, and the conditions under which the offer will be made. Informed consent documents should include a detailed account of the terms of the remuneration, including a description of the conditions under which a subject might not receive the full remuneration (e.g., plan for prorating incentives, etc.)

C. Informed Consent

Informed consent is a process – not a form. The informed consent information or script that will be used with potential research participants plays a central role in the review of the IRB study protocol. The IRB will examine the issue of informed consent from a holistic perspective that takes into account all of the information provided in the protocol and related materials. Because subject understanding is

a necessary/essential component of informed consent, information must be presented in a language and at a level that is appropriate for the population. In general, informed consent information should be provided in lay language at a 6th to 8th grade level.

General Requirements:
The following specific requirements for informed consent, whether written or oral, apply to research subject to the revised Common Rule:

1. Before involving a human subject in research, an investigator shall obtain the legally effective informed consent of the subject or the subject's legally authorized representative (LAR)
2. An investigator shall seek informed consent only under circumstances that provide the prospective subject or the LAR sufficient opportunity to discuss and consider whether or not to participate and that minimize the possibility of coercion or undue influence
3. The information that is given to the subject or the LAR shall be in language understandable to the subject or the LAR
4. The prospective subject or the LAR must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information
5. Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or LAR in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension.
6. Informed consent as a whole must present information in sufficient detail relating to the research, and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject's or LAR's understanding of the reasons why one might or might not want to participate
7. No informed consent may include any exculpatory language through which the subject or the LAR is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

D. Elements of Consent:

Exempt Consent Elements (including limited IRB review):
In general, some form of informed consent or permission is required for exempt research (especially when interacting/intervening with participants) unless justification is provided.

While there are no specific consent requirements for exempt research, general elements to include are:

- A statement that the study involves research
- An explanation of the purposes of the research
- The expected duration of the subject's participation
- A description of the procedures/activities
- A description of any reasonably foreseeable risks or discomforts to the subject (as applicable)
- A description of any benefits to the subject or to others that may reasonably be expected from the research (as applicable)
- A statement that participation is voluntary and the refusal to participate or the decision to withdraw will involve no penalty or loss of benefits to which the subject is otherwise entitled
- A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained (address audio recordings, video, use of quotations, use of identifiers, use of data for other studies, etc.)
- Investigator contact information for answers to pertinent questions about the research
- IRB office information for answers to questions about research subjects' rights

IRB-Reviewed Elements of Consent (general, for research subject to the Common Rule):

- A statement that the study involves research
- An explanation of the purposes of the research
- The expected duration of the subject's participation
- A description of the procedures to be followed, and identification of any procedures that are experimental
- A description of any reasonably foreseeable risks or discomforts to the subject
- A description of any benefits to the subject or to others that may reasonably be expected from the research
- A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject
- A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained
- Information regarding grant/contract/award/sponsor supporting the research
- For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained
- An explanation of whom to contact for answers to pertinent questions about the research
- An explanation of whom to contact in the event of a research-related harm or injury to the subject (can be the same as the person above)
- An explanation of whom to contact for answers to pertinent questions about research subjects' rights (e.g., IRB office)
- A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled
- One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:
    - A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or
    - A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

Additional IRB-Reviewed Elements of Informed Consent (as appropriate, for research subject to the Common Rule):

- Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's or the legally authorized representative's consent
- Any additional costs to the subject that may result from participation in the research
- The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject
- A statement that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation will be provided to the subject
- The approximate number of subjects involved in the study
- A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit
- A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions
- For research involving biospecimens, whether the research will (if known) or might include

whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen)

E. Screening, Recruiting, or Determining Eligibility

The revised Common Rule removes the requirement for partial waivers of consent for the use of information or specimens for the purposes of screening, recruiting, or determining the eligibility of prospective subjects for inclusion in the research. Pursuant to the revised rule, the IRB may approve a research proposal in which an investigator will obtain information or biospecimens for these purposes without the informed consent of the prospective subject or the subject's LAR if either of the following conditions is met:

1. The investigator will obtain information through oral or written communication with the prospective subject or LAR, or
2. The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.

When research is subject to the revised Common Rule, and the above conditions are met, investigators do not have to request waivers of consent for the purposes of screening, recruiting, or determining eligibility but do have to describe the activities in the application or protocol submitted to the IRB. The above does not negate the requirements of other rules, such as HIPAA, when applicable. It also does not negate the requirement to obtain consent, or a waiver of consent, before involving a subject (including the use of their identifiable private information or biospecimens) in other research activities.

F. Documentation of Informed Consent

Unless the requirement for documentation of consent (i.e., signature of participant of consent information) is waived by the IRB, informed consent must be documented by the use of written informed consent form (ICF) approved by the IRB and signed (including in an electronic format) by the subject or the subject's LAR. A written copy must be given to the person signing the ICF. An original, signed consent form for each subject must be kept by the investigator.

The ICF may be either of the following:

1. A written consent document that embodies the basic and required additional elements of informed consent. The investigator shall give either the subject or the subject's LAR adequate opportunity to read the informed consent form before it is signed; alternatively, this form may be read to the subject or the subject's legally authorized representative; or
2. A short form written consent document stating that the elements of informed consent have been presented orally to the subject or the subject's LAR and that the key information required by §46.116(a)(5)(i) was presented first to the subject, before other information, if any, was provided. When this method is used:
    - The oral presentation and the short form written document should be in a language understandable to the subject; and
    - There must be a witness to the oral presentation; and
    - The IRB must approve a written summary of what is to be said to the subject (the approved full consent document may serve as this summary); and
    - The short form document is signed by the subject;
    - The witness must sign both the short form and a copy of the summary; and
    - The person actually obtaining consent must sign a copy of the summary; **and**
    - A copy of the summary must be given to the subject or representative, in addition to a copy of the short form.

G. Waiver of Documentation of Consent

Frequently called “Verbal Consent,” the process is more correctly referred to as Informed Consent with Waiver of Documentation. The investigator must obtain consent following the same requirements as written consent but the subject does not sign a consent form.

Waiver of documentation of consent is permitted under a limited set of circumstances. The first requirement is that the research is not greater than minimal risk. This process is sometimes referred to as verbal consent. To waiver documentation of consent, the research must meet the regulatory criteria of 45 CFR 46.117(c).

Under the Common Rule, there are three conditions under which an IRB may waive the requirement for an investigator to obtain a signed consent form:

1. The requirement for the participant's signature on the consent form can be waived if the research involves no more than minimal risk and does not involve any procedures for which written consent is required outside the research context. Waivers of the signature requirement are often granted for telephone and online surveys and questionnaires.
2. The participant's signature on a consent form can also be waived if the only record linking the subjects and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject (or legally authorized representative) will be asked whether the subject wants documentation linking the subject to the research, and the subject’s wishes will govern.
3. The subjects or LARs are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects, and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

When a waiver of documentation of informed consent is issued by the IRB the consent process needs to adhere to all of the requirements of consent. In addition, if the study is subject to HIPAA, written HIPAA authorization may still be required unless the study also qualifies for alteration of the requirement for written HIPAA Authorization.

The IRB's preference is for the investigator to create informed consent document but with a substitution for the usual signature page with one that allows the investigator to document the subject's verbal consent. Examples of situations and options for verbal consent are included below: Unless the requirement for documentation of consent is waived by the IRB, informed consent must be documented by the use of written informed consent form (ICF) approved by the IRB and signed (including in an electronic format) by the subject or the subject’s LAR. An original, signed consent form for each subject must be kept by the investigator.

In all cases, a written copy must be given to the participant or LAR.

H. Waiver or Alteration of Consent

When reviewing research, the IRB will evaluate requests for waivers or alterations of informed consent in accordance with the requirements and criteria specified in the Common Rule and summarized below. The IRB’s determination will be documented in the IRB record and communicated to the investigator.

In order to approve a request from an investigator to waive the requirement for informed consent, or to omit or alter one or more basic or additional element of consent (an “Alteration”), under this provision the IRB must determine and document that the below criteria are satisfied.

1. The research involves no more than minimal risk to the subjects;
2. The research could not practicably be carried out without the requested waiver or alteration;
3. If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;
4. The waiver or alteration will not adversely affect the rights and welfare of the subjects; and
5. Whenever appropriate, the subjects or LARs will be provided with additional pertinent information after participation.

Investigators may be asked to provide justification, or additional information or documentation, to support that the above criteria are satisfied.

Restrictions when research is subject to the Common Rule:

1. Waivers:
    - If an individual was asked to provide broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens under the Common Rule regulations relating to broad consent, and refused to consent, an IRB cannot waive consent for the storage, maintenance, or secondary research use of the identifiable private information or identifiable biospecimens.
2. Alterations:
    - An IRB may not approve a request to alter or omit any of the six general requirements for informed consent.
    - If a broad consent procedure is used, an IRB may not alter or omit any of the elements of broad consent.

Waiver or Alteration of Consent in Research Involving Public Benefit and Service Programs:

These requirements and restrictions apply to research subject to the Common Rule. In order to approve a request from an investigator to waive the requirement for informed consent, or to omit or alter one or more basic or additional element of consent (an “Alteration”), under this provision the IRB must determine and document that the below criteria are satisfied.

1. The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:
    - Public benefit or service programs;
    - 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; and
2. The research could not practicably be carried out without the waiver or alteration.

Restrictions:

a) Waivers –
    - If an individual was asked to provide broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens in accordance with the Common Rule requirements for broad consent, and refused to consent, an IRB cannot waive consent for the storage, maintenance, or secondary research use of the identifiable private information or

identifiable biospecimens.

b) Alterations –
   - An IRB may not approve a request to alter or omit any of the 6 general requirements for informed consent.
   - If a broad consent procedure is used, an IRB may not alter or omit any of the elements of broad consent

I. Privacy and Confidentiality

For the majority of social and behavioral science research, ensuring confidentiality is the most important procedure to minimize risks to research participants. Researchers should implement appropriate precautions to maintain the confidentiality of the research data, in accordance with the sensitivity and identifiability of the data to be collected. Methods to protect confidentiality include coding data, separating face sheets and consent documents from survey instruments, limiting access to identifiable data, and storing records in secured locations. More elaborate procedures may be appropriate for research involving sensitive data that may involve a greater risk should confidentiality be breached. In some cases, the investigator may want to seek a Certificate of Confidentiality to protect the data from compelled disclosure.

V. Special Populations: Additional Safeguards

When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, additional safeguards must be included in the study to protect the rights and welfare of these subjects.

A. Students

Universities afford investigators with a ready pool of research subjects: students. When recruiting students, investigators should be aware of the possibility that, in some instances depending on the design of the study, students may feel pressured to participate in research. Therefore, when appropriate, investigators should make every effort to clarify that participation in research is voluntary and their decision whether to participate will not affect their academic standing or their relationship with the researcher, other faculty, and the University.

If offering participation in research as a way to receive course credit (or extra credit), there are two important issues to address: (1) participation in the research must be only one of a number of options; and (2) the other options must be roughly equivalent in terms of the amount of time and effort required. For example, participation in a 30-minute survey should not be offered as an alternative to completing a 10-page term paper.

Another issue raised by the involvement of students as subjects is confidentiality. As with any research involving human subjects, the researcher should make every effort to protect the confidentiality of data on sensitive subjects such as mental health, sexual activity, or the use of illicit drugs or alcohol. This is especially important for research involving students, since other students are often members of the research team and may be involved in data collection and/or analysis. Researchers should ensure that their research staff understands the importance of protecting confidentiality. The IRB Staff is available to provide educational sessions and guidance on this topic.

B. Employees

Many of the same issues arise when recruiting employees to participate in research. Just as student

participation raises questions regarding the ability of students to truly exercise free choice because they may be concerned that grades or other important factors will be affected by their decision whether to participate, employees may be concerned that their decision whether to participate may affect performance evaluations or job advancement. Also, it may be difficult to maintain the confidentiality of personal medical information or research data when the subjects are employees.

C. Individuals with Cognitive Impairments

The primary ethical concern in research involving individuals with psychiatric, cognitive, or developmental disorders, or individuals who are active substance abusers, is that their disorders may compromise their capacity to understand and/or appreciate the purpose and risks and benefits of the research and to participate in the consent process in a meaningful way. Investigators should provide a rationale for involving cognitively impaired subjects and should include additional means to protect the rights and welfare of these subjects.

Some individuals with cognitive impairments may be institutionalized and this may further compromise their ability to exercise free choice. It is also important to protect the privacy of all subjects and the confidentiality of information gathered in research exploring emotionally sensitive topics, since some individuals would not want the fact of their institutionalization divulged.

It is important to note that all adults, regardless of their diagnosis or condition, should be presumed competent to provide informed consent unless there is evidence of a serious condition that would impair their reasoning or judgment. Individuals who have a diagnosed mental disorder may be capable of providing informed consent. Mental disability alone should not disqualify a person from consenting to participate in research.

Persons who have been determined to be incompetent by a judge will have a court-appointed guardian who must be consulted and provide consent before that individual can be enrolled in research. Note that legally authorized representatives (LAR) are generally not officials of the institution in which these individuals reside, since their supervisory duties may give rise to conflicting interests. Also, it should not be assumed that family members or others financially responsible for the individual are able to provide legally authorized consent, since they too may have conflicting interests because of financial pressures, emotional distancing, or other ambivalent feelings common in such circumstances.

D. Children

The regulations provide additional protections for children involved in research, as set forth in 45 CFR 46 Subpart D. The IRB may approve research involving children as subjects only if the research fits into one of four specific categories. These categories are based on the level of risk and the possibility of direct benefit to individual subjects. In New York, children include all those who have not yet reached their 18th birthday (e.g., 0 through 17 years old), but investigators should be aware that the age of majority may vary even within the United States (e.g., 19 in Alabama). The risk categories for research in which children will be participants are set out at 45 CFR 46.404 through 45 CFR 46.407.

Requirements for Permission by Parents or Guardians and for Assent by Children

1. Adequate Provisions for Child's Assent
   The investigator must make adequate provisions for soliciting the assent of child subjects when the children are capable of providing assent. In determining whether children are capable of assenting, the investigator should take into account the ages, maturity, and psychological state of the children involved. This judgment may be made for all children to be involved in research under a particular protocol, or for each child. The child should be given an explanation of the proposed research procedures in a language that is appropriate to the child's age, experience, maturity, and condition.

Waiver of Assent

If the IRB determines either of the following to be true, then the assent of the children is not a necessary condition for proceeding with the research:

- The capability of some or all of the children is so limited that they cannot reasonably be consulted; or
- When the research offers the child the possibility of a direct benefit that is important to the health or well-being of the child and is available only in the context of the research.

Assent" means a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.

Even when the IRB determines that child subjects are capable of assenting, the IRB may still waive the assent requirement under circumstances in which consent may be waived for adults.

E. Wards of the State or Other Agency

Children who are wards of the state or any other agency, institution, or entity can be included in research meeting categories 45 CFR 46.406 or 45 CFR 46.407 only if the research is:

(i) related to their status as wards; or
(ii) conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards.

If the research is approved under this authority, the IRB must require appointment of an advocate for each child who is a ward, in addition to any other individual acting on behalf of the child as guardian or in loco parentis. One individual may serve as advocate for more than one child. The advocate shall be an individual who has the background and experience to act in, and agrees to act in, the best interests of the child for the duration of the child's participation in the research and who is not associated in any way (except in the role as advocate or member of the IRB) with the research, the investigator(s), or the guardian organization.

F. Prisoners

The special vulnerability of prisoners makes consideration of their involvement as research subjects particularly important. Prisoners may be under constraints because of their incarceration that could affect their ability to make a truly voluntary and uncoerced decision whether or not to participate as subjects in research. To safeguard their interests and to protect them from harm, special ethical and regulatory considerations apply for research involving prisoners as subjects. The IRB may approve research involving prisoners as subjects if these special provisions are met.

For research studies that have no federal funding, if the only procedure is secondary analysis of data that includes, or may include, data from prisoners, then the research team need not select prisoners as a category of participant in the IRB submission form and need not meet all of the criteria described below. Instead, the IRB's review will focus on whether the proposed data security procedures are adequate. For other studies without federal funding, investigators will
select prisoners as a population in the IRB application, and the IRB will consider the elements below and apply commensurate protections but will generally not document the specific findings under Subpart C (unless otherwise required).

Definitions and Requirements Pertaining to Research Involving Prisoners Subject to Subpart C:

Minimal Risk

For research involving prisoners, the definition of minimal risk differs from the definition of minimal

risk used for other populations. The definition for prisoners includes reference to physical or psychological harm, as opposed to harm or discomfort, to risks normally encountered in the daily lives, or routine medical, dental or psychological examination of healthy persons.

Prisoner
"Prisoner" means 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.

When Subjects Become Prisoners During the Course of the Research:

If a subject becomes a prisoner after enrollment in research, the investigator is responsible for reporting in writing this situation to the IRB immediately. Upon its review, the IRB can either:

1) approve the involvement of the prisoner-subject in the research in accordance with this policy or
2) determine that this subject must be withdrawn from the research.

Specific Findings of IRB Required to Approve Research:

When the IRB is reviewing a protocol in which a prisoner is a subject, the IRB Committee must make seven findings as follows:

1. Research falls within at least one of four acceptable categories:

(i) 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 subjects;
(ii) 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 subjects;
(iii) Research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults) provided that the study may proceed only after the Secretary has consulted with appropriate experts including experts in penology, medicine, and ethics, and published notice, in the FEDERAL REGISTER, of his intent to approve such research; or
(iv) Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject. 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 Secretary has consulted with appropriate experts, including experts in penology, medicine, and ethics, and published notice, in the FEDERAL REGISTER, of the intent to approve such research.

“Minimal risk” means 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. Any Advantage of Participation Does Not Impact Prisoner's Ability to Weigh Risks

Any possible advantages accruing to the prisoner through their 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 their ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired;

3. The risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers;

4. Procedures for the selection of subjects 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 Board justification in writing for following some other procedures, control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project;

5. The information is presented in language which is understandable to the subject population;

6. Adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on their parole; AND

7. Where 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 prisoners' sentences, and for informing participants of this fact.

Permitted Research Involving Prisoners funded by DHHS.

For research conducted or supported by HHS to involve prisoners, two actions must occur:

(i) the IRB must certify to OHRP that it has reviewed and approved the research under the federal regulations; and
(ii) OHRP must determine that the proposed research falls within one of the categories of permissible research described above.

If an investigator wishes to engage in non-HHS-supported research such certification is not required.

Prisoners Who Are Minors

When a prisoner is also a minor (*e.g.*, an adolescent detained in a juvenile detention facility a prisoner) the special protections regarding the inclusion of children as subjects also apply.

Federal Bureau of Prisons
The Federal Bureau of Prisons places special restrictions on research that takes place within the Bureau of Prisons. Investigators should review the regulations at 28 CFR Part 512 when considering such research.

G. International Research

International research often requires additional safeguards to protect the rights and welfare of subjects. These include everything from the use of a translator if the person(s) seeking consent and/or collecting data is not fluent in the subject's language to waiving the requirement to obtain written consent due to local custom or because of risks subjects may face due to social or political conditions. Investigators who will be conducting research internationally should provide the IRB with at least the following information:

- Information about where the research will be conducted (both the geographic location and the

performance site, where applicable).
- A copy of local IRB or equivalent ethics committee approval, where possible. Depending on the local context, this may take the form of a letter of approval from a local IRB, a local university department sponsoring the research, a local institutional oversight committee, or an indigenous council.
- Information about the investigator's knowledge of the local research context, including information about the current social, economic, and political conditions. This should include a detailed description of the investigator's personal experience conducting research (or studying or residing) in the region.
- Information about whether there are any additional risks subjects might face as a result of the population being studied and/or the local research context.
- Information about the language(s) in which consent will be sought from subjects and the research will be conducted, as well as whether the investigator fluent in this language, or whether a translator will be used. If a translator will be used, it should be clear what risks, if any, this might pose for subjects, as well as how they will be minimized.

When composing an IRB protocol for an international research project, researchers should clearly demonstrate that the proposed procedures are appropriate given the culture, norms, and mores of local communities. Whenever practical, researchers should include local community representatives in the design of the research and consent processes to ensure that local concerns about research practices, goals, or uses of collective cultural or intellectual property are considered. Community collaboration in research design demonstrates concern for the ethical principles of justice (by articulating the equitable distribution of research risks and benefits in relation to community needs) and respect for persons (by recognizing the right of individuals to form groups with corporate agency).

H. Non-English Speakers

Instigators should clearly indicate when non-English speakers will be included in the research and where translated materials will be used.

Copies of translated versions of informed consent document(s) and any other written materials (recruitment, instruments, instructions, etc.) to be used with participants must be submitted along with a name/description of service or person that provided the translations.

VI. Audits, Unanticipated Problems, and Non-Compliance

A. Audits and Monitoring

To help ensure compliance with federal regulations and IRB policies regarding research with human subjects, and to ensure that human subjects are adequately protected, the IRB staff and IRB members may conduct routine, targeted, or random audits of research protocol files subject to their jurisdiction. In addition, the IRB staff and members may request monitoring of approved projects that may take the form of routine, targeted, or random audits. These activities may include, but are not limited to the following:

a. Request progress reports from investigators;
b. Examine research records;
c. Contact research subjects;
d. Dispatch observers to the sites where research involving human subjects and/or the informed consent process is being conducted;
e. Verify from sources other than investigators that no material changes in the study have occurred;
f. Audit advertisements and other recruiting materials to confirm proper IRB approval;

g. Review projects to verify from sources other than the investigator(s) that no material changes have occurred since previous IRB review; and/or
h. Other monitoring or auditing activities deemed appropriate by the IRB.

Reporting of Audit results to Full Board

The results of any targeted or random audits by the IRB members or staff will be reported to the full IRB on the agenda of the next regularly scheduled meeting. However, if the information gained during the monitoring or auditing process indicates that human subjects may be exposed to unexpected serious harm, the IRB may suspend or terminate approval of the research prior to the next regularly scheduled IRB meeting.

B. Unanticipated Problems Involving Risks to Participants or Others

Unanticipated problems involving risks to participants or other individuals, or that generate complaints from research participants, must be reported promptly to the IRB.

Unanticipated problems include any incident, experience, or outcome that is:

1) unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol and related documents; and (b) the characteristics of the participant population being studied; AND
2) related or possibly related to participation in the research; AND
3) suggests that the research places participants or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

Some unanticipated problems involve social or economic harms rather than the physical or psychological harm typically associated with adverse events.

An unanticipated problem that is also a serious adverse event should be reported to the IRB within 1 week (7 days) of the researcher becoming aware of the event. A "serious adverse event" is any adverse occurrence that results in participant death; places a participant at immediate risk of death; results in a participant's inpatient hospitalization or prolongation of existing hospitalization; results in a persistent or significant disability/incapacity; results in a congenital anomaly/birth defect; or based on appropriate medical judgement, may jeopardize the participant's health and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition.

Any other unanticipated problem (that is not a serious adverse event) should be reported to the IRB within 2 weeks (14 days) of the researcher becoming aware of the problem.

An unanticipated problem report can be submitted to the IRB. The Research Compliance Officer will initially evaluate any unanticipated problem report and consult with the IRB Chair as needed to determine whether the reported problem creates additional or new risks to participants or other individuals, and what appropriate remedial action should be taken by the research team to address the situation and, if needed, to notify research participants of the problem. For federally-funded research, unanticipated problems that create risks to subjects or others will be reported to the HHS Office for Human Research Protections (and other federal agency as appropriate).

If a study that is designated minimal risk enrolls more than the number of participants listed in the protocol, the IRB will not require that the research team submit an unanticipated problem report or a modification solely due to “over-enrollment.” The enrollment total in the protocol is regarded as an estimate of enrollment, not as a “hard cap” on enrollment – if the study is minimal risk, enrolling more than the number of individuals listed in the enrollment estimate in the protocol does not affect the risk/benefit ratio of the study. If a study is greater than minimal risk and enrolls more than the

enrollment total listed in the protocol, the IRB will require a modification to increase the enrollment total in the protocol and an explanation of whether the "over-enrollment" has affected the risk/benefit ratio of the study.

C. Protocol Deviations and Noncompliance

Deviation from the IRB-approved protocol as well as noncompliance with applicable University policies, regulatory requirements, and/or IRB determinations must be reported to the IRB. Such occurrences can have a negative impact on research participants. Protocol deviation and noncompliance can alter the risk-benefit ratio for participants or otherwise jeopardize the safety, rights, and welfare of subjects. Nevertheless, there are also times when it is necessary to deviate from the approved research plan or continue aspects of the research during a lapse in approval in order to protect research subjects.

Reported incidents will be considered *possible* noncompliance until a final determination is made by the IRB. The IRB will assess the severity of the event and, if necessary, require corrective action. Serious and continuing noncompliance will be reported to the appropriate institutional officials and regulatory agencies.

Definitions

Noncompliance. Failure to comply with the requirements of an applicable law, regulation, or institutional policy pertaining to the protection of human subjects, and/or with the requirements or determinations of an IRB. In addition, failing to submit a continuing review application in a timely manner and permitting IRB approval to expire is considered noncompliance. However, it is not noncompliance when there is a need to deviate from the approved protocol or continue aspects of the research after expiration of approval in order to protect the welfare of research participants. Also, departure from the protocol that is due to a study participant's non-adherence is not considered to be a protocol deviation but may need to be reported to the IRB.

Noncompliance

- *Minor Noncompliance*. These are incidents which are the result of an unintentional deviation or omission from the protocol that the IRB has approved or determined to be exempt. A minor noncompliance shall not have negatively affected the rights, safety, or welfare of the subjects. The conduct of unsubmitted or unreviewed human subjects research that would have qualified for an exempt determination had it been reviewed and determined exempt by the IRB staff in advance of initiating the research will also be considered minor noncompliance.

- *Serious Noncompliance.* Noncompliance that adversely affects the rights or welfare of participants. These are incidents of noncompliance involving non-exempt protocols where: the noncompliance increases the risk and/or decreases the benefit to individual subjects; the research takes place without appropriate IRB review and approval; egregious or intentional noncompliance occurs; and/or another situation exists which the IRB determines to be a serious noncompliance.

- *Continuing Noncompliance.* A pattern of noncompliance that indicates an inability or unwillingness to comply with the requirements of an applicable law, regulation, or institutional policy pertaining to the protection of human subjects and/or with the requirements or determinations of an IRB.

Reporting Requirements and Procedures

Reports by the investigator: Protocol deviations and noncompliance should be reported to the IRB as soon as possible. An initial report should be made to the Research Compliance Officer within *1 week*

(7 calendar days) of when the investigator became aware of the event. The initial report must be followed by a formal report within no more than *2 weeks* (14 calendar days) of when the investigator became aware of the event. In some cases, reporting requirements may be met by submitting a preliminary report to the Research Compliance Officer, IRB, and other officials/agencies involved, with a follow-up report submitted at a later date when more information is available. These determinations will be made on a case-by- case basis, with the IRB Chair, Research Compliance Officer, investigator, institutional official(s) and/or others involved as appropriate. The primary consideration in making these judgments will be the need to take timely action to prevent avoidable harms to subjects and others.

Reports by other parties (e.g., research staff, general public, research subjects, etc.): Whenever possible, reports should be submitted via the investigator. However, if the reporting party deems it necessary and/or wishes to remain anonymous to the investigator, he or she may contact the IRB directly.

Protocol deviations and/or noncompliance incidents may be discovered by IRB members or IRB staff as part of continuing review of nonexempt protocols, as part of a Quality Assurance or audit activity, or an incidental awareness (e.g., due to a news article, errant email or incidental finding of recruitment material). Such discoveries must be promptly reported to the Research Compliance Officer.

The reporting party should use their judgment when determining if an event is reportable. If an individual is unsure of whether there are grounds to report an event, he or she may call upon the Research Compliance Officer to discuss the situation informally.

Alternatively, individuals always have the option of making reports through the Whistleblower process. A protected disclosure is a good faith communication about an incident that constitutes improper governmental activity or may significantly threaten the health or safety of employees or the public, if the disclosure or intention to disclose was made for the purpose of remedying that condition.

Reports of possible noncompliance should include a complete description of the event and include sufficient detail to allow the IRB to make an assessment.

Special Considerations

Deviations from the IRB approved protocol that cannot wait for IRB review because of the immediate need to eliminate apparent hazards to the subject are not considered noncompliance.

The continued participation of enrolled subjects in research for which approval has expired is also not considered noncompliance if it is necessary to protect the best interests of enrolled subjects.

The determination of whether it is necessary to deviate from the approved protocol or to continue aspects of the research to protect subjects may initially be made by the investigator. This determination may be made for enrolled subjects as a group or for individual subjects. However, the investigator must submit a report to request IRB confirmation of agreement as soon as possible.

IRB Review and Actions

The IRB will fully investigate and review reports of possible noncompliance to determine if the event was (1) not noncompliance, (2) minor noncompliance, (3) serious noncompliance, or (4) continuing noncompliance. If necessary, the IRB will require corrective action. The IRB will attempt to resolve alleged instances of noncompliance without interrupting the conduct of the study, especially if the rights, safety, and welfare of subjects may be jeopardized by the interruption. All reports of potential noncompliance as well as the outcome of investigations that are substantiated will be noted in the protocol record.

If the IRB finds that no noncompliance occurred because: (1) the reported noncompliance was unsubstantiated, (2) the investigator deviated from the protocol in order to eliminate immediate and apparent hazards to subjects, or (3) continued participation of enrolled subjects in research for which approval has expired was necessary to protect the best interests of enrolled subjects, actions by the IRB may include but are not limited to:

- Requiring no further action.
- Requiring submission of a modification to the protocol or consent form.
- Requiring submission of a continuing review application.

If minor noncompliance is found to have occurred, actions by the IRB may include but are not limited to:

- Requiring no further action.
- Requiring remedial training (e.g., online educational program, attendance at workshop, one-on-one training).
- Requiring re-consent of subjects.
- Requiring the submission of a modification to the protocol or consent form.

Whenever appropriate, investigators will be assisted so that they can achieve compliance without the need for sanctions. However, if the investigator fails to cooperate with IRB requests to correct minor noncompliance, this inaction will be treated as continuing noncompliance.

If serious and/or continuing noncompliance is found to have occurred, actions by the IRB may include but are not limited to:

- Establishing a corrective action plan.
- Asking the Investigator to voluntarily halt the research until he or she is in compliance.
- Requiring the Investigator to participate in and complete further training.
- Requiring more frequent IRB review of the project.
- Requiring re-consent of subjects.
- Making recommendations to the Institutional Official (IO) for further sanctions, stipulations, or restrictions. Such recommendations could include (but are not limited to): the research data not be published, the data be destroyed, the data not be used in a dissertation or thesis, and/or that the University take away the researcher's privilege of conducting research with human subjects.
- Sharing information of noncompliance with other institutional units (e.g., Conflict of Interest Committee, University research administration, and Office of General Counsel) as deemed necessary.
- Suspending or terminating IRB approval for some or all parts of the research activity.

The IRB and, when appropriate, the institution will act promptly to ensure remedial action regarding any breach of regulatory or institutional human subject protection requirements. The IRB also has the authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB policies, is not in compliance with federal regulations, or deviates from the approved protocol.

All serious and/or continuing noncompliance must be reported promptly to the Institutional Official (IO) and, for federally funded research, the appropriate department, agency head or sponsor. Reports will only be made to OHRP for research that is regulated by this agency per University at Albany's Federalwide Assurance (FWA). Copies of reports or correspondence sent to outside agencies will be maintained by the IRB Office.

The Research Compliance Officer (or designee) is responsible for assisting the IRB Chair with the initial fact gathering and review of the possible noncompliance. The IRB Chair reviews the potential

noncompliance and may make a decision on the action to be taken, may convene an ad hoc subcommittee to conduct an investigation and/or ask the convened IRB to make a decision. Incidences of potential serious or continuing noncompliance will generally be referred to the convened IRB for deliberation and a final decision on the process and/or the outcome.

If appointed by the Chair, an ad hoc IRB subcommittee may review the possible noncompliance, conduct interviews and hearings as needed, review pertinent data or findings of the investigation, and may make recommendations to the convened IRB as to a course of action.

The convened IRB reviews information gathered about the possible noncompliance, reviews pertinent data or findings of the investigation, deliberates, and makes a decision about the nature of the incident and course of action.

The Research Compliance Officer will confirm that corrective action has been taken (if applicable) or designate an IRB staff member to take on this task. The Research Compliance Officer is also responsible for notifying the Institutional Official (IO) about any serious or continuing noncompliance and will cooperate in notifying the funding agency and other regulatory bodies about the noncompliance, as appropriate. The Research Compliance Officer or Staff will notify the Investigator of the review outcome in writing promptly.

If the IRB determines that the noncompliance is serious and/or continuing, the IRB Chair, in cooperation with the Research Compliance Officer, reports this in writing to the IO along with any further recommendations from the IRB for institutional action. Regulatory authorities or Sponsors may also be notified by the IO (or their designee) as applicable and required.

Suspension and Termination of IRB Approval

The IRB has the authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. When the IRB suspends or terminates its approval it will include a statement of its reasons in writing and report the suspension or termination promptly to the investigator.

- *Suspension of IRB approval:* temporarily or permanently withdrawing approval for some or all research procedures short of permanently stopping all research procedures. Suspended research must undergo continuing review.
- *Termination of IRB approval:* permanently withdrawing approval for all research procedures. Terminated research is closed and does not require continuing review.

When study approval is suspended or terminated by the IRB**,** in addition to stopping all research activities, the IRB will, if appropriate, inform any subjects currently participating that the study has been terminated. The IRB will consider whether procedures for withdrawal of enrolled subjects are necessary to protect their rights and welfare.

Suspending or terminating approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects will be authorized by the full IRB. The IRB Chair is authorized to issue orders immediately suspending IRB approval, in which case the decision will be reported to the full IRB for review.

Appendix 1: Definitions

Human subject means a living individual about whom an investigator (whether professional or student) is conducting research:

(i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or

(ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

Intervention includes both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

Interaction includes communication or interpersonal contact between investigator and subject.

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 that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record).

Identifiable private information is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

An **identifiable biospecimen** is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

Legally authorized representative means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research. If there is no applicable law addressing this issue, legally authorized representative means an individual recognized by institutional policy as acceptable for providing consent in the non-research context on behalf of the prospective subject to the subject's participation in the procedure(s) involved in the research.

Minimal risk means that that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities. For purposes of this rule, the following activities are deemed not to be research:

(i) 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 focus directly on the specific individuals about whom the information is collected.

(ii) 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 signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals,

risk factors, patterns in diseases, or increases 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).

(iii) 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.

(iv) Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

Written, or in writing, refers to writing on a tangible medium (e.g., paper) or in an electronic format.

Appendix 2: IRB Exemption Categories

The Common Rule Categories for Exemptions:

Although the HHS IRB regulations list eight exemption categories, the University at Albany has opted to implement 4 six of those categories at this time (see the list below).

Unless otherwise required by law or a federal agency or department, research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from the additional requirements of the revised Common Rule, except as specified.

Note: Other than exempt category 6, these categories do not apply to research that is also FDA- regulated.

1. Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

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): *"When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data."*

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:
    (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): *"When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data."*

For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

4. 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 ['HIPAA'], 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.

<u>Limited IRB Review for Exempt Research</u>

Limited IRB Review is a new provision under the revised Common Rule that allows certain research to be considered Exempt from IRB review even when the identifiable information might be sensitive or potentially harmful if disclosed. In order to qualify for the exemption, the study must meet the standards of Limited IRB review.

For Exempt categories 2 and 3, the requirement for Limited IRB Review is triggered when:

1) The information obtained is recorded by the investigator in such a manner that the identify of the participants can be readily ascertained, directly or through identifiers

linked to the subjects, AND
2) Any disclosure of the participants' responses outside the research would reasonably place the subjects at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, educational advancement, or reputation.

Limited IRB Review under Exempt categories 2 and 3 requires that the IRB determines that the criteria for IRB approval under the revised Common Rule at 45 CFR 46.111(a)(7) is satisfied:

45 CFR 46.111(a)(7):

> When appropriate, there are adequate provisions to protect the privacy of subjects and maintain the confidentiality of data.
>
> (i) The Secretary of HHS will, after consultation with the Office of Management and Budget's privacy office and other Federal departments and agencies that have adopted this policy, issue guidance to assist IRBs in assessing what provisions are adequate to protect the privacy of subjects and to maintain the confidentiality of data.

The factors below should be considered when conducting Limited IRB Review:

- The extent to which identifiable private information is or has been de-identified and the risk that such de-identified information can be re-identified;
- The use of the information;
- The extent to which the information will be shared or transferred to a third party or otherwise disclosed or released;

Appendix 3: IRB Expedited Categories

Categories of Research That May Be Reviewed by the Institutional Review Board (IRB) through an Expedited Review Procedure[1]

Applicability

A. Research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the following categories, may be reviewed by the IRB through the expedited review procedure authorized by 45 CFR 46.110 and 21 CFR 56.110. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

B. The categories in this list apply regardless of the age of subjects, except as noted.

C. The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects= 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.

D. The expedited review procedure may not be used for classified research involving human subjects.

E. IRBs are reminded that the standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review--expedited or convened--utilized by the IRB.

F. Categories one (1) through seven (7) pertain to both initial and continuing IRB review.

Research Categories

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

    a. (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)

    b. Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

    a. (a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or

b. from other adults and children [2], considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, 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 per week.

3. Prospective collection of biological specimens for research purposes by noninvasive means. Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) 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; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- 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; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

4. Collection of data through noninvasive 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/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: (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 subject or an invasion of the subject=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, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)

6. Collection of data from voice, video, digital, or image recordings made for research purposes.

7. 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. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

8. Continuing review of research previously approved by the convened IRB as follows:

   a. where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or

b. where no subjects have been enrolled and no additional risks have been identified; or

c. where the remaining research activities are limited to data analysis.

9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

[1] An expedited review procedure consists of a review of research involving human subjects by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB in accordance with the requirements set forth in 45 CFR 46.110.

[2] Children are defined in the HHS regulations 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." 45 CFR 46.402(a).

Appendix 4: IRB Approval Periods

Research projects under the 2018 human subject rules removed the requirement for renewals except for projects that are greater than minimal risk (e.g., full committee projects). The University at Albany, however, has determined that some minimal risk projects should still have a renewal requirement as identified below.

Exempt Research Human Research projects that are deemed exempt do not have a renewal requirement. This includes exempt research that received a limited IRB review. However, exempt research will be given a five (5) year expiration date so that the Human Subject Protection Program can update its records.

Projects that are not federally funded or supported and would normally qualify for an exemption if they were funded, will also receive a five (5) year expiration date.

Minimal Risk Research

The 2018 human subject rules eliminated the requirement to submit renewal paperwork at least annually for minimal risk research. This research will be given either a three (3) or five (5) year expiration date so that the Human Subject Protection Program can update its records. In addition, the University at Albany has determined that some projects may require more routine monitoring and has identified the following types of projects or instances when a renewal may be required:

- Projects involving vulnerable populations;
- Principal Investigator (PI) or Co-PI that have received serious or continuing non-compliance determinations in the past two (2) years; or
- As determined by the IRB on a project basis depending on the risks in the research project.

Appendix 5: Department of Defense (DoD) Supported Research Involving Human Subjects

Research under the review of the IRB and sponsored by the Department of Defense, involving collaboration with the DoD, or involving DoD facilities or personnel both military and civilian must meet additional requirements including special protections for research participants, as well as additional review and reporting requirements outlined below.

Training Requirements: The DoD requires that all individuals involved in the design, conduct, and approval of human subject research complete human subject research protections training. In addition to the CITI IRB training required by UA IRB, the Department of Navy (DON), including the Marine Corps, requires that investigators, institutional and IRB leadership complete the additional CITI Training Module for DON- Supported Extramural Performers. Refresher training must be completed every three years.

Scientific Review: For research projects involving the Army or Navy (including the Marine Corps) additional documentation of independent scientific review prior to IRB review of new applications and substantive modifications is required. This scientific review may be provided by the funding agency, by an established internal review mechanism within the investigator's academic unit, or through an ad hoc scientific review by the investigator's chair or dean. Evaluation of scientific merit conducted by the IRB as part of its review may be sufficient in some cases, as well.

Scientific review should include the name and qualifications of the reviewer(s) and must demonstrate that the research uses procedures consistent with sound research design and is likely to yield the expected results. Additionally, the scientific review must include an assessment of the following elements:

- Significance of the research question;
- Scientific approach;
- Research team qualifications;
- Facilities and resources available.

Amendments not meeting the criteria to be considered a substantive modification should include documentation that additional scientific review is not needed.

Surveys and Interviews: Research involving surveys or interviews with DoD military or civilian personnel or their families may require additional DoD approval. Documentation from the DoD component should be provided regarding any additional review requirements along with the timing of the review.

International Research: For DoD research conducted outside of the United States, the IRB must consider the laws and requirements of the host country as well as the cultural context of the research. In conduct of such research, the laws, customs, and practices of the country in which the research takes place or those required by the regulations at 32 CFR § 219.101, whichever are more stringent, will take precedence. The research must meet the same standards of ethics and safety that apply to research conducted within the Unites States involving U.S. citizens, and will be conducted in accordance with applicable international agreements. This may be documented via an in-country or IRB/ethics review and/or a review by a consultant with expertise in that country. For Navy research involving subjects who are not US citizens or DoD personnel, the investigator must provide documentation of permission from the host country and an ethics review and approval by the host country or local Naval IRB with host country representation.

Collaboration: Collaborating institutions in multi-site research must have a federal wide assurance. Investigators must provide documentation of IRB approval or an IRB Authorization Agreement for collaborators. The roles and responsibilities of each institution must be specified in any such agreement along with a statement by which the parties agree to comply with any special DoD requirements.

Prohibited Research: Research with detainees (prisoners of war), except research with investigational new drugs or devices where such treatment would also be offered to U.S. military service members at the same location and with the same medical condition consistent with established medical practice. Research involving human testing of chemical or biological agents is prohibited, except for certain prophylactic, protective or peaceful purposes.

Classified Research: Written permission to engage in classified research must be granted by the Institutional Official prior to engaging in such work and prior to the submission of applications for grants, contracts, or regulatory permission to conduct the work.

DoD Limitations on Waivers of Informed Consent and Consent by LARs: Consent cannot be waived for any research using DoD funds and meeting the definition of research involving a human being as an experimental subject according to 10 USC 980. This places limitations on research involving deception, decisionally-impaired individuals, or research being conducted under emergency conditions where the subject may not be able to provide consent. This does not apply to retrospective research involving analysis of data or specimens, observational projects, blood draws, or tissue collection, and does not apply to screening of records to identify potential subjects - for activities such as these, the IRB may grant a waiver of consent. This consent requirement may be waived by the Assistant Secretary of Defense for Research and Engineering for a specific project in order to advance the development of a medical product necessary to the Armed Forces, but only if the research may directly benefit the subject and the research is carried out in accord with all other applicable laws and regulations. For research involving a human being as an experimental subject, informed consent must be obtained from the subject or the subject's Legally Authorized Representative (LAR). Informed consent may be provided by a legally authorized representative (LAR) only if the subject lacks decision – making capacity and the IRB has determined that the research is intended to be beneficial to the individual subjects.

Inclusion of Subject Populations: The selection of human subjects must reflect gender and minority participation in DoD projects in accordance with public law 103-160 § 252. The requirement to include women and minorities may be waived by the Secretary of Defense if the Secretary determines that the project is inappropriate with respect to the health of subjects, inappropriate with the purpose of the research, or inappropriate under such other circumstances as the Secretary of Defense may designate.

Research Monitor: A research monitor must be appointed for all research considered more than minimal risk. The monitor should be independent of the team conducting the research involving human subjects. The monitor's duties may include observation of recruitment, enrollment, and the consent process, as well as reviewing safety monitoring and overseeing data collection and analysis. The monitor shall have the authority to take necessary steps to protect the safety and well-being of human subjects by stopping research in progress until the IRB can assess the monitor's report. The monitor must promptly report observations and findings to the IRB or other designated official. The Investigator must identify the monitor by name, provide a written summary of the monitors' duties, authorities, and responsibilities, and the selection must be approved by the IRB. More than one monitor may be appointed even if the research is deemed to be no more than minimal risk.

DoD Personnel as Research Subjects:

Adult Status: The age of majority in the state of New York is eighteen years; however, in DoD research projects, active duty service members and reserve component members are considered to be adults even if they are under the age of eighteen.

Command Approval: As it may impact readiness in the field, command approval may be required prior to military personnel participating in human subject research. Investigators must provide documentation of command approval in the form of an attached letter of agreement indicating that the investigator has permission to conduct the research. Civilian researchers attempting to access military volunteers should seek collaboration with a military research familiar with service-specific requirements.

Protection of Service Members from Undue Influence: Officers and senior noncommissioned officers may not influence the decisions of subordinates to participate in human subject research and may not be present at the time of recruitment. Superior officers must be recruited in a separate session from subordinates. Military status of any research team members obtaining consent must be documented in the project application in order for the IRB to assess this requirement.

For research considered more than minimal risk and where recruiting is conducted in a group setting, an ombudsman must be present to ensure information is clearly, accurately, and adequately presented and the voluntary nature of participation is emphasized. A research monitor may act as ombudsman.

Civilian Personnel: DoD civilian personnel recruited for research shall be afforded the same protections as military personnel. The requirement of an ombudsman is at the discretion of the IRB.

Additional Reporting Requirements: Determinations of serious or continuing noncompliance, unanticipated problems involving risks to subjects or others, project suspensions or terminations, audits, inspections or investigations of DoD research, results of continuing review, changes to the reviewing IRB, and substantive amendments to the protocol (reviewed and approved by the IRB prior to implementation) must be promptly reported to the IRB within 30 days of the event.

Limitations on Compensation: Compensation is allowed for general research participation if approved by the IRB. Payment may come from a federal or non-federal source.

Compensation paid to DoD employees, both military and civilian, must comply with the requirements in the DoD Instruction 3216.02 § 11. Investigators who plan to compensate subjects may need to inquire about their military status in order to comply with these requirements. Investigators should describe their plan for assessment of military status.

Record Keeping: To be consistent with University policy, research records should be maintained for a minimum of 3 years after the completion of the research; however, individual DoD components may have additional requirements, including the transfer of records to the DoD. If the DoD requires that research records be transferred to the DoD component, University should retain the original copy of the research record and provide a copy to the DoD component unless there is an executable data usage agreement specifying otherwise. Retained records should be made accessible for inspections and copying by authorized representatives of the DoD.

Appendix 6: IRB Reliance Agreements

All non-exempt human subject research (or exempt research for which limited IRB review takes place pursuant to §46.104(d)(2)(iii), (d)(3)(i)(c)) that UA is engaged in must be reviewed and approved by the UA IRB or an external IRB that UA has agreed to rely upon prior to the initiation of the research.

Investigators should contact the IRB Staff in the Office of Regulatory and Research Compliance early in the process to discuss possible IRB Reliance Agreement options.

Reliance Agreements

Reliance agreements must be in place for all shared IRB review arrangements. The IRB Staff ensures that these agreements are negotiated to reflect study-specific, respective responsibilities of the reviewing IRB and the relying Institutions. The Reliance Agreement:

- Documents the respective authorities, roles, responsibilities, and communication between an organization providing the ethical review and a participating organization relying on a reviewing IRB.
- Describes the responsibilities of all parties and how communication between parties will occur, for example, notifications of the outcome of regulatory review and management of federally-mandated reports such as reports of unanticipated problems, serious or continuing noncompliance, and suspensions or terminations of IRB approval.
- When IRB certification requirements apply (e.g., for NIH Genomic Data Sharing, Certificates of Confidentiality), the agreement or written procedures will indicate who is responsible for meeting the certification requirements.
- Specifies contact information and personnel for both the sIRB and relying institution(s).
- Addresses whether the relying organization applies its FWA to some or all research and ensures that the IRB review is consistent with requirements in the relying organization's FWA.
- Addresses which organization is responsible for obtaining any additional approvals from DHHS when the research involves Subpart B, C, or D determinations.
- The institution that is awarded the funding for the research is responsible for maintaining all agreements and for ensuring that adequate and appropriate communication channels between the sIRB and participating sites are in place. Participating sites are responsible for maintaining copies of the site agreement in accordance with the terms of their FWA.

Factors Considered by the ORRC to have UA provide IRB oversight

The Reliance Administrator evaluates the following factors, and others as appropriate, when considering a request for an UA IRB to serve as the IRB of record for a particular study or studies:

1. The terms of the external site(s) FWA;
2. The accreditation status of the external site(s)
3. Prior experience with the site(s) and investigators;
4. The compliance history of the site(s) and investigators (e.g., outcomes of prior audits or inspections, corrective actions);
5. The research activities to be conducted at the external site(s);
6. The willingness of the external site(s) to accept SBU's reliance terms and procedures;
7. and/or the ability the site(s) to collaboratively provide meaningful oversight of the proposed research, taking into account factors such as:
8. The risks and procedures of the research;

9. The resources available at each site and ability to accommodate or collaborate with each other in observing the consent process, performing compliance reviews,
10. investigations of potential noncompliance, and similar matters;
11. The expertise and experience of the UA IRB with the proposed research, subject population, and applicable regulations;
12. The ability of the UA IRB to comply with the relevant local context considerations of the external site(s), as provided by that site(s); and/or
13. The willingness or ability of the external site(s) to provide information and respond to questions regarding investigator qualifications, conflicts of interest, organizational requirements, local context, and other matters that may inform the IRB of record.
14. The Reliance Administrator will present relevant factors for consideration by the IO or AVP-RCO,
15. who will make the final decision regarding whether or not the UA IRB will serve as the IRB of record. The PI will be notified of the decision.

Responsibilities when UA is the Reviewing IRB

1. Responsibilities of the UA IRB
   - Policies and procedures in the conduct of review for all sites (UA and external) will mirror those outlined throughout these SOPs
   - IRB responsibilities are to be applicable for all sites:
     - Have the authority to request an audit of research being reviewed.
     - Make relevant IRB policies readily available to relying external sites, including their IRB staff, researchers, and research staff, and ensure that changes to those policies are communicated as well.
     - Ensure that an ORRC contact person along with contact information is specified for researchers and research staff to obtain answers to questions, express concerns, and convey suggestions regarding the UA IRB.
     - Adding sites to an already approved IRB study will be considered a modification, and will be conducted by the expedited or full board process. In order for the review to be conducted via the expedited process criteria, such a modification is usually considered a “minor change to previously approved research”. Additional site amendments (regardless of type of review) do not change the expiration date of the IRB approval for protocol.

2. Responsibilities of the UA Principal Investigator
   - Coordinate with ORRC for the PI’s at collaborating sites to have access to current status and current protocols, consent documents, etc. regarding the study. Submit information to the IRB pertaining to the particular characteristics of each site’s local research context to be considered through knowledge of its local research context (a) by the IRB, (b) through consultants, or (c) through review by appropriate designated institutional officials at external site(s). Additionally, the submission will also include details for the IRB’s evaluation regarding the management plan for information that is relevant to the protection of participants (e.g., unanticipated problems involving risks to participants or others, interim results, protocol modifications). When the University at Albany researcher is the lead researcher of a multi-site study, this information will also be made known to the IRB of record.

When UA Cedes IRB Review to another IRB

1. Standing Reliance Agreement -UA has a standing agreement in place for certain

collaborative research with the NYS Department of Health IRB.

2. UA is a participating institution in the SMART IRB initiative as well, having signed an overarching agreement indicating willingness to cede to other institutions' IRBs.

Factors Considered by the ORRC in the decision to allow UA to Cede to another IRB

UA may choose to enter into an agreement to rely upon other another IRB, most commonly when required as a condition of a grant or contract. The Reliance Administrator evaluates the following factors, and others as appropriate, when considering a request to rely upon another IRB:

1. The accreditation status of the proposed IRB;
2. The compliance history of the IRB (e.g., outcomes of prior audits or inspections, corrective actions);
3. Prior experience with the IRB;
4. The federal IRB registration and organizational FWA, as applicable;
5. The expertise and experience of the proposed IRB (e.g., with reviewing the type of research, research procedures, and subject population(s));
6. The research activities to be conducted at the University
7. The risks and complexities of the proposed research;
8. The proposed reliance terms and procedures, including acceptance of UA local context issues, as well as the procedures for collaborative management of matters such as conflicts of interest disclosures, investigator training, noncompliance, unanticipated problems, and federal reports;
9. The plan for review and allowance of the incorporation of site-specific consent language; and
10. The plan for incorporation of other relevant local requirements or context information in the review process.

UA, External IRB, and UA Investigator Responsibilities When UA Cedes Review

The External IRB has the same authority as the UA IRB and all determinations and requirements of the external IRBs are equally binding.

University at Albany remains responsible for the conduct of the research in which it engages.

Research reviewed by external IRBs remains subject to review, approval, oversight, and monitoring by UA (in cooperation with the reviewing IRB when appropriate) and must adhere to all applicable policies, procedures, and requirements of the IRB. As with UA IRB-reviewed research, officials of UA may not approve research that is subject to a reliance agreement if it has not been approved by the reviewing IRB.

ORRC is responsible for notifying the reviewing IRB when UA policies that may impact IRB review are updated.

Responsibilities of the UA Investigator When Using an External IRB

General Compliance Requirement:

- The UA Investigator must be familiar with and comply with the external IRB's policies and procedures for initial and continuing review, record keeping, prompt reporting, and any additional requirements or procedures outlined in the IRB reliance agreement or companion materials (e.g., reliance SOPs).
- All information requested by the reviewing IRB must be provided in a timely manner. University at Albany will support investigator compliance with the terms of reliance

agreements by providing investigators with a Reliance Arrangement Form that provides information relevant to their responsibilities.
- Expectations of PI compliance remain in place regardless of the reviewing IRB.
- Even though the External IRB may be reviewing the study, the study must not begin at
- UA until all HSR training and any required ancillary reviews and certifications have been satisfied.

Post-IRB Approval Requirements:

- Investigators approved through external IRB review must report local unanticipated problems, complaints, and any noncompliance to the ORC via the IRB electronic management system in addition to reporting to the external IRB. Copies of the report submitted to the external IRB are generally acceptable, but additional information may be requested on an as needed basis.
- Investigators must also submit copies of continuing review reports, updated protocols, updated consent forms, study closures and corresponding IRB approval or acknowledgment.
- Changes in PI and the addition of other research team members must be submitted to the UA IRB prior to the new PI or research team member assuming any study responsibilities. CITI trainings and any other applicable requirements will be verified.
- In general, Investigators are reminded that all other University reporting requirements, remain applicable in addition to IRB reporting requirements.