Office of Research and Sponsored Programs, 600

Institutional Review Board (IRB) Policy

1.0 Purpose

This policy has been established to uphold regulations pertaining to rights and welfare of subjects participating in research in *Title 45 Code of Federal Regulations Part 46*, "Federal Policy for the Protection of Human Subjects" and including *Subparts A, B, C, and D.*

2.0 Scope

This policy is applicable to all research projects involving human subjects, regardless of sponsorship.

3.0 Policy

It is the policy of Albany State University to abide by federal regulations governing the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of the Albany State University.

This policy will be governed by the below manual.

4.0 Accountability

The Office of Research and Sponsored Programs, under the supervision of the Office of Academic Affairs

5.0 Contacts

Provost/ Vice President for Academic Affairs
Associate Provost for Research and Sponsored Programs
Director of Sponsored Programs
Research Compliance Officer
Institutional Review Board Chair

6.0 References

Georgia Technology Institute. (2011). *Research Integrity Assurance.* Retrieved November 2011, from Gearogia Tech: http://researchintegrity.gatech.edu/about-irb/irb-policies-and-procedures/

7.0 Last Update

February 5, 2014

OFFICIAL UNIVERSITY POLICY

Albany State University

INSTITUTIONAL REVIEW BOARD

Policies and Procedures Manual

8.0 Table of Contents

I. Mission

Albany State University's Institutional Review Board is charged with the responsibility of safeguarding the rights and welfare of human participants in research. The university's program

of human research participant protection is based on the three primary ethics principles set forth in the Belmont Report, issued in 1979 by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research:

- Respect for persons,
- Beneficence, and
- Justice.

The Albany State University Institutional Review Board will apply these principles to all human research projects, regardless of sponsorship.

II. Institutional Commitment to the Protection of Human Research Participants

Safeguarding the rights and welfare of human participants in research is an institutional policy directed by the President through the Associate Vice President for Research and Sponsored Programs. It is their responsibility to exercise appropriate administrative oversight to assure that Albany State's *Policies and Procedures* designed for protecting the rights and welfare of human participants are effectively applied in compliance with the university's Federalwide Assurance.

Research covered by this policy that has already been approved by an IRB may be subject to further appropriate review and approval or disapproval by university officials. *The IRB may approve research related to Albany State University students' performance; however, the Provost and Vice President of Academic Affairs and or the President can disapprove.*

III. Statutory Basis of Institutional Review Board Authority

The IRB is an administrative body established to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of the Albany State University. The IRB has the authority to approve, require modifications in, or disapprove all research activities that fall within its jurisdiction as specified by both the federal regulations and Albany State policy. Research that has been reviewed and approved by an IRB may be subject to review and disapproval by officials of the institution. However, those officials may not approve research if it has been disapproved by the IRB.

The IRB also functions independently of but in coordination with other committees. For example, an institution may have a research committee that reviews protocols to determine whether the institution should support the proposed research. The IRB, however, makes its independent determination whether to approve or disapprove the protocol based upon whether or not human subjects are adequately protected.

The Albany State University program of protections for human research participants is subject to regulation and inspection, as provided in the regulations cited below.

A. Department of Health and Human Services (DHHS)

DHHS regulations pertaining to rights and welfare of subjects participating in research supported with federal funding are specified in *Title 45 Code of Federal Regulations Part 46*, "Federal Policy for the Protection of Human Subjects" and including *Subparts A, B, C, and D*.

B. Food and Drug Administration (FDA)

FDA regulations pertaining to rights and welfare of subjects participating in research involving drugs, medical devices, and biological products and other products regulated by the FDA are specified in *Title 21 Code of Federal Regulations, Parts 50* Protection of Human Subjects*, 56* Institutional Review Boards*, 312* Investigational New Drug Application*,* and *812* Investigational Device Exemptions

C. State of Georgia

1. Prisoner Studies

Medical experiments involving prisoners require prior written approval of the Commissioner of Corrections. Ga. Comp. R. & Regs. 125-4-4-.12. Albany State University would need to seek additional certification approval from the Office for Human Research Protections (OHRP) for research in a prison population.

2. Gene Research

Genetic information is the unique property of the participant. Its use may be abused if disclosed to unauthorized third parties without consent. Official Code of Georgia Annotated 33-54-1. Definition of "genetic testing." Ga.Code 33-54-2. Informed consent is required prior to genetic testing for insurance reasons. Ga.Code 33-54-3. Genetic information may be released only to the individual tested or authorized persons or to a third party with explicit written consent. Ga.Code 33-54-3. Insurers may not use genetic information for non-therapeutic purposes. Ga.Code 33-54-4 (but see Ga.Code 33-547). Research facilities may conduct genetic testing and use the information for scientific research purposes if the individual's identity is not disclosed. Ga.Code 33-54-6.

3. Consent Age

The State of Georgia defines minors as those persons under the age of 18 years. Emancipated minors may participate in some studies otherwise unsuitable for children, provided adequate justification. Sponsored research may have age requirements that differ from the State of

Georgia. For example NIH defines a child as an individual under the age of 21. The IRB will consult and confer as necessary.

4. Controlled Substances

Persons who handle controlled substances or dangerous drugs for the purpose of conducting research, and who are not registered as a pharmacy, drug wholesaler, distributor, supplier or medical practitioner, must register biennially with the Board of Pharmacy and obtain a drug researcher permit. Official Code of Georgia Annotated 26-4-49. The registered person must maintain accurate records of purchase, receipt, use, and disposal of the drugs for at least two years. Ga.Code 26-4-49 where applicable a copy of the researcher's controlled substances permit is on file in the Office of Research and Sponsored Programs.

5. Medical and Other Records Privacy

Any hospital, health care facility or other organization rendering patient care may provide information, reports, statements, memoranda or other data relating to the condition and treatment of Physicians, hospitals and health care facilities are not required to release raw medical data used in research except where authorized by law or by the patient or guardian. Ga.Code 24-9-40. The legislature declares that protecting the confidentiality of research data is essential to safeguarding the integrity of research they define "confidential raw research data" as that provided in support of a study approved by an oversight committee of a hospital, health care facility or educational institution, where the subjects' identities will not be material to the results, and will not be disclosed except to the subject or with the subject's written authorization or to a research sponsor. Ga.Code 24-9-40.2. Records must be furnished within a reasonable period of time to the patient, a provider designated by the patient or any other person designated by the patient. Ga.Code 3133-2. Fees for search, retrieval and other direct administrative costs related to the provision of patient records established; may be adjusted annually by the state Office of Planning and Budget in accordance with the medical component of the consumer price index. All records remain the property of the provider. Ga.Code 31-33-3. Vital records may be disclosed for research purposes. Ga.Code 31-1025; Ga. Comp. R. & Regs 290-1-3-.33.

6. STD Reporting

HIV/AIDS information is confidential and shall not be disclosed except with the patient's consent. Physicians may inform the spouse, sexual partner or child if they are at risk of being infected and the physician attempted to notify the patient of the disclosure. Official Code of Georgia Annotated 24-9-40.1, Ga.Code 24-9-47. Health care providers, health care facilities or other persons who order an HIV test shall report each positive result to the Dept. of Health, along with information on patient's age, sex, race, address. Ga.Code 31-22-9.2. HIV tests may be ordered only after counseling the person, which may include information on AIDS,

transmission, confidentiality, medical treatment. Ga.Code 31-22-9.2, Definitions Ga.Code 31-22

9.1. Minors may consent to treatment of STDs. Information may be given to or withheld from parents in the physician's judgment. Ga.Code 31-17-7. Any physician, hospital manager or other person who diagnoses or treats a case of venereal disease shall report it to the Dept. of Health. Ga.Code 31-17-2; Ga Comp. R & Regs. 290-5-17.02.

Labs shall comply with reporting requirements for STDs unless operated exclusively for research purposes. Ga.Code 31-17-6, Ga.Code 31-22-9.

D. Health Insurance Portability and Accountability Act (HIPAA)

The Department of Health and Human Services' *National Standards to Protect the Privacy of Personal Health Information* is promulgated in the Health Insurance Portability and Accountability Act (HIPAA), commonly referred to as the "Privacy Act." This Act specifies requirements for protection of individually identifiable health information, or "protected health information" (PHI). See Section XX of these policies, *"Health Insurance Portability and Accountability Act (HIPAA) for Protected Health Information,"* for a complete discussion of HIPAA and the procedures to comply at Albany State University.

Training on Health Information Privacy and Security can be obtained at the Collaborative Institutional Training Initiative (CITI) website https://www.citiprogram.org/

Information on the Family Educational Rights and Privacy Act (FERPA) can be found at http://www2.ed.gov/policy/gen/guid/fpco/ferpa/index.html

IV. Federal wide Assurance and Administration of Albany State Program of Human Research

The Albany State University IRB is registered with the Office for Human Research Protections (OHRP) and holds Federalwide Assurance. The Board is supported by the Office of Research and Sponsored Programs. Administrative decisions related to the Albany State University IRB rest with the AVP Office of Research and Sponsored Programs.

A. Federalwide Assurance

Albany State University holds a **Federalwide Assurance (FWA) of Compliance (FWA00008372)** with the Office for Human Research Protections (OHRP). A fully executed copy of Albany State's Assurance is maintained by the Office of Research and Sponsored Programs. The Albany State University Institutional Review Board is also registered with the Office for Human Research

Protections under number **(IRB00004776).**

The Federalwide Assurance and Institutional Review Board *Policies and Procedures* apply to all Albany State University faculty, staff, and students, regardless of whether the research activity is funded. Also included is any research for which an assurance or another formal agreement (e.g., Inter-Institutional Agreement) identifies the Albany State Institutional Review Board as the IRB of record.

The Albany State University Institutional Review Board's approval is required in advance for all projects with human subjects, regardless of whether the project is funded, and regardless of whether it is a subgrant or subcontract to or from another institution.

B. Institutional Review Board at Albany State University

The IRB was established pursuant to *Title 45 Code of Federal Regulations Part 46 i*ncluding *Subparts A, B, C, and D*, and *Title 21 Code of Federal Regulations Part 56*. The IRB is sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review specific research activities, the IRB is able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB therefore includes persons knowledgeable in these areas. IRBs' that regularly review research involving a vulnerable category of subjects, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, shall include one or more individuals knowledgeable about and experienced in working with these subjects.

C. Institutional Official

Federal regulations require that there be a point of responsibility within the institution for the oversight of research and IRB functions. This point should be an official of the institution who has the legal authority to act and speak for the institution, and should be someone who can ensure that the institution will effectively fulfill its research oversight function. The institution's president shall appoint or delegate the appointment of the individual. The President of Albany State University has delegated this authority through the Associate Vice President of the Office of Research and Sponsored Programs.

The Associate Vice President of the Office of Research and Sponsored Programs also serves as the Institutional Official (IO) and has the authority to legally commit Albany State University to meet federal regulatory requirements. The Institutional Official is responsible for appointing the Institutional Review Board membership. As Institutional Official, Associate Vice President for

Research and the Office of Research and Sponsored Programs signs the Federalwide Assurance. The Institutional Review Board reports to the Institutional official.

D. Office of Research and Sponsored Programs

The Office of Research and Sponsored Programs provides administrative support to the Institutional Review Board. The chair of the IRB makes recommendations to the Associate Vice President of the Office of Research and Sponsored Programs for consideration by institution senior leaders.

The University's Federalwide Assurance and Registration are maintained by the Office of Research and Sponsored Programs.

In close coordination with the IRB, the Office of Research and Sponsored Programs facilitates ethical conduct of research through advance and continuing protocol review; monitoring and reporting; convening regular meetings for review of proposed and continuing research; and providing educational programs for faculty, staff, and students. The Office of Research and Sponsored Programs oversees the development and implementation of policies, procedures, and educational programs which satisfy the many regulations governing the conduct of such research.

1. Official Institute Records Maintained by the Office of Research and Sponsored Programs

Federal regulations set forth specific record keeping requirements for the institution and the IRB. Adequate documentation of IRB activities must be prepared and maintained. In addition to written IRB procedures and membership lists required by the Assurance process, such documentation must include copies of all research

- proposals reviewed
- minutes of IRB meetings
- records of continuing review activities
- copies of all correspondence between the IRB and investigators; including investigators project summary and completion
- statements of significant new findings provided to subjects.
- minutes of IRB meetings must be kept in sufficient detail to record the following information:
    - Attendance at each meeting; actions taken by the IRB
    - The vote on actions taken (including the number of members voting for, against, and abstaining)
    - The basis for requiring changes in or disapproving research
    - A written summary of the discussion of controversial issues and their resolution

IRB records must be retained for at least three years; records pertaining to research that is conducted must be retained for 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.

The University's repository of official Institutional Review Board records is maintained by the Office of Research and Sponsored Programs and includes the following:

- The Federalwide Assurance
- The Federalwide Assurance Current rosters of Albany State University IRB membership and credentials
- IRB Policies and Procedures
- Minutes of meetings, including information regarding member attendance, discussions held, decisions made, and voting results
- All materials submitted to the committee for initial and continued review of each study including: the Albany State IRB applications, protocol, submitted and final consent forms, adverse event reports, proposed amendments, progress reports, and all correspondence generated between the committee, the investigators, and sponsoring agencies
- Records are maintained in accordance with federal directives and Board of Regents policy, but a minimum of three years following the inactivation of any protocol. Records in the IRBNet's database, it should be noted, are maintained indefinitely.

2. Communications

The Office of Research and Sponsored Programs uses www.IRBNet.org as the communication hub for the program of human protection at Albany State. This software keeps the Albany State University members, researchers, and others informed as appropriate.

V. Institutional Review Board Membership and Meetings

Federal policy provides that IRBs must have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB must be sufficiently qualified through the experience and expertise of its members and the diversity of their backgrounds, including considerations of their racial and cultural heritage and their sensitivity to issues such as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects.

The membership of the Albany State IRB is constituted in accordance with federal regulations, and board meetings are conducted in compliance with those directives.

A. IRB Membership Appointments

The IRB must have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The authority to appoint board members has been delegated by the President of the Albany State University through the Associate Vice President of the Office of Research and Sponsored Programs. Members of the Albany State University IRB are appointed with consideration given to recommendations from Deans, Department Chairs, current IRB members, the Vice President of Academic Affairs and/or members of the community. Members are generally appointed for a renewable, three year term and typically serve for several terms. All members, with the exception of the Associate Vice President of ORSP (ex-officio), have full voting rights. The IRB Chair is nominated by the committee.

The active engagement of members through meeting attendance and review is expected. When such engagement cannot be honored, the member may be reviewed and removed from the committee.

1. Nondisclosure of Research Materials and Protocols

All members of the Institutional Review Board are ethically bound to respect confidentiality of research materials submitted for their review. All members sign nondisclosure agreements on an annual basis.

2. Liability Coverage for IRB Members

Since the Albany State University IRB is a constituted committee of the Albany State University, liability coverage (excluding personal liability coverage) is provided by the University for members serving on the committee and performing their duties in accordance with University policy.

B. Education of Institutional Review Board Members

The Office of Research and Sponsored Programs conducts an orientation for new members in which relevant materials are provided (Belmont Report, federal regulations, Albany State University IRB *Policies and Procedures*), and the details concerning committee function and procedures are discussed. Board members are also provided training on use of the electronic proposal submission and tracking tool. Board members are provided the opportunity to attend professional conferences in order to stay informed about changes in federal guidance related to human subject protections.

C. Meetings and Quorum

1. IRB Meeting Schedule

The ASU IRB generally meets monthly depending on the holiday schedule and whether there are matters to consider. Additional meetings will be called if necessary for the Board to fulfill its responsibilities.

2. Quorum

A meeting quorum is a (fifty percent plus one), including at least one member whose primary concerns are in nonscientific areas. When the quorum fails because attendance falls below a majority due to recusal of members with conflicting interests or early departures, or absence of a nonscientist member, no further actions or votes may be taken.

3. Conflict of Interest Related to Proposed Research

No Albany State University IRB member may participate in the review of any study on which he is an investigator or where a potential for conflict of interest exists. Members who have such a conflict of interest must leave the room during deliberation and vote.

4. Use of Telecommunications for IRB Meetings

Through use of telecommunications (e.g., telephone- or videoconferencing), Albany State University IRB may conduct official business without all members physically present. In this case, the following criteria must be met:

- The forum allows for real time verbal interaction equivalent to that occurring in a physically-convened meeting (i.e., members can actively and equally participate, and there is simultaneous communication).
- All members are given advance notice of the meeting
- Documents normally provided to members during a physically-convened meeting are provided to all members in advance of the meeting
- All absent members must have access to the documents and the technology necessary to fully participate
- A quorum of voting members is convened; and if a vote is called for, the vote occurs during the meeting and is taken in a manner that ensures an accurate count of the vote. Written minutes of the meeting are maintained in accordance with the PHS Policy

A mail ballot or individual telephone polling cannot substitute for participation in a convened meeting. Opinions of absent members that are transmitted by mail, telephone, fax or e-mail may be considered by the convened IRB members but shall not be counted as votes.

D. Consultation with Experts

The Albany State University IRB may, at its discretion, invite consultants with competence in

special areas to assist in the review of complex issues requiring expertise beyond, or in addition to, that available on the committee. The consultant does not vote. Similarly, investigators may attend the Albany State University IRB meetings to clarify issues concerning their proposed research activity.

VI. Requirements for the Title of Principal Investigator

A. Eligibility for Title of Principal Investigator

The term "Principal Investigator" refers to the single individual who shall have full and final responsibility for the conduct of a research study involving human subjects. The designation of Principal Investigator is purely for assignment of responsibility in the context of IRB approval and not for any other purposes such as authorship or intellectual property.

B. Eligibility Exceptions for Graduate and Undergraduate Students as Principal Investigators

Generally, the Principal Investigator must be a full time faculty member who meets the definition of Principal Investigator, defined in D. below. A student may be named as Co-Investigator, as this title designates key personnel but does not have the oversights responsibilities of Principal Investigator.

C. Other Exceptions Requiring Approval by the Associate Vice President for Research and Office of Research and Sponsored Programs

Exceptions to the general eligibility requirements for designation as Principal Investigator will be considered upon submission of a written request to the Associate Vice President for Research and Sponsored Programs. The request should justify why the individual should qualify for the role of Principal Investigator and must be signed by the appropriate departmental representative (Chair/Director/Department Head). Upon approval, a copy of the exception, signed by the Associate Vice President for Research and Office of Research and Sponsored Programs, should be submitted to the Office of Research and Sponsored Programs along with the IRB application via www.IRBNet.org .

D. Definitions

1. Principal Investigator

This title identifies the individual responsible for the conduct of the study. This responsibility includes all administrative aspects and the study's adherence to relevant policies and regulations (institutional, state and federal).

2. Co-Principal Investigator

This designation refers to individuals who share the responsibility for the study with the Principal Investigator and therefore requires the same qualifications as for PI.

3. Co-Investigator

This title designates key personnel for a project, but without the oversight responsibility of a Principal Investigator. A faculty member who is advising a student on a research project should be listed as the PI for IRB purposes.

In addition, faculty members may be listed as Co-Investigators if their role on the study is not that of PI or Co-PI.

E. Authorship

The title of Principal Investigator is a designation of institutional responsibility for the conduct of an IRB reviewed study. Therefore, the title does not necessarily represent principal authorship on subsequent papers. Authorship is a separate consideration that should be agreed upon by all members of the research team. It is important that authorship be appropriately attributed.

VII. Categories of Review: Exempt, Expedited, Full

Research involving human research participants will fall into one of three review categories: exempt, expedited, and full board review. Research with human subjects must be submitted to the IRB for approval. Each category is defined and discussed below. The IRB will make a final determination as to the correct review category of all protocols submitted.

A. Exempt Review Categories

Many social, behavioral and educational studies involve little or no risk to participants. Research of existing data, medical records, and pathological specimens also usually present little risk to subjects, particularly if identifiers are removed from the data. While subjects' rights and welfare must still be protected, the federal regulations permit less detailed scrutiny by the Institutional Review Board in most studies of these kinds. Research in this category is considered *exempt from further committee review*. However, federal regulations require a determination of exemption be made *not by the Principal Investigator* but by someone authorized by the Institution. Therefore, the Albany State University IRB requires that such activities be on file with the Office of Research and Sponsored Programs and that they be reviewed and approved as *exempt* by the Associate Vice President of the Office of Research and Sponsored Programs and/or the IRB Committee.

Survey and questionnaire research involving children is specifically prohibited from exemption, as is observation of a minor's public behavior, unless the researcher has absolutely no interaction

with the child. Research that involves prisoners, pregnant women, fetuses, and in vitro fertilization is also not eligible for exemption from further committee review. See §45CFR46, Subpart B: Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research; *Subpart C:* Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects, and *Subpart D:* Additional Protections for Children Involved as Subjects in Research.

Research activities in which the only involvement of human subjects will be in **one or more of the following categories** meet the requirement for approval as *Exempt from Further IRB Review*:

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as
   (i) research on regular and special education instructional strategies, or
   (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

2. Research involving the use of educational tests (cognitive diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
   (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and
   (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior is **not exempt**, if:
   (i) the human subjects are elected or appointed public officials or candidates for office; or
   (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

5. Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:

(i) Public benefit or service programs;
(ii) Procedures for obtaining benefits or services under those programs;
(iii) Possible changes in or alternative to those-program procedures; or
(iv) Possible changes in methods or levels of payments for benefits or services under those programs.

Once a determination of exemption has been made, the investigator will be notified in writing. The full Institutional Review Board is to be informed of all protocols reviewed and approved under the exempt review process. The responsibility for this communication lies with the Office of Research and Sponsored Programs.

B. Expedited Review Categories

The Department of Health and Human Services and the Food and Drug Administration regulations governing protection of human subjects recognize that full Institutional Review Board review is not necessary for every protocol. Hence, certain types of research may be reviewed and approved under an *expedited* procedure. Expedited approvals may be granted by the Institutional Review Board Chair or any other IRB members designated by the Chair. Reviewers may exercise all authority of the IRB, except that no individual member, including the Chair, may disapprove a research protocol. Any proposed disapproval is to be referred to the full board for review and disposition.

In order to qualify for expedited review, research activities must present no more than minimal risk to human subjects and involve only procedures listed in one or more of the nine categories listed below. The categories in this list apply regardless of the age of subjects, except as noted. The expedited review procedure is not permitted when identification of the subjects and/or their responses would reasonably place subjects 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.

A. Collection of data about moderate exercise, muscular strength testing, body composition assessment, and flexibility testing.
B. Collection of data from voice, video, digital, or image recordings made for research purposes.
C. 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: See section I.A. for similar research that may fall into the exempt category. This listing refers only to research that is not exempt.)*
D. Continuing review of research previously approved by the full committee 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.

Once an expedited review has been completed, the investigator will be notified regarding the status of the application. This written notification will indicate whether the application was fully approved, required modifications/clarifications in order to secure approval, or deferred for full committee review. The full Institutional Review Board is to be informed of all protocols reviewed and approved under the expedited review process. The responsibility for this communication lies with the Office of Research and Sponsored Programs.

C. Full Board Review

Protocols presenting greater than minimal risk, or that otherwise do not qualify for review under exempt or expedited procedures, must be reviewed by the full Institutional Review Board at a convened meeting.

Protocols to be reviewed by the full board are distributed to members via IRBNet no later than seven (7) calendar days prior of the meeting. After the meeting, the investigator is notified regarding the IRB's determination. The Board may determine to approve the protocol, require clarifications or modifications in order to secure approval, defer the protocol (that is, the investigator's response must be considered at another meeting of the full board), or disapprove the protocol outright. The IRB determination is communicated in writing to the Principal Investigator via IRBNet.

VIII. Deciding Whether Institutional Review Board Approval Must Be Obtained

Prior IRB approval must be obtained in advance for *any research activity* that meets the Department of Health & Human Services (DHHS) definition of research that involves humans as subjects. Some exceptions to this policy are listed at the end of this section. This requirement includes any proposed research activity conducted by Albany State University faculty, staff, or students and that involves contact with live persons OR identifiable biological specimens.

A. Research Activities That Require IRB Approval

If the answer is *yes* to the two following questions, the activity must be submitted to the IRB for review prior to initiation of the activity:

- Is the activity a systematic investigation, including protocol development, testing, and evaluation, designed to contribute to generalized knowledge?
- Does the activity involve living individuals about whom the investigator obtains data through intervention or interaction with the individual, or obtains identifiable private information?

A determination as to whether the activity constitutes human subjects research will be made by the IRB committee.

1. Review Required Under Department of Health and Human Services (DHHS) Regulations

The Department of Health and Human Services (DHHS) is responsible for implementing the regulations at §45CFR46 governing biomedical and behavioral/social science research involving human subjects. DHHS regulations **define *human subject*** as a living individual about whom an investigator conducting research obtains data through intervention or interaction with an individual, or identifiable private information. *Intervention* includes both physical procedures by which data are gathered and manipulations of the subjects' environment that are performed for research purposes. Intervention includes surveys, questionnaires, focus groups, human factors, behavioral observations, and more. *Interaction* includes communication or interpersonal contact with a subject or their private identifiable information. *Private Information* is that information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public. Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the Investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects. This definition may include identifiable private information obtained from a primary subject about a third party ("secondary subject"). DHHS **defines research** as any systematic investigation (including research development, testing and evaluation) designed to develop or contribute to generalizable knowledge. Activities must be *systematic* to be considered research and include those involving predetermined methods for answering a specific question, testing hypotheses or theories, and may include interviews, program evaluations, and observational studies. Activities must contribute to *generalizable knowledge* or be intended to extend beyond a department or internal use. Generally, a thesis is considered research for IRB purposes.

Another research activity that involves human subjects is ethnographic research, wherein the investigator will participate, overtly or covertly, in people's daily lives for an extended period of time. The investigators watch what happens, listens to conversations, asks questions and collects additional data to create a broader understanding of a particular environment, ethnic

group, gender, and so on.

Internet Research frequently employs online questionnaires and surveys, "chat rooms", and other web-based interactions. Any expectation of privacy should be addressed in designing studies of this type.

The regulations extend to the use of human organs, tissue, and body fluids from individually identifiable human subjects. The use of autopsy materials is not regulated by §45CFR46 and is not subject to IRB review.

2. Pilots and Feasibility Studies

Pilot studies (feasibility studies), even those involving only one or two individuals, are subject to the same scrutiny as a full scale research project. Protocols should clearly indicate that the project is a pilot or feasibility study, and the informed consent process must disclose that information to subjects. IRB review is required prior to initiating the activity.

3. Other Activities that Require IRB review

In addition to the foregoing, other types of research activities require prior Institutional Review Board approval, either under DHHS and/or FDA regulations.

- Innovative Procedures, Treatment, or Instructional Methods: A systematic investigation in instructional methods with multiple participants in order to compare to standard procedure. The investigation is designed to test a hypothesis, permit conclusions to be drawn, and thereby develop or contribute to generalizable knowledge.
- Repositories of data: Preliminary activities typically designed to help the Investigator refine data collection procedures.
- Retrospective Data: Retrospective review of patients' medical records with the intent to report or publish the summary.
- Research Conducted by Students: Student-conducted research activities are subject to these guidelines; thus, any student-conducted research activity that meets the definition of research with human subjects must be reviewed and approved prior to initiation. This includes class projects, master's theses and any other project involving human subjects and from which findings may be published or otherwise disseminated. When students are engaged in research, the faculty member who is serving as the research mentor should serve as the official PI.

B. Certain Activities Not Requiring IRB Review

Some research activities do not require prior approval from the Institutional Review Board. The

following list is representative but not exhaustive.

1. Applications and Proposals Lacking Complete Research Plans

Per §45CFR46.118, applications and proposals lacking complete plans for involvement of human subjects will not require IRB review at the time that the funding proposal is submitted to the potential sponsor. Certain types of applications for grants, cooperative agreements, or contracts are submitted to departments or agencies with the knowledge that subjects may be involved within the period of support, but definite plans would not normally be set forth in the application or proposal. These include activities such as institutional type grants when selection of specific projects is the institution's responsibility; research training grants in which the activities involving subjects remain to be selected; and projects in which human subjects' involvement will depend upon completion of instruments, prior animal studies, or purification of compounds. These applications with incomplete plans need not be reviewed by an IRB before an award may be made. However, except for research exempted or waived under §45CFR46.101 (b) or (i), no human subjects may be involved in any project supported by these awards until the project has been reviewed and approved by the IRB, as provided in this policy, and certification submitted, by the institution, to the Department or Agency.

2. Quality Assurance and Control, Program Evaluation and Improvement, and Fiscal Auditing

Activities that constitute quality assurance or control, program evaluation or improvement, and fiscal auditing generally do not meet the definition of research. These include activities that are typically not generalizable, such as course evaluations that cannot be generalized to others, and quality assurance activities intended to improve the performance of a unit, division, or department.

C. Requirement for IRB Review Dependent

When Albany State University is engaged in human subjects research activities, the Albany State University IRB must review the proposed work.

1. Institutions Engaged in Human Subjects Research

The Office for Human Research Protections (OHRP) considers an institution *engaged* in a non-exempt human subjects research project when its employees or agents for the purposes of the research project obtain:

- data about the subjects of the research through intervention or interaction with them;
- identifiable private information about the subjects of the research; or
- The informed consent of human subjects for the research
- Data by intervening for research purposes with any human subject of the research by manipulating the environment. Examples of manipulating the environment include controlling environmental light, sound, or temperature; presenting

sensory stimuli; and orchestrating environmental events or social interactions.

- Data by interacting for research purposes with any human subject of the research. Examples of interacting include engaging in protocol dictated communication or interpersonal contact; and conducting research interviews or administering questionnaires.
- Data for research purposes identifiable private information or identifiable biological specimens from any source for the research. It is important to note that, in general, institutions whose employees or agents obtain identifiable private information or identifiable specimens for non-exempt human subjects research are considered engaged in the research, even if the institution's employees or agents do not directly interact or intervene with human subjects. In general, obtaining identifiable specimens includes, but not limited to:
    - observing or recording private behavior;
    - using, studying, or analyzing for research purposes identifiable private information or identifiable specimens provided by another institution; and
    - using, studying, or analyzing for research purposes identifiable private information or identifiable specimens already in the possession of the investigators.

In general, OHRP considers private information or specimens to be individually identifiable as defined in **§**45CFR46.102(f) when they can be linked to specific individuals by the investigator(s) either directly or indirectly through a coding system.

2. Institutions Not Engaged in Human Subjects Research

It is possible for an entity not to be engaged in research, even if the research takes place on its premises. If the ASU IRB makes a determination that the institution is not engaged, the IRB will not usually review the proposed work.

The following examples of activities that would not render ASU engaged are for illustration purposes; contact the Office of Research and Sponsored Programs for a determination of engagement.

- Institutions whose employees or agents perform commercial or other services for investigators provided that all of the following conditions also are met:
    - the services performed do not merit professional recognition or publication privileges;
    - the services performed are typically performed by those institutions for non-research purposes; and
    - the institution's employees or agents do not administer any study intervention

being tested or evaluated under the protocol.

- Institutions not selected as a research site whose employees or agents provide clinical trial-related medical services that are dictated by the protocol and would typically be performed as part of routine clinical monitoring and/or follow-up of subjects enrolled at a study site by clinical trial investigators (e.g., medical history, physical examination, assessment of adverse events, blood test, chest X-ray, or CT scan) provided that all of the following conditions also are met:
    - the institution's employees or agents do not administer the study interventions being tested or evaluated under the protocol;
    - the clinical trial-related medical services are typically provided by the institution for clinical purposes;
    - the institution's employees or agents do not enroll subjects or obtain the informed consent of any subject for participation in the research; and
    - when appropriate, investigators from an institution engaged in the research retain responsibility for:
        - overseeing protocol-related activities; and
        - ensuring appropriate arrangements are made for reporting protocol-related data to investigators at an engaged institution, including the reporting of safety monitoring data and adverse events as required under the IRB-approved protocol.

Note that institutions (including private practices) not initially selected as research sites whose employees or agents administer the interventions being tested or evaluated in the study—such as administering either of two chemotherapy regimens as part of an oncology clinical trial evaluating the safety and effectiveness of the two regimens—generally would be engaged in human subjects research.

- Institutions (including private practices) not initially selected as a research site whose employees or agents administer the study interventions being tested or evaluated under the protocol limited to a one-time or short-term basis (e.g., an oncologist at the institution administers chemotherapy to a research subject as part of a clinical trial because the subject unexpectedly goes out of town, or is unexpectedly hospitalized), provided that all of the following conditions also are met:
    - an investigator from an institution engaged in the research determines that it would be in the subject's best interest to receive the study interventions being tested or evaluated under the protocol;
    - the institution's employees or agents do not enroll subjects or obtain the informed consent of any subject for participation in the research;
    - investigators from the institution engaged in the research retain responsibility for:

- overseeing protocol-related activities;
- ensuring the study interventions are administered in accordance with the IRB-approved protocol; and
- ensuring appropriate arrangements are made for reporting protocol-related data to investigators at the engaged institution, including the reporting of safety monitoring data and adverse events as required under the IRB-approved protocol; and
- an IRB designated on the engaged institution's FWA is informed that study interventions being tested or evaluated under the protocol have been administered at an institution not selected as a research site.

- Institutions whose employees or agents:
  - inform prospective subjects about the availability of the research;
  - provide prospective subjects with information about the research (which may include a copy of the relevant informed consent document and other IRB approved materials) but do not obtain subjects' consent for the research or act as representatives of the investigators;
  - provide prospective subjects with information about contacting investigators for information or enrollment; and/or
  - seek or obtain the prospective subjects' permission for investigators to contact them.

An example of this would be a clinician who provides patients with literature about a research study at another institution, including a copy of the informed consent document, and obtains permission from the patient to provide the patient's name and telephone number to investigators.

- Institutions (e.g., schools, nursing homes, businesses) that permit use of their facilities for intervention or interaction with subjects by investigators from another institution.

Examples would be a school that permits investigators from another institution to conduct or distribute a research survey in the classroom.

- Institutions whose employees or agents release to investigators at institution identifiable private information.

  Note that in some cases the institution releasing identifiable private information may have institutional requirements that would need to be satisfied before the information or specimens may be released, and/or may need to comply with other applicable regulations or laws. In addition, if the identifiable private information or identifiable biological specimens to be released were collected for another research study covered by

§45CFR46, then the institution releasing such information or specimens should:

- Ensure that the release would not violate the informed consent provided by the subjects to whom the information or biological specimens pertain (under §45CFR46.116), or
- If informed consent was waived by the IRB, ensure that the release would be consistent with the IRB's determinations that permitted a waiver of informed consent under §45CFR46.116 (c) or (d).

Examples of institutions that might release identifiable private information or identifiable biological specimens to investigators at another institution include:

a. *Schools that release identifiable student test scores;*
b. *AN HHS agency that releases identifiable records about its beneficiaries; and*
c. *Medical centers that release identifiable human biological specimens.*

Note that, in general, the institutions whose employees or agents obtain the identifiable private information or identifiable biological specimens from the releasing institution would be engaged in human subjects research.

- Institutions whose employees or agents:
  - are unable to readily ascertain the identity of the subjects to whom the coded information or specimens pertain.
  - obtain coded private information or human biological specimens from another institution involved in the research that retains a link to individually identifying information (such as name or social security number); and *the institution's employees or agents and the holder of the key enter into an agreement prohibiting the release of the key to the those employees or agents under any circumstances; the releasing institution has IRB-approved written policies and operating procedures applicable to the research project that prohibit the release of the key to the institution's employees or agents under any circumstances; or there are other legal requirements prohibiting the release of the key to the institution's employees or agents.*

    For purposes of this discussion, coded *means that identifying information (such as name or social security number) that would enable the investigator to readily ascertain the identity of the individual to whom the private information or specimens pertain has been replaced with a number, letter, symbol, and/or combination thereof (i.e., the code); and a key to decipher the code exists, enabling linkage of the identifying information to the private information or specimens.*

- Institutions whose employees or agents access or utilize individually identifiable private information only while visiting an institution that is engaged in the research, provided their research activities are overseen by the IRB of the institution that is engaged in the

research

- Institution whose employees or agents access or review identifiable private information for purposes of study satisfying U.S Food and Drug Administration reporting requirements.

- Institutions whose employees or agents author a paper journal article or presentation describing a human subject research study.

Is it important that the Institutional Review Board concurs with the engagement determination; contact the Office of Research and Sponsored Programs for guidance.

IX. Procedures for Obtaining Institutional Review Board

Research activities that involve the participation of human subjects must be filed with the Office of Research and Sponsored Programs for IRB review prior to initiation of the activity. The following steps are required to seek IRB review and approval.

A. Training in Human Subjects Protection

Successful completion of specified training in the protections of human subjects is required for all Albany State University researchers, faculty, staff, students and/or administrators involved in any category of human subjects research (exempt, expedited, full review), regardless of funding source or status. The Albany State University IRB has approved the Collaborative Institutional Training Initiative (CITI) modules for this purpose. Modules can be found at www.citiprogram.org. This requirement is mandated by Albany State University's Federalwide Assurance and includes those individuals working directly with human subjects or with data or biological specimens derived there from. Off-campus researchers must also complete the training. (Those completing CITI modules through another entity may affiliate themselves with Albany State University, thus allowing their CITI training records to be viewed by the Office of Research and Sponsored Programs.

IBR approval for pending protocols will be withheld until training has been verified by the Office of Research and Sponsored Programs for all members of the research team named in the protocol. (When new researchers are added to a currently approved protocol, an amendment must be submitted and approved by the IRB, and training must be verified by the Office of Research and Sponsored Program).

The only options for satisfying this training requirement are described below. Due to the great variety of other training programs the IRB cannot evaluate training obtained through other methods.

Training Requirement for Off-Campus Researchers

Off-campus researchers who completed CITI modules through another entity may forward their certificates to the Albany State University Office of Research and Sponsored Programs. Completion of the National Institutes of Health IRB modules will also satisfy the training requirement for off-campus researchers. Other human subjects training modules will be reviewed upon request. The Associate Vice President of ORSP can approve other comparable training.

IRB approval for pending protocols will be withheld until training has been verified by the Office of Research and Sponsored Programs for all members of the research team named in the protocol.

1. CITI Online Modules

Instructions for accessing the online modules are posted on the Office of Research and Sponsored Programs website at http://www.asurams.edu. First time users should complete the INITIAL courses; thereafter, users will complete the REFRESHER courses every three years. After completing the required modules, users should check the grade book to ensure that all modules have been completed and recorded. The Office of Research Sponsored Programs is automatically informed by email when a person associated with Albany State University completes certification requirements. Certification is manually recorded in IRBNet upon the researcher uploading their certification(s) into the system.

2. Expiration of Training after Three Years

Effective July 1, 2012, the Institutional Review Board will require completion of training every three years. CITI will email expiration notices a few weeks ahead of certification expiration, and users should then take the CITI IRB Refresher modules.

B. Protocol Application

1. Study Description and Methodology

Protocols must include a study description that states the purpose of the study, including specific objectives and scientific significance. The research methodology must be provided and should define the study population, any instrumentation to be used, and data analysis plans to address the research question. A lay summary is also required and should be written so that a person unfamiliar with the research can grasp the concepts.

Study types may include:

- observational
- record reviews

- historical studies
- surveys
- questionnaires
- interviews
- ethnographic studies
- case-control studies

2. Participant Inclusion, Exclusion Criteria and Justification

Defining the appropriate group of subjects for a research project involves a variety of factors such as the requirements of scientific design, susceptibility to risk, likelihood of benefit, practicability, and considerations of fairness. Note that IRBs are required to make a specific determination that the selection of subjects is equitable.

Inclusion and exclusion criteria for participation must be specified. The investigator must disclose if he intends to include himself or members of his family as participants. The inclusion of women and members of minority groups and their subpopulations must be addressed in developing a research design appropriate to the scientific objectives of the study. The research plan should describe the composition of the proposed study population in terms of gender and racial/ethnic group, and provide a rationale for selection for such subjects. The exclusion of women must be scientifically justified. The exclusion of children must be scientifically justified in studies where their inclusion is otherwise appropriate.

3. Recruitment

Participant recruitment procedures should be described, and copies of all advertisements, posters, and verbal scripts must be submitted for review. Who will be recruited and how? By recruitment ads, word of mouth, email? If by word of mouth, provide a brief script. The IRB does not expect the script to be followed verbatim; however, the recruitment language must be reviewed. If using flyers, email, advertisements, screen shots from websites, or other documents, submit copies with this protocol.

If recruitment will be at off-campus locations, written permission from those sites must be provided.

4. Compensation for Research Participation

Plans for compensating participants must be described in the protocol and disclosed in a separate section of the consent form. See “Under What Circumstances Can Class Credit Be Given to Student Participants;” “Research Involving Albany State University Employees as Participants;” and “Compensation and Incentives for Research Participation” in these *Policies and Procedures.*

5. Benefits and Risks

Potential benefits, if any, to participants must be stated. If participants are not expected to benefit from being in the study, which is often the case in social and behavioral research, the

possible eventual benefits of the research to society should be described. *Compensation is not a benefit of participating in the study.*

Likewise, any known or anticipated potential discomforts or risks (probability of harm) to participants must be disclosed in the consent process and documents. Risks may be physical, psychological, social, and economic. In social and behavioral research, disclosure of personal information is the greatest risk to participants.

If a protocol poses minimal risk, some version of the following statement is appropriate for use in the consent documents:

"The probability and magnitude of harm or discomfort anticipated in the proposed research are not greater than those ordinarily encountered in everyday life or during performance of routine physical or psychological examinations or tests." If the reading level needs to be lowered for the subject pool, this statement might be rephrased as follows: *"The chances of your being harmed or uncomfortable are about the same as with your regular everyday activities or with taking physical or psychological exams or tests."*

6. Special Protections for Vulnerable Participants

The federal regulations provide for special protections for vulnerable groups, defined in the regulations as fetuses, minors, those who are unable to consent for themselves, prisoners, economically or educationally disadvantaged persons and, in some cases, pregnant women. In some cases, research involving students may render them vulnerable. If members of vulnerable groups are to be enrolled, the additional protections that will be put into place must be specified to ensure that the rights and welfare of such groups are protected. See guidance at Section XI.C., *"Research Involving Vulnerable Populations: Children, Prisoners, Pregnant Women and Fetuses"* in these *Policies and Procedures*.

7. Consent, Parental Permission, and Assent Forms

See *"Informed Consent General Requirements"* in these *Policies and Procedures* for a more complete discussion of consent.

Note that *consent forms* are used when enrolling participants 18 years or older, *assent forms* are used when enrolling minors, defined in the Georgia Statutes as those persons under age 18; and *parental permission forms* are used to obtain permission from parents of participants 17 years or younger (since minors cannot consent to being in the study).

a. Consent Templates

Consent and assent forms and parental permission forms should generally conform to the appropriate format, and templates are posted in IRBNet.org under the forms and templates section.

b. Consent for Non-English Speaking Participants

Another important aspect of the consent process is to provide the information in a language understandable to the subjects. See also *"Research in Foreign Countries," "Obtaining and Documenting Informed Consent of Subjects Who Do Not Speak English"* and Appendix 7, *"Sample Short Form Written Consent Document for Subjects Who Do not Speak English"* of these *Policies and Procedures* for a complete discussion of methods for obtaining consent from non-English speaking subjects/participants.

- **Written consent:** For those consent forms that must be translated into a foreign language, an affidavit of accurate translation must be provided from an appropriate translator who is unaffiliated with the study. The translated consent form and affidavit must be submitted and approved by the IRB before use of the consent form. Translations provided by a member of the Albany State University community are acceptable.
- **Oral presentation of informed consent information in conjunction with a short form written consent document:** The second method involves use of an IRB-approved English language consent form, an IRB-approved short consent form written in the non-English language, and a witness fluent in both English and the language of the subject. See also "Informed Consent" within these *Policies and Procedures*. The consent form(s) must be submitted to the IRB in English and in the participants' native language.
- While research subjects should be compensated for their time and trouble, it is important to remember that *such compensation does not constitute wages for services performed*. There is no employer/employee relationship between a researcher and a research subject. Nevertheless, US tax law imposes a mandatory withholding of 30% for nonresident alien payments; therefore, all payments made to nonresident aliens must be processed by Accounts Payable, regardless of the amount.

8. Data Storage and Confidentiality

See the Office of Information Technology Services (ITS) guidance on protecting sensitive data in electronic format and best practices for backing up sensitive data.

See the USG Data Handling and Storage Policy at the following site: http://www.usg.edu/infosec/policies_and_standards/USG_Data_Handling_Policy_and_Standard-v1.pdf

This section of the protocol should describe the extent to which confidentiality of records identifying the participant will be maintained. If the study involves use of video- or audio-taping of participants, specifically address who has access to the tapes, how tapes are stored, for what purposes they will be used, and what happens to the tapes once the study ends. Disclose whether

tapes are erased after all the necessary information is collected from them and whether tapes are kept for archival purposes.

Student research data must be secure and retained by the PI.

9. Grant or Sponsor Proposal

When funding is being sought from an external sponsor, whether federal or industry, the funding proposal must be attached. If the protocol is not funded, the related thesis, dissertation or seed grant description, if any, should be attached. This is in addition to, not in lieu of, the project description described herein.

10. Additional Materials to Be Submitted for Review

Interview guides, surveys, standardized tests, and questionnaires must be reviewed along with all other elements of the proposed study.

a. **Documentation of Authorization to Collect Data at Non-Albany State University Site**
   If the Albany State University investigator will collect data or conduct other research activities at sites other than Albany State University, he/she must submit documentation of authorization from each site.

C. Protocol Signoffs

Several electronic signoffs (within IRBNet.org) are required before the IRB will review a protocol.

1. Faculty Member as Principal Investigator

The faculty member serving as Principal Investigator electronically signs off on the protocol, documenting that he ensures accuracy of the submitted materials and certifying his lack of a conflict of interest (or disclosing it), and that, upon IRB approval, he will ensure compliance with the IRB policy, "Investigator's Responsibilities When Conducting Research Activities Subject to DHHS or FDA Regulations," presented in these *Policies and Procedures.*

a. Thesis Research Conducted by Student

Students should not be Principal Investigators on protocols. When a student is conducting research for his/her thesis, the academic advisor should be named Principal Investigator and the student takes the role of co-investigator. The faculty member's electronic signature documents that he has read the student's protocol and assumes responsibility for all aspects of the study including recruitment, informed consent, data collection, storage and confidentiality of data, and participant safety.

b. Electronic Signature of the Department Chair

The electronic signature of the department head or designee indicates that peer review has been conducted, and the Department head endorses the activity as scientifically meritorious.

2. Department Chair as Principal Investigator

When the Principal Investigator is also the Department Chair, the Dean should provide an eclectic signature approving the research in IRBNet. The Chair should submit his protocol directly to the Institutional Review Board via IRBNet.

3. Dean as Principal Investigator

When the Principal Investigator is also the Dean, the Provost and VPAA should provide an eclectic signature approving the research in IRBNet. The Dean should submit his protocol directly to the Institutional Review Board via IRBNet.

X. Informed Consent

The principle of *respect for persons*, as set forth in the *Belmont Report*, states that the consent process must address three elements:

- *Information*
- *Comprehension*
- *Voluntariness*

Sufficient and complete information about the study must be provided in language comprehensible to the participant. The investigator must clearly convey to participants what they are agreeing to do and ensure that they understand (comprehend). Participants' agreement must be given voluntarily (freely) and without undue influence. This communication occurs in the consent process and is generally documented in the written consent form.

A participant may not be enrolled in research unless the investigator has obtained his informed consent or that of the participant's legally authorized representative. See X.C.1., 2., and 3. for a discussion of consent waivers and studies involving deception or concealment.

The process of obtaining and documenting informed consent must comply with the requirements of DHHS regulations at §45CFR46.116 and §45CFR46.117 and the FDA consent requirements provided in §21CFR50.20-27 and §21CFR56.109. The IRB may impose additional requirements that are not specifically listed in the regulations to ensure that adequate information is presented in accordance with institutional policy and local law.

A. Elements of Consent

1. The federal regulations require that certain information must be provided to each subject

- A statement that the study involves research

- An explanation of the purposes of the research and the expected duration of the subject's participation

- A description of the procedures to be followed and identification of any procedures which are experimental

- That participants are being asked to be a volunteer in a *research* study

- a description of all research procedures; the frequency, scheduling and time commitment of each procedure and visit; and the total time commitment. Any audio- or video-taping should be addressed in this section as well. If participants are being randomly assigned to different groups, this should be disclosed with a statement such as "You will be randomly (by chance, like flipping a coin) assigned to one of…." Investigators should ask potential participants short questions after the research has been described and the consent form read, in order to assess that the potential participant has at least a basic understanding of what the research involves. For example:

  "Tell me in your own words what this study is all about."
  "What do you think will happen to you in this study?"
  "What do you expect to gain by being in this study?"
  "What risks might you experience?"
  "What options do you have if you decide you don't want to be in this study?"

Note: Research conducted through the Department of Nursing and/or Student Health Services must submit protocols that will be reviewed and must be approved by the ASU IRB. If a consultation is needed, then experts will be solicited. No research in the Department of Nursing or Student Health Services will be allowed by entities without oversight and approval.

2. A description of any reasonably foreseeable risks or discomforts to the subject;

- Any known or anticipated research-related injury (i.e. physical, psychological, social, financial, or otherwise) must be disclosed during the consent process and described in the consent documents. In research that is more than minimal risk, an explanation must be given regarding whatever voluntary compensation and treatment will be provided in the event of injury, harm, or discomfort. Note that the regulations do not limit injury to physical injury, which is a common misinterpretation.

3. A description of any benefits to the subject or to others which may reasonably be expected from the research;

- Describe the benefits that subjects may reasonably anticipate. If none are anticipated, it is appropriate to say so and to indicate the benefits that may eventually accrue to society.

4. **A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;**
   - In some studies, the greatest risk to participants is that of inadvertent disclosure of personal information that could reasonably place participants at risk. For other good reasons, researchers should also desire to securely store research data.

   - Will participant responses be separated from their identities? Will there be a key or code that links these? If so, how will these be safeguarded?

   - If the study involves use of video- or audio-taping of participants, specifically address who has access to the tapes, how tapes are stored, for what purposes they will be used, and what happens to the tapes once the study ends. State whether tapes are erased after all the necessary information is collected from them and whether tapes are kept for archival purposes.

   - Web-based research has its own special set of privacy concerns. State whether the server to be used is a secure https server of the kind typically used to handle credit card transactions. What information will be stored on the server, for how long, and who has access to it?

   - See the Office of Information Technology Services guidance on protecting sensitive data in electronic format and best practices for backing up sensitive data.

   - Some studies inherently are in need of a Certificate of Confidentiality which protects the investigator from involuntary release (e.g., subpoena) of the names or other identifying characteristics of research subjects. The IRB will determine the level of adequate requirements for confidentiality in light of its mandate to ensure minimization of risk and determination that the residual risks warrant involvement of subjects.

5. **An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject;**

6. **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. The statement regarding voluntary participation and the right to**

withdraw at any time can be taken almost verbatim from the regulations (§45CFR46.116[a][8]).

The regulations further provide that the following additional information be provided to subjects, where appropriate, if applicable:

1. A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;

2. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;

3. Any additional costs to the subject that may result from participation in the research;

4. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

5. A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject;

6. The approximate number of subjects involved in the study;

7. Inclusion and exclusion criteria for studies that, based on a scientific justification, are limited to certain categories of participants;

8. Compensation scheme. This section of the consent form should specify participant compensation and reimbursement, whether monetary, gift card, or class credit. Compensation should be prorated in cases where participants may make several trips or go through a number of sessions. It is generally inappropriate to pay bonuses for completion or to withhold payment until the study is completed. Disclose whether compensation will be prorated to those who withdraw early or do not complete the study. If there is no compensation at all, this should be disclosed. The IRB recommends that full compensation be given when participants must stop due to a physical inability to complete the study. See “Research Involving Albany State University Students as Participants;” “Research Involving Albany State University Employees as Participants;” and “Compensation and Incentives for Research Participation” in these *Policies & Procedures*.

9. Disclosure of Conflict of Interest is required if the Principal Investigator or anyone else on

the research team has a conflict of interest in this study. It is not inherently unethical to have a conflict of interest; it is, however, prudent—and required— that it be disclosed to potential participants and be suitably managed. Such conflicts must be disclosed to the faculty member's department, and a management plan must be on file with ASURC. Contact the Office of Research and Sponsored Programs for guidance.

10. Language and readability must be appropriate for the subjects. Think of the consent document as a teaching tool, not as a legal instrument. It is not a contract between participant and researcher! The consent document should be written in second person; i.e., *"If you agree to be in this study, you will be asked to…."* Use of the first person (e.g., *"I understand that …"*) can be interpreted as suggestive, may be relied upon as a substitute for sufficient factual information, and can constitute coercive influence over a subject. Use of scientific jargon and legalese is not appropriate.

Note that the average person reads at the 8th grade level, and consent forms intended for that population should be written at that reading level. Investigators are encouraged to use computer software applications or other techniques to assess reading level of the finished document; use a large font; use short, simple sentences, and avoid technical language; define all abbreviations and acronyms when they first appear in text. Before submitting a consent form for IRB review, the reading level should be checked. One resource for checking reading level is in Microsoft Word; the Flesch-Kincaid Grade Reading Level can be found under the Tools menu, Spelling and Grammar section, under Options.

B. Resources for Developing a Consent Process

1. Templates

Consent document samples containing the required elements of consent and the additional language required by the Albany State University are posted under the forms and template section of IRBNet. You may also search for sample consent forms using the internet.

C. Exception to the Requirement for Documenting Informed Consent

DHHS provides for waiving or altering elements of informed consent under certain conditions. FDA has no such provision because the types of studies that would qualify for waiver or alteration are either not regulated by FDA or are covered by the emergency treatment provisions of §50.23. Where a protocol is subject to review under more than one department or agency's regulations, the requirements of each set of regulations must be met.

1. Waiver of Documentation of Informed Consent:

In certain circumstances (use of an anonymous survey, a telephone survey, or a web-based survey), investigators may seek a waiver from the requirement to document informed consent.

That is, *they intend to obtain informed consent, but there will be no written document signed by the participants.*

The Albany State University IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if the IRB determines that:

- The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or

- The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

Please note that IP addresses must be blinded if the study is anonymous.

In cases where the requirement of documentation is waived, a consent document in IRB-recommended format should still be used. However, the document is written in letter format ('Dear Subject') and, rather than requiring the subject's signature to verify consent, the following text is used to end the letter:

"If you _____ (e.g., complete the attached survey, answer these few questions etc.), it means that you have read (or have had read to you) the information contained in this letter and would like to be a volunteer in this research study. Thank you, (signatures of investigators)"

2. Waiver of Informed Consent

Written informed consent is not always appropriate, especially in the social and behavioral studies. The DHHS regulations at §45CFR46.116(d) establish four criteria for waiving consent or altering the elements of consent in minimal risk studies. *There are no corresponding provisions in FDA regulations, and these criteria may not be used to waive or alter the elements of consent in FDA-regulated studies*:

1. The research involves no more than minimal risk;

2. The waiver or alteration will not adversely affect the rights and welfare of the subjects;

3. The research could not practicably be carried out without the waiver or alteration;

and

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

Most complete waivers of consent involve studies in which there are minimal risks to subjects, but complete waivers are also possible in emergency care and a few other circumstances.

An example of research for which a waiver of informed consent is appropriate is one in which the only involvement of human subjects is that of anonymous observation, as provided in the federal guidance governing exempt studies.

Studies regulated under the FDA regulations differ from HHS regulations and are generally more restrictive in the area of waiver of informed consent. The differences are noted below.

3. Deception or Concealment in Research

Sometimes, particularly in social/behavioral research, investigators plan to withhold information about the real purpose of the research or even to give subjects false information about some aspect of the research. ***Deception*** in a study occurs when participants intentionally are told something untrue about the study, such as its real purpose. By its very nature, deception in research violates the principles of voluntary and informed consent to participate in research. Therefore, deception is an extraordinary measure that is not normally permitted in human subjects' research. ***Concealment*** occurs when the researcher intentionally withholds some of the research details from participants and may elicit somewhat less heightened concern.

a. Consent Criteria When Deception is Used

Deception can only be allowed when a waiver of informed consent is justified in accordance with §45CFR46.116(d). When proposed, the deception must meet all the following criteria:

- Risks to subjects are no greater than minimal.
- The rights and welfare of subjects must not be adversely affected.
- Deception is essential in order for the investigator to carry out the research.
- At the earliest possible time, subjects must be informed of the nature of the deception, and given a reasonable opportunity to withdraw from participation and to have their data excluded.

b. Other Important Issues with Deception Studies

The IRB will expect the following issues to be addressed in protocols involving deception:

- A reasonable person would be willing to participate in the research if he or she knew the nature and procedures of the study.

- Any data collected during the deception may be used only with a subject's explicit approval, obtained *after* the subject has received full disclosure regarding the study.
- The proposed research is sound in theory and methodology.
- Anticipated findings will contribute significantly to the general body of knowledge.
- Vulnerable subjects (the cognitively impaired, children, or prisoners) are excluded from research involving deception.

c. Consent Language When Deception or Concealment Will Be Used

When deception will be used during a study, the investigator should either disclose during the consent process that deception or concealment will be used OR justify withholding that information. If investigators will disclose the use of deception or concealment, some version of the following language should appear in the procedures section of the consent documents:

"During the study, you may be led to believe some things that are not true. When the study is over, we will tell you everything. At that time you may decide whether to allow us to use your information. You have the right to require your information be destroyed."

For studies proposing concealment, the following language is recommended for the procedures section of the consent documents:

"We will not tell you everything about the study in advance. When the study is over, we will tell you everything. At that time you may decide whether to let us use your information. You have the right to require your information be destroyed."

During the consent process, participants must be informed that the study involves deception or concealment. Depending on the circumstances, the IRB, when reviewing concealment studies, may impose requirements as onerous as those for approving deception.

If deception is proposed in internet research, see "Research Using the Internet" in these *Policies and Procedures*.

D. Obtaining and Documenting Informed Consent of Subjects Who Do Not Speak English

The Albany State University IRB follows the November 9, 1995 guidance issued by the Director, Division of Human Subject Protections, Office for Protection from Research Risks (OPRR), as follows:

Department of Health and Human Services regulations for the protection of human subjects

require that informed consent information be presented *in language understandable to the subject* and, in most situations, that informed consent be documented in writing (§45CFR46.116 and §46.117).

1. Written Consent

Where informed consent is documented in accordance with §46.117(b) (1), the written consent document should embody, in language understandable to the subject, all the elements necessary for legally effective informed consent. Subjects who do not speak English should be presented with a consent document written in a language understandable to them.

2. Oral Presentation of Consent Information with Short Form

Alternatively, §46.117(b)(2) permits oral presentation of informed consent information in conjunction with a short form written consent document stating that the elements of informed consent required by §46.116 have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form.

The IRB must receive all foreign language versions of the short form document as a condition of approval under the provisions of §46.117(b) (2). In some cases, the IRB may require that the documents be translated back into English by another translator, to ensure accuracy and completeness. This additional translation will usually be required only in cases where the study is of greater than minimal risk.

When this procedure is used with subjects *who do not speak English,*

- the oral presentation and the written short form document should be in a language understandable to the subject;
- the IRB-approved English language informed consent document may serve as the summary; and
- the witness should be fluent in both English and the language of the subject.
- the short form document should be signed by the subject (or the subject's legally authorized representative);
- the summary (i.e., the English language informed consent document) should be signed by the person obtaining consent as authorized under the protocol; and
- the short form document and the summary should be signed by the witness. When the person obtaining consent is assisted by a translator, the translator may serve as the

witness.

XI. Research Involving Vulnerable Populations: Children, Prisoners, Pregnant Women and Fetuses

When some or all of the research participants are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, the Institutional Review Board is required to verify that additional safeguards have been included in the study to protect the rights and welfare of these participants. Federal regulations stipulate that if Institutional Review Boards regularly review research involving a vulnerable category of subjects, consideration should be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these subjects.

A. Research Involving Children (Minors)

See the March 6, 1998 National Institutes of Health Policy and Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects in the Appendices to these *Policies and Procedures* and on the web at http://grants.nih.gov/grants/guide/notice-files/not98-024.html.

The State of Georgia defines children, or minors, as those persons under the age of 18. Please be advised that the funding agency may define the age of majority differently.

1. Determination of Risk in Research Involving Children

1. Research of Minimal Risk Involving Children

The IRB will approve research of minimal risk that involves children if it finds that no greater than minimal risk to children is presented and only if adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians.

2. Research of Greater Than Minimal Risk Involving Children

The IRB will approve this type of research only if the proposed intervention or procedure holds out the prospect of direct benefit for the individual subject, or by a monitoring procedure that is likely to contribute to the subject's well-being and only if the IRB finds that:

- The risk is justified by the anticipated benefit to the subjects;
- The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches; and
- Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians, as set forth in §46.408.

Should questions arise, the IRB will seek guidance from the OHRP or other recognized experts

(school system and juvenile justice system)

2. Parental or Guardian Permission and Assent

With some exceptions, the Albany State University IRB requires that *parental* or *guardian* permission be obtained prior to a minor's participation in a research study, since the minor cannot legally consent to such participation. Depending on the age and maturity of the potential subjects, the Albany State University IRB may require that the minor be presented with an assent form to review and sign.

Researchers may not utilize "implied permission," wherein a parent's permission is assumed unless they specifically decline in writing. That is, if permission forms are sent home and not returned, the researcher may not assume that parental permission has been granted. The researcher may also not send children home with a parental permission form that says "Send this signed form back if you don't want your child to participate."

Guidance on developing language for parental/guardian permission and assent can be found in the forms and templates section on IRBNet.

3. Waiver of Parental or Guardian Permission

Per §45CFR46.116 (d), an Institutional Review Board may approve a consent procedure which does not include some or all of the elements of informed consent, or the Board may waive the requirements to obtain informed consent provided the IRB finds and documents that:

- the research involves no more than minimal risk to the subjects;
- the waiver or alteration will not adversely affect the rights and welfare of the subjects;
- the research could not practicably be carried out without the waiver or alteration; and
- whenever appropriate, the subjects will be provided with additional pertinent information after participation

4. Research Involving Children Who Are Wards or Juvenile Detainees

In accordance with §45CFR46.409, the Albany State University IRB will approve research proposing to enroll children who are wards of the State or any other agency, institution, or entity only under certain conditions. If the research fits into one of the following two categories, it can only be approved if related to their status as wards or conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards:

- Research involving involves greater than minimal risk and no prospect of direct benefit to individual subjects, but is likely to yield generalizable knowledge about the subject's disorder or condition

- Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.

In certain circumstances, the IRB shall 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.

Juvenile detainees constitute an especially vulnerable population. In addition to considerations required by §45CFR46, Subpart C (*Additional DHHS Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects*), the guidance at Subpart D (*Additional DHHS Protections for Children Involved as Subjects in Research*) must be followed.

a. Constructive Emancipation of Minors

In some cases, a minor may be constructively emancipated and be granted by the state the legal authority to consent to participate in research. In these cases, the IRB must carefully weigh the potential subject's vulnerability, developmental age, and the fact that the parents' rights have been subjugated to the state or other agency, institution, or entity. The IRB may, at its discretion, appoint an advocate for these emancipated minors.

5. Categories of Review When Participants Are Minors

All protocols involving minors will fall into one of these categories.

a. Expedited

The expedited review category and corresponding review procedure are applicable to secondary data research involving minor subjects.

b. Full Board

All other research involving minor subjects must be reviewed by the full board.

B. Research Involving Prisoners

The Albany State University Institutional Review Board is not properly constituted to review and approve research involving prisoners as subjects.

A prisoner may be defined as any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statue. 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 (**§**45CFR46.303(c).

In most cases of research involving human subjects, respect for persons demands that subjects enter into the research voluntarily and with adequate information. In some situations, however, application of the principle is not obvious. The involvement of prisoners as subjects of research provides an instructive example. On the one hand, it would seem that the principle of respect for persons requires that prisoners not be deprived of the opportunity to volunteer for research. On the other hand, under prison conditions they may be subtly coerced or unduly influenced to participate in research activities for which they would not otherwise volunteer. Respect for persons would then dictate that prisoners be protected. Whether to allow prisoners to "volunteer" or to "protect" them presents a dilemma.

For these purposes, “prisoners” include incarcerated persons convicted of crimes and other persons held against their will, such as detainees awaiting bail or trial. The term is intended to encompass individuals sentenced 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.

Federal regulations specifically preclude protocols involving prisoners from review under the exempt category and from research involving deception.

The federal regulations at *§45CFR46 Subpart C* specifically address research involving prisoners and says that the Office for Human Research Protections (OHRP) the institution must certify to OHRP that an IRB has reviewed the proposal and made seven required findings, and receive OHRP authorization prior to initiating any research involving prisoners (45 CFR 46.305(c)). Another stipulation of these regulations is that Institutional Review Boards are required to have a prisoner representative as a member of the IRB when protocols involving prisoners are being reviewed. Albany State University’s IRB does not have a prisoner representative member as part of the committee, so the ASU IRB is not properly constituted to review and approve research involving prisoners.

If a research subject becomes a prisoner while enrolled in a research study, the Investigator must immediately report this in writing to the Office of Research and Sponsored Programs. All interactions or interventions with the prisoner-participant must be halted until approval can be obtained from Albany State University IRB and, *if funded by NIH,* the federal Office for Human Research Protections (OHRP). As stated earlier, Albany State University IRB is not properly constituted to review and approve research involving prisoners.

C. Research Involving Pregnant Women and Fetuses

In much behavioral research, participant pregnancy may be irrelevant for purposes of the study. For example, the completion of opinion surveys and questionnaires would hardly be viewed as posing greater than minimal risk to the pregnant woman or fetus. There are additional precautions and requirements, however, that apply when enrolling pregnant women in research, particularly that of a clinical nature.

In accordance with §45CFR46.204, research involving pregnant women or fetuses may be approved if all of the following conditions are met:

- Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on non-pregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses;

- The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus; or, if there is no such prospect of benefit, the risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means;

- Any risk is the least possible for achieving the objectives of the research;

- If the research holds out the prospect of direct benefit to the pregnant woman, the prospect of a direct benefit both to the pregnant woman and the fetus, or no prospect of benefit for the woman nor the fetus when risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means, her consent is obtained in accord with the informed consent provisions of §45CFR46 Subpart A;

- If the research holds out the prospect of direct benefit solely to the fetus then the consent of the pregnant woman and the father is obtained in accord with the informed consent provisions of §45CFR46 Subpart A, except that the father's consent need not be obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest.

- Each individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate;

- For children as defined in §45CFR46.402(a) who are pregnant, assent and permission are obtained in accord with the provisions of §45CFR46 Subpart D;

- No inducements, monetary or otherwise, will be offered to terminate a pregnancy;

- Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy; and

- Individuals engaged in the research will have no part in determining the viability of a neonate.

1. Pregnancy Testing

Some research studies may present a risk to pregnant women and their fetuses. In order to determine whether a pregnancy test is appropriate for women of childbearing potential who may enroll in a study, the IRB has developed the following guidance.

a. Greater Than Minimal Risk to Fetus with No Benefit to Fetus or Mother

If participation in research involves exposure to a risk factor known to be more than minimal risk to a fetus, with no benefit to the fetus or mother, the investigator has a responsibility to actively screen for pregnancy before enrolling, and if exposure continues, the pregnancy screening must continue. Simply relying on the participant's knowledge or belief about whether she is pregnant is insufficient if better screening methods are available. Pregnancy screening may involve a urine test or blood test, or if these are not practical, it could involve explicit questioning about behavior and medical history, e.g., whether the person is sexually active and using birth control, whether the person has had a medical procedure (or a health condition) that prevents her from being pregnant, etc.

b. No additional Risk to Fetus

If participation in research involves exposure to risk factors that are known to pose no additional risks to a fetus, such as participation in a typical test of cognitive functioning, it is improper to exclude women who are or might be pregnant from the study on that basis.

c. Unknown but Presumed Risk to Fetus

If participation in research involves exposure to risk factors that are of unknown significance to a fetus, but might reasonably be expected to be a potential risk because they involve exposure to chemicals, radiation, physical forces, pathogens, etc. that are known to adversely affect human tissue or cell division or nutrition, etc., the investigator (with IRB oversight) must weigh the potential risk against any benefits. If there are no potential benefits to the mother or fetus, these exposures may be treated as category a above until such time as evidence can be obtained to move it into category b. (If there are potential benefits to the mother, these may be considered and weighed against the risk to the mother + possible fetus).

d. Unknown Risk to Fetus

If participation in research involves exposure to risk factors that are generally held to be safe for humans, but effects on fetuses are simply unknown, this must be disclosed to all participants so they can make an informed decision about whether to participate, but pregnancy or potential pregnancy cannot be used as an exclusion criteria. Consent documents for these cases shall include the following language: *"Women of childbearing potential who are considering being in this study should especially note that the risk to the fetus(es) of exposure to XXXX are currently unknown."*

XII. Research Involving Albany State University Students as Participants

Given the amount of research conducted at the Albany State University, it is not surprising that Albany State University students are often participants in research studies conducted by faculty and other students. Participation in research can be a valuable experience for students who learn about the conduct of scientific research; therefore, the educational benefit of their participation should not be discounted.

Students are entitled to the same protections and considerations given other research subjects but some issues are of special concern when students are being recruited for studies conducted by their teachers. For example, there may be a perception of coercion to participate. There is also some controversy about whether students are entitled to a reasonable expectation of privacy in the classroom and whether behavior in the classroom constitutes public behavior. Videotaping in the classroom can present a dilemma for students who do not wish to participate but who also realize that they cannot inconspicuously decline. For these and other reasons, the Albany State University IRB includes a student as a full voting member of the Board.

A. Use of Researcher's Students as Subjects

These guidelines are designed to assist researchers who wish to use their current students as subjects in research protocols. An underlying principle of the regulations governing use of human subjects in research is that the subject's participation is voluntary, based upon full and accurate information. The relationship of teacher and student is inherently one that raises the issue of "voluntariness." No matter how well intentioned the teacher is, students may feel compelled to participate and may believe that failure to do so will negatively affect their grades and the attitude of the teacher (and perhaps other students) toward them. *For this reason, the* Albany State University *IRB has taken the position that teachers should not use their own students as subjects in their research if it can be avoided.* This general policy is in accord with that of other Institutional Review Boards. However, students who are not involved in research course are able to participate in studies.

The Albany State University IRB recognizes, however, that in some research situations, use of one's students is integral to the research. This is particularly true of research into teaching methods, curricula and other areas related to the scholarship of teaching and learning. The following are two models of research design that have been approved by the Albany State University IRB for such circumstances.

1. Collection of Data by Third Party

In situations where the activities to be undertaken by the students *are not part of required class activities*, and thus students may choose whether to participate, the instructor/researcher should arrange to have the data collected by an independent third party, so that the instructor does not

know who participated, and does not have access to the identifiable data or identity of participants for any purpose until grades have been assigned and entered.

For example, if the instructor wants to administer pre- and post-tests to determine the efficacy of a particular curriculum, the necessary consent forms could be obtained, and administration of the tests conducted, by a third party who will not release the consent documents until after the course ends and final grades have been posted. For the purposes of obtaining consent in this case, another faculty member may serve as a third party.

2. Collection of Data by Instructor/Researcher

Instructors should provide students a written explanation at the beginning of the course concerning the study, which prominently discloses that students will have an opportunity to agree or not to agree to the inclusion of their data in the instructor's study. The students will be asked to sign the consent form before the end of the course and return it to a third party who will not release the consents until after the end of the course and after grades have been posted. By fashioning the student's participation in this manner, we do not place the student in the position of having to either choose to participate or final selection of alternative classes is not likely to be possible.

In situations where the collection of data by a third party is not feasible (such as the use of a particular teaching method or the use of students' test results, written papers, and homework over the semester), the Albany State University IRB requires that the students' written consent to be obtained by a third party but not released until grades are entered.

(Some studies will qualify for a waiver of documentation of consent. For example, a faculty member may ask students to anonymously post comments on Survey Monkey or other on-line survey tools regarding instruction methodology. While students will be provided a consent document, the faculty member will not collect signatures or know who participates. In such cases, the IRB recognizes that it is not necessary for a third party to administer consent).

3. Studies Posing Greater Than Minimal Risk to Student Participants

Participation by students in any teaching activity which involves the potential of more than minimal risk (i.e., more that the risk found in everyday activities) to the student, or is unusual or not necessary to the course of study or training in which it occurs, must be accompanied by the student's voluntary, informed consent and must first be reviewed and approved by the full Albany State University IRB during a convened meeting prior to commencement of the activity.

4. Additional Points to Consider

a. Group Activities

Group activities that are required as part of the course instruction pose a particularly difficult situation because the practicality of a student opting out is very limited. If the data is a group project or perhaps a videotape of the group interaction, each student's consent is necessary for the use of that data in the instructor's research. If one student does not consent, the data may be used only if the non-consenting student's data can be effectively excluded. In many cases this will not be possible. Thus, none of the data can be used.

b. Use of Student Grades and Other Assessments

In research where the instructor wants access to identifiable student academic records, signed consent forms are required even if the research activities conducted in the classroom are conducted by a third party and otherwise fall under an exempt category of research. For example, administration of a pre- and post-test by a third party will normally qualify as exempt research under either category 1 or 2, requiring the provision of an information sheet, but not signed consent. If, however, part of the research also includes access to the individual, identifiable student's other grades etc., signed consent from each student is necessary.

c. Minors

Research involving minors (under 18 years of age) as subjects (even 17 year old college students) in most instances requires a signed parental consent. Some types of research may qualify for a *waiver of parental permission*. The Principal Investigator may request a waiver; however, the IRB will decide if a waiver is appropriate.

d. Graduate Teaching Assistants

Research conducted by graduate students in a class or laboratory in which he/she teaches, assists in the class/laboratory, or does any grading is subject to the same restraints described above.

e. Templates to be Utilized in Preparing Consent Documents for Collection of Data by Instructor/Researcher

Two consent templates have been prepared for use by faculty who wish to seek IRB approval to enroll their students in studies. They are located the forms and template section of IRBNet:

- **Template 1: STUDY INFORMATION SHEET** (Given to students at beginning of course)
- **Template 2: INFORMED CONSENT STATEMENT** (To be signed before the end of the course. A third party will hold the consents until after grades are posted, and faculty will not know which students enroll until that time.)

f. Under What Circumstances Can Class Credit Be Given to Student Participants?

The Albany State University IRB has approved the giving of course credit or extra credit to students who participate in research as part of a course requirement only when alternative and

equitable means of obtaining credit is made available to students who do not wish to volunteer as research subjects. The Albany State University IRB carefully reviews these alternatives to make sure that students are not being coerced into becoming subjects.

Participation in studies may be offered for credit in a class, but students should be given other options for fulfilling the research component that are comparable in terms of time, effort, and educational benefit. To fulfill the research component, students could participate in research, write a brief research paper, or attend faculty research colloquia. The paper should not be graded, and students who attend the colloquia should only have to show up. If students do choose to participate in studies, they should be given several studies from which to choose.

The informed consent statement should make clear the consequences of withdrawing from a project prior to completion (e.g., will credit be given despite withdrawal?). In accordance with federal requirements, participants must be able to withdraw from a study *without penalty*. As a general matter, the Albany State University IRB favors giving credit even if the subject withdraws, unless the student withdraws immediately after enrolling and does not begin participation, or there is evidence of bad faith on the part of the student.

g. Participation as Human Subjects by Albany State University Students Who Are Minors

Albany State University students who are under the age of 18 may participate in certain studies that are specifically approved for the enrollment of minors. Further, unless a waiver of parental permission has been requested by the investigator and granted by the Albany State University IRB, permission of the parent of the minor subject will need to be obtained. Regardless of whether or not such a waiver is granted, assent of the minor subject will be required in all cases. Referenced approvals and waivers will be granted for projects for which the risks to the subject are determined by the committee to be minimal.

XIII. Research Involving Albany State University Employees as Participants

University employees may occasionally participate as subjects in research. In every case, they should undergo the same IRB-approved consent process that other participants experience.

A. Employees as Vulnerable Participants

In cases where employees participate as volunteers in projects being conducted by their supervisor, they represent a vulnerable population. Despite their seeming enthusiasm, employees should not be subjected to even subtle coercion. Investigators must ensure that all personnel who participate in even minimal risk research activities do so entirely voluntarily.

B. Compensation of Participating Albany State University Employees

It is the policy of the Albany State University IRB that, if compensation is to be provided for any participants, it should also be provided for those who are employees. Such participants shall be paid through the Payroll Office and the payment will be reported on the employee's W-2. Employees participating in research studies during the work day should note the special requirements below:

1. **Exempt (Salaried) Employees**
   Employees classified as exempt must have their supervisor's approval to participate in research studies during normal work hours.

2. **Non-Exempt (Hourly Paid) Employees**
   Non-exempt employees must make arrangements to be in the study during lunch or outside of normal work hours. All employees may want to check with the Office of Human Resources regarding the tax implications for participation compensation. Note that payments of $600 or more to an individual in a single year necessitate the issuance of IRS 1099s.

C. Prohibition on Charging Salary and Participation Compensation to Same Sponsored Project

Employees, graduate students, and undergraduate students who are funded by the research grant to which the human subject payments will be charged may not be enrolled as research participants under the associated protocol.

XIV. Compensation and Incentives for Research Participation

Compensation may be in the form of funds, course credit, or other incentive.

A. Purpose of Compensation

Compensation is intended to thank the participant for his/her time and trouble and to reimburse out-of-pocket expenses associated with participating in the study, such as the cost of transportation and parking, meals away from home, and so on. Compensation might also include certain incentives for participation.

Compensation schemes must be fully described in the protocol, be clearly explained in the consent documents, and be approved by the IRB.

B. Avoidance of Coercion and Undue Influence

It is Albany State University policy that compensation for participation in studies shall not constitute an undue influence to participate. Unusually generous payments may blind prospective subjects to the risks of a study or impair their ability to exercise proper judgment,

and they may prompt subjects to conceal information that, if known, would prevent their enrolling or continuing as participants in research projects. For example, the indigent may be willing to take greater risks with their health in return for greater compensation.

The Albany State University IRB standards for judging whether incentives constitute undue influence must vary according to research procedures and subject populations, but the following questions from the general basis for determining whether incentives are appropriate:

- Are all research conditions in keeping with standards for voluntary and informed consent?
- Are the incentives reasonable and proportional based on the time commitment, complexities and inconveniences of the study and the particular subject population?
- Would a reasonable person consider the incentive to be appropriate?

C. Proration and Bonuses

Proration of compensation is reasonable when participants will be asked to come for several sessions or to stay for several hours. (If there are to be ten 30-minute focus group meetings over two months with a total compensation of $100, participants who withdraw should be compensated at the rate of $10 for each meeting they attended). Participants must be free to withdraw from a study at any time without penalty or loss of benefits to which they are otherwise entitled.

D. Compensation for Participating Children

Compensation for the participation of children should only cover out-of pocket expenses, since the parent gives permission for the child's participation and receives any monetary compensation. It is reasonable to also give young children a small toy to thank them for their participation.

E. Lotteries and Raffles

It is a felony in the State of Georgia to conduct a lottery, raffle, or similar game of chance without a license. The Georgia Code defines lotteries and raffles as "any scheme or procedure whereby one or more prizes are distributed by chance among persons who have paid or promised consideration for a chance to win such prize." This definition encompasses almost any contest in which something is given away, as long as the participant is required to provide something of value ("consideration"), in exchange for the chance to win. Consideration can be in any form and can be as simple as requiring someone to fill out a survey or questionnaire.

Lotteries and raffles may be lawfully conducted without a license if participants are allowed to enter without having to provide anything of value. For example, if you are asking research participants to complete a questionnaire for a chance of winning $50, you must provide the opportunity to enter the raffle and win the $50 *without* having to actually complete the questionnaire. This can be likened to the "no purchase required" disclaimer in most commercial contests and giveaways.

If the use of a lottery, raffle, or other game of chance is proposed as compensation, the consent form and recruitment materials must state in the compensation section that participation in the research is not required in order to have a chance to win.

F. Other Special Incentives

Occasionally an investigator will propose a contest or competition in order to encourage participation in studies. Examples of those proposed schemes include:

- the elementary school classroom with the most participants may be given an ice cream party,
- the department with the most participants may be given a breakfast buffet, or
- the teacher who signs up the most student participants will receive a $50 gift certificate.

These schemes are evaluated according to their coerciveness, the age and developmental level of participants, the risk level of the study, and so on. In general, these kinds of contests are frowned upon by the IRB.

G. Payment of Referral or "Finder's Fee" for Enrolling Participants

The Albany State University IRB has determined that it may be appropriate for investigators to provide a small fee paid to individuals who refer willing human subject research participants. Such fees are paid per individual referral, must be nominal, and may only be used for the recruitment for minimal risk studies. While the IRB approves the general concept of referral fees, the specific use and appropriateness of referral fees will still be considered on a protocol by protocol basis.

H. Institute Policy for Departmental Accounting of Payments to Subjects

Senate Bill 300, the Transparency in Government Act, was passed during the State of Georgia 2008 legislative session and was signed by Governor Perdue in May 2008. This bill requires state agencies and state institutions to extract all trade vendor payment data (vendor ID, vendor name, amount & number of payments) to the Department of Audits and Accounts (DOAA). The DOAA will then make these data available to be viewed by the public via a searchable website. *DOAA approved procedures allowing state agencies and state institutions to exclude from this extraction any payments related to human research subjects and/or the Health Insurance Portability and Accountability Act (HIPAA).*

(Note that payments of $600 or more to an individual in a single year necessitate the issuance of IRS 1099s).

I. Compensation to Nonresident Aliens

While research subjects should be compensated for their time and trouble, it is important to remember that *such compensation does not constitute wages for services performed*. There is no

employer/employee relationship between a researcher and a research subject.

Nevertheless, US tax law imposes a mandatory withholding of 30% for nonresident alien payments; therefore, all payments made to nonresident aliens must be processed by Accounts Payable, regardless of the amount.

XV. Research Involving the Collection of Human Biologic Specimens

Due to the potential implications of disclosure of subjects' genetic information, the Albany State University IRB has developed the following guidance to assist researchers in protecting subjects and in developing research protocols.

A. Use of Human Tissue and Cell Lines

Research often involves the use of stored human samples or data. Use of these samples obliges research investigators and Institutional Review Boards (IRBs) to consider the rights and welfare of the individuals who provide them, especially when samples retain identifiers or codes. Individuals (sources) who provided samples or from whom information was obtained in the past are no less deserving of protection than are prospective research subjects.

Some research involving the use of cell lines or human tissues may be exempt from submission of IRB materials. The following chart will help you determine whether IRB submission is required.

Type of Cell Line/Tissue Sample	**ASU Requirement**
Established cell lines publicly available to qualified scientific investigators [e.g., cell lines commercially available from the American Type Culture Collection (ATCC)], including cell lines that have been published and are available by request from the investigator.	None. Not covered under definition of "human subject."
Cell lines originally obtained from a commercial source (e.g., ATCC) and subsequently modified in the investigator's laboratory	None. Not covered under definition of "human subject."
Samples from deceased individuals or cadaverous tissue*	None. Not covered under definition of "human subject."
Self-sustaining, cell-free derivative preparations including viral isolates, cloned DNA, or RNA	None. Not covered under definition of "human subject."

B. Definitions

Anonymous Samples: specimens lacking any code or identifier that would allow a link back to the subject who provided it.

Genetic Research: any research involving the analysis of human DNA and chromosomes as well as biochemical analysis of proteins and metabolites when the intent of the research is to collect and evaluate information about heritable disease.

Identifiable/Coded Samples: specimens that can be linked back to the subject who provided them.

Prospective Collection: specimens do not exist 'on the shelf' when request is made to Albany State University IRB for approval.

Retrospective Collections: proposed research involves using specimens that already exist, i.e., already collected and are 'on the shelf', stored or frozen at time of protocol submission to Albany State University IRB.

Third Party: Tissue is not obtained from the human subject directly, but via another source, i.e., tissue bank. The third party may have the tissue coded with respect to subject identity, but the investigator receives the tissue in an anonymous manner, i.e., no way to link the subject's identity to the tissue once it is in the investigator's hands.

C. Points to Be Addressed in the Protocol When Proposing Research on Biological Specimens

If an Albany State University researcher plans to conduct research on biological specimens, protocols will need to be developed in advance of the research. If biological specimens can be linked back to the subject who provided them, IRB review must be undertaken to protect the identity of those who donated their biologic material.

XVI. Research Using the Internet

The internet, for the purpose of this discussion, includes email, websites, bulletin boards, chat rooms, and any other online interaction via the World Wide Web. When using the internet as a research tool, the following issues must be addressed and incorporated into the protocol and, where appropriate, into the consent process. Internet research considerations can be generally categorized into research participant issues, research design issues, and security issues.

A. Public or Private Space?

While the internet is generally considered a public domain, the expectation of privacy on the

internet is relative and largely dependent upon the purpose of users. Participants in a casual online chat room may have little expectation of privacy, while members of virtual communities for vulnerable populations, such as HIV patients or substance abusers, correctly or incorrectly assume some privacy within that community. The online community's purpose and level of accessibility are central to any discussion about informed consent in this environment. Therefore, researchers must be sensitive to how internet users define their online activities.

B. Research Participants

Logistical challenges are posed for researchers using the internet. The good news is that internet research can provide hundreds of participants quickly, and the bad news is that internet research can provide hundreds of participants quickly. Contacting each one to obtain documented consent is impracticable, if not impossible. If research is to be cond*u*cted within a specific internet community, such as a support group, the internet site community leader can perhaps be contacted for a discussion of the proposed research and informed consent process. At a very minimum, informed consent should be obtained from the core members of the community. Email is an acceptable medium for the informed consent document.

However, the validation of the virtual informed consent process proves difficult because the direct researcher-subject interaction is missing; the actual age, mental competency and comprehension of the potential subject are not known. The issue of authenticating informed consent remains unsolved at this time. At a minimum, though, researchers in all studies are encouraged to identify their positions from the outset of the research study.

C. Participation of Minors

Internet research presents a challenge for protecting minors. Internet environments offer no reliable way to confirm the ages of online participants. When recruiting children for an internet study, the IRB generally prefers that parental consent and child's assent be obtained, and researchers will be asked to describe how these are validated. Unfortunately, federal guidance is woefully lacking in this area. Therefore, the IRB will exercise cautious deliberation of any online research involving children (or any other vulnerable population).

D. Research Design

Researchers must justify that data collection via the internet is warranted by a research design that is scientifically credible and satisfactorily addresses whether the subject pool adequately represents the study population. For example, the selection of respondents for internet studies could be non-representative due to inherent characteristics of internet use, which could be problematic unless such lack of diversity is intentionally designed into a study. Researchers must state how the identity of participants will be confirmed and whether or how the identity of the researcher will be provided to research participants.

Deception poses special challenges and must be adequately justified. Deception occurs, for

example, when a researcher "lurks" in a chat room, giving a false identity and purpose for his participation, but really observing and perhaps recording interactions among other chat room members. When his true purpose and identity are revealed, chat room members may react with anger, feel that their privacy and trust have been assaulted, and suffer anxiety.

Federal regulations permit deception only when a waiver of informed consent is approved by the IRB which has affirmed that risks to subjects are no greater than minimal; the rights and welfare of subjects will not be adversely affected; deception is essential in order for the investigator to carry out the research; and at the earliest possible time, subjects must be informed of the nature of the deception and given a reasonable opportunity to withdraw from participation and to have their data excluded. It is exceedingly difficult to ensure that all individuals involved are included in the debriefing process.

E. Confidentiality and Privacy

Internet research protocols must specify how anonymity, confidentiality, or privacy will be assured for research participants. Researchers should address the risks and benefits of conducting the study via the internet, including whether participants will incur any costs for their participation (e.g., online time).

The protocol should address whether participants in the study are cooperating voluntarily and that any personal information will be obtained with their knowledge and consent. In general, participants should be fully aware of how the data collected in the study will be used. Research protocols must also state whether participants can be assured that their information or data collected will not be used for subsequent non-research purposes (e.g., direct marketing, fundraising).

Researchers must consider potential pitfalls and compromises to data that can occur when using computer and information technology, which can breach participant confidentiality. Forethought should be given to necessary technology, hardware, or software needed to minimize or eliminate problems that might occur. For example, if email data are to be collected, researchers should state whether email identification software is necessary to remove email addresses from respondents or whether Institutional firewall protection is adequate. Researchers must also determine whether the informed consent document ought to include information about any of these precautions.

XVII. Off-Campus Study Locations, including Private Residences, Daycare Facilities, Elementary and Secondary Schools

Researchers, who wish to conduct research in off-campus locations, including private residences, daycare facilities, or elementary and secondary schools, must comply with the guidance provided here. Study locations, including recruitment sites, must be specified in the protocol, and site

permission must be provided.

Written permission may be by email or on the entity's letterhead.

A. Private Residences

The Albany State University IRB prohibits research conducted in the private residences of any faculty member or other investigator, student, study staff, family member, or friend.

In certain situations, research may be conducted in the home of the research participant. This will require review and approval by the IRB and will depend on the type of research being conducted. If the study will take place in a subject's residence, separate written permission is not required for that purpose. The consent document must, however, specify that the subject's residence is the study location.

B. Recruitment and Research Conducted in Public and Private Primary or Secondary Schools or Daycare Facilities

Investigators seeking to perform research in schools or daycare facilities must provide written permission from an authorized individual with the protocol submission. In the case of public schools, the investigator must contact the *school district* and follow its guidance on securing permission to conduct the research. Many school districts have established policies, and the superintendent's office maintains the authority to approve or disapprove requests. Some school districts, private schools, and daycare facilities have elaborate application processes requiring lengthy lead time and including a criminal background check before permission to conduct research will be granted. Approval must also be obtained from the teacher/direct supervisor of the children. As indicated, parental consents and/or participant assents may need to be obtained.

In cases where the school or daycare has no existing policy on research being conducted with its students, investigators are to contact the principal on site and obtain a signed statement on school letterhead granting permission to conduct the research at the school.

XVIII. Research in International Settings

A. Review Requirements Differ for Research in Foreign Countries

The U.S. regulations recognize that procedures normally followed in foreign countries (in which the research will take place) may differ from those set forth in the U.S. federal policy. Therefore, research may be approved by a U.S.-based IRB if the procedures prescribed by the [foreign] institution afford protections that are *at least equivalent* to those provided in the U.S. federal policy. The foreign country's procedures may then be substituted for the procedures required by

the federal regulations.

B. Local Review and Approval May Be Required Before ASU IRB Will Approve

The Albany State University IRB approval alone does not convey the right or authority to conduct research at a site in another country. Approval from the local IRB or ethics board may be required before final approval is issued by the Albany State University IRB. This requirement will generally be invoked for protocols of greater than minimal risk. If there is no equivalent IRB or ethics board, investigators may rely on local experts or community leaders to provide approval of the proposed study.

C. Consideration of Local Context and Investigator Experience as Important Criteria

The IRB will consider local research context when reviewing international studies to assure protections are in place that are appropriate to the setting in which the research will be conducted. Protocols should contain a description of the investigators' knowledge or experience regarding the culture of the foreign country. Do investigators speak the local language(s), or will a translator be needed?

The IRB may require that an expert consultant evaluate issues of local research context if the IRB does not have a board member with the expertise or knowledge required to adequately evaluate the research in light of local context. In such cases, investigators should provide the IRB with names of individuals qualified to conduct this review, including other members of the Albany State University faculty.

D. Consent Issues in Foreign Countries

Since customs differ from country to country, investigators need to be sensitive to local cultural and religious norms when recruiting and enrolling human subjects. For example, signing a consent document for a study collecting opinions about government policy may put subjects at risk.

The consent process must provide information in a language understandable to the subjects. The process may include a written document or be entirely oral. When consent forms must be translated into a foreign language, the investigator must provide the IRB with an affidavit of accurate translation from an appropriate translator unaffiliated with the study. The translated consent form and affidavit must be submitted and approved by the IRB before use of the consent form. Translations provided by a member of the Albany State University community are acceptable.

It may be appropriate to orally present informed consent information in conjunction with a short form written consent document: This method involves use of an IRB-approved English language consent form, an IRB-approved short consent form written in the non-English language, and a

witness fluent in both English and the language of the subject. The consent form(s) must be submitted to the IRB in English and in the participants' native language.

Consider the special consent requirements for an illiterate or low-literacy study population. If children or other vulnerable populations will be enrolled, special assent requirements will apply.

E. Other Issues to Consider for Protocols Conducted in Foreign Countries

Researchers proposing international research should allow additional time for the IRB review process. Consider data protection, storage issues, and safe transport of data. Will collected data be recorded on paper or via computer? It is recommended that personal identifiers not be collected unless essential.

1. Special IRB Considerations for Federally Funded International Research

Approval of federally funded research at foreign institutions engaged in research is only permitted if the foreign institution holds an Assurance with the federal Office for Human Research Protections (OHRP) and if local IRB review and approval is obtained.

2. Review of Research at Foreign Institutions Engaged in Research

When the foreign institution is a performance site *engaged* in research, the IRB will review the proposed protocol to ensure that adequate provisions are in place to protect the rights and welfare of the participants. Because Albany State University holds an assurance with the Office for Human Research Protections (OHRP), the foreign institution must file an Assurance of compliance (FWA) with OHRP if the study is federally funded. Federal regulations provide for approval of such research if "the procedures prescribed by the foreign institution afford protections that are *at least equivalent to those provided in §45CFR46.*" The Albany State University IRB must receive and review the foreign institution IRB (or equivalent) review and approval of each study prior to the commencement of the research at the foreign institution or site. Albany State University IRB approval to conduct research at the foreign institution is contingent upon the Albany State University IRB receiving a copy of the performance site's IRB (or equivalent) letter of approval.

3. Review of Research at Foreign Institutions Not Engaged in Research

When the foreign institution is a performance site *not engaged* in research and if the foreign institution has an established IRB (or equivalent), the investigator must obtain from the site's IRB (or equivalent) approval to conduct the research at the site. Failing that, the investigator must provide documentation that the site's IRB (or equivalent) has determined that approval is not necessary for the investigator to conduct the proposed research at the site.

When the foreign institution does not have an established IRB (or equivalent) a letter of cooperation must be obtained. This letter must state that the appropriate institutional or oversight officials are permitting the research to be conducted at the performance site. The

Albany State University IRB approval to conduct research at the foreign institution is also contingent upon receiving a copy of the performance site's IRB (or equivalent) or a letter of cooperation.

F. Monitoring of Approved International Research

The IRB is responsible for the ongoing review of international research conducted under its jurisdiction. Documentation of regular correspondence between the investigator and the foreign institution may be required. In certain cases, the IRB may require verification from sources other than the investigator that there have been no substantial changes in the research since its last review.

G. Compilation of National Policies

The Office for Human Research Protection (OHRP) has compiled a list of foreign countries that have at least some human subject research guidelines that may be essentially equivalent to U.S. requirements. This list can be found at http://www.hhs.gov/ohrp/international/intlcompilation/hspcompilation-v20101130.pdf

Investigators are permitted to substitute the foreign procedures for protecting human subjects except for some FDA-regulated studies. The International Compilation of Human Subject Research Protections) is a listing of the laws, regulations, and guidelines that govern human subjects research in many countries around the world. See http://www.hhs.gov/ohrp/international/index.html.

OHRP Disclaimer: Though this Compilation contains information of a legal nature, it has been developed for informational purposes only and does not constitute legal advice or opinions as to the current operative laws, regulations, or guidelines of any jurisdiction. In addition, because new laws, regulations, and guidelines are issued on a continuing basis, this Compilation is not an exhaustive source of all current applicable laws, regulations, and guidelines relating to international human subject research protections. While reasonable efforts have been made to assure the accuracy and completeness of the information provided, researchers and other individuals should check with local authorities and/or research ethics committees before starting research activities.

The National Institutes of Health has posted additional international ethical guidelines, codes, regulations, policies and declarations at http://bioethics.od.nih.gov/internationalresthics.html.

XIX. Health Insurance Portability and Accountability Act (HIPAA) for Protected Health Information

Research of health information that is not obtained from a covered entity, that is self-disclosed by research participants and that, is kept only in the researcher's records is not subject to HIPAA but is regulated by other human subjects protection regulations.

The Department of Health and Human Services' *National Standards to Protect the Privacy of Personal Health Information* are promulgated in the Health Insurance Portability and Accountability Act (HIPAA) of 1998, commonly referred to as the "Privacy Act." This Act specifies requirements for protection of individually identifiable health information (IIHI) or "protected health information" (PHI). PHI is individually identifiable health information (IIHI) such as name, address, social security number, email address, telephone number, etc., that is created, received or maintained by a Covered Entity (CE). A CE is a Health Care Provider that performs one of the standard electronic transactions identified in the HIPAA Privacy Rule; a Health Plan; or a Health Care Clearinghouse. Virtually all doctors, hospitals, and other health care facilities are CE's.

A. Definitions

For the purposes of this discussion, it is important to understand certain definitions within the context of HIPAA:

1. Covered Entity

Covered entities are health care providers, health plans, and health care clearinghouses.

2. Hybrid Entity

Albany State University is a *hybrid entity*, where only portions of the Institute are subject to HIPAA. A postsecondary institution may have health information to which the Privacy Rule may apply not only in the health records of nonstudents in the health clinic, but also in records maintained by other components of the institution that are not education records or treatment records under *FERPA*, such as in a law enforcement unit or research department. In such cases, the institution, as a *HIPAA* covered entity, has the option of becoming a "hybrid entity" and, thus, having the *HIPAA* Privacy Rule applies only to its health care unit. The school can achieve hybrid entity status by designating the health unit as its "health care component." As a hybrid entity, any individually identifiable health information maintained by other components of the university (i.e., outside of the health care component), such as a law enforcement unit, or a research department, would not be subject to the *HIPAA* Privacy Rule, notwithstanding that these components of the institution might maintain records that are not "education records" or treatment records under *FERPA*. To become a hybrid entity, the covered entity must designate and include in its health care component all components that would meet the definition of a covered entity if those components were separate legal entities. (A covered entity may have more than one health care component.) However, the hybrid entity is not permitted to include in its health care component other types of components that do not perform the covered

functions of the covered entity or components that do not perform support activities for the components performing covered functions. That is, components that do not perform health plan, health care provider, or health care clearinghouse functions and components that do not perform activities in support of these functions (as would a business associate of a separate legal entity) may not be included in a health care component. Within the hybrid entity, most of the *HIPAA* Privacy Rule requirements apply only to the health care component, although the hybrid entity retains certain oversight compliance requirements.

3. Authorization (Consent)

Authorization is the HIPAA equivalent of consent to use and disclose data.

4. Protected Health Information (PHI)

Training on Health Information Privacy and Security (HIPS) can be found at the Collaborative Institutional Training Initiative (CITI) at https://www.citiprogram.org/ .

Protected health information includes all *individually identifiable* health information transmitted or maintained by an organization covered by the HIPAA regulations (a "covered entity"), regardless of form. Specifically, if it is Individually Identifiable Health Information (IIHI) that is:

- Created or received by a health care provider, health plan, employer, or health care clearinghouse; and
- Personal health information that relates to: (the past, present, or future physical or mental condition, the past, present, or future provision of care to an individual, or the past, present or future payment for provision of health care to an individual, and)
- Identifies the individual (or there is a reasonable basis to believe that the information can be used to identify the individual).

Health-related information is PHI if:

- The researcher obtains the information from a healthcare provider, health plan, health clearinghouse, or employer (other than records solely relating to employment status;
  OR
- The records were created by a healthcare provider, health plan, health clearinghouse, or employer, AND the researcher obtains the records from an intermediate source which is not a school or employer record related solely to employment status;
  OR
- The researcher obtains the records directly from the study subject in the course of providing treatment to him.

Health-related information is not considered PHI if the researcher obtains it from:

- Student records maintained by a school, OR
- Employee records maintained by the employer for employment status, OR
- The research subject directly, if the research does not involve treatment.

B. What Research Is Subject to the HIPAA Regulations?

Any research conducted under the auspices of Albany State University that creates, uses, or discloses protected health information obtained from a covered entity is subject to the Health Insurance Portability and Accountability Act (HIPAA). Other research activities subject to HIPAA include chart reviews, epidemiological studies, behavioral and social science studies, basic science research activities, and research that involve the provision of treatment as well as research that provides neither treatment nor diagnosis. All studies involving creation, use, or disclosure of Protected Health Information (PHI) must be reviewed and approved in advance by the Institutional Review Board.

C. Types of Health Information

There are three categories of health information. The requirements for use are different for each.

1. Individually Identifiable Health Information (IIHI)

IIHI includes any subset of health information, including demographic information collected from an individual, that:

- Identifies the individual (or there is a reasonable basis to believe that the information can be used to identify the individual.)
- The general rule is that an authorization signed by the research subject is required for the disclosure of individually identifiable health information. An IRB may waive this requirement.

2. De-Identified Data Sets

Health information is considered de-identified when it does not identify an individual and the covered entity has no reasonable basis to believe that the information can be used to identify an individual. Information is considered de-identified if 18 identifiers are removed from the health information and if the remaining health information could not be used alone, or in combination, to identify a subject of the information. An IRB may waive authorization for the use of de-identified data.

The 18 identifiers that may not be included in de-identified data sets are:

1. Names;
2. All geographical subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code, if according to the current publicly available data from

the Bureau of the Census:

- The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and
- The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people are changed to 000.

3. All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older
4. Phone numbers;
5. Fax numbers;
6. Electronic mail addresses;
7. Social Security numbers;
8. Medical record numbers;
9. Health plan beneficiary numbers;
10. Account numbers;
11. Certificate/license numbers;
12. Vehicle identifiers and serial numbers, including license plate numbers;
13. Device identifiers and serial numbers;
14. Web Universal Resource Locators (URLs);
15. Internet Protocol (IP) address numbers;
16. Biometric identifiers, including finger and voice prints;
17. Full face photographic images and any comparable images; and
18. Any other unique identifying number, characteristic, or code (This does not refer to the unique code assigned by the investigator to code the data).

3. Limited Data Sets

A *limited data set* is information disclosed by a covered entity to a researcher who has no relationship with the individual whose information is being disclosed. The covered entity is permitted to disclose PHI, with direct identifiers removed, *subject to obtaining a data use agreement from the researcher receiving the limited data set*. The PHI in a limited data set may not be used to contact subjects. The IRB may waive authorization for use of limited data sets in research.

Direct identifiers that must be removed from the information for a limited data set are:

1. Name
2. Social Security number
3. Address information (other than city, State, and zip code)
4. Telephone and fax numbers
5. E-mail address

6. Certificate/license number
7. Vehicle identifiers and serial numbers
8. URLs and IP addresses
9. Full face photos and other comparable images
10. Medical record numbers, health plan beneficiary numbers, and other account numbers
11. Device identifiers and serial numbers
12. Biometric identifiers including finger and voice prints
13. Identifiers that are allowed in the limited data set are

Identifiers that are allowed in the limited data set are:

1. Admission, discharge and service dates
2. Birth date
3. Date of death
4. Age (including age 90 or over)
5. Geographical subdivisions such as state, county, city, precinct and five digit zip code

D. Authorization (Consent) Requirements

HIPAA regulations use the term "authorization" to describe the process through which a patient allows researchers to access protected health information. Blanket authorizations for research to be conducted in the future are not permitted. Each new use requires a specific authorization. The authorization for disclosure and use of protected health information may be combined with the consent form that a research subject signs before agreeing to be in a study. It may also be a separate form. In either case, the information must include:

1. Elements of Required Authorization

- A description of the information to be used for research purposes;
- Who may use or disclose the information
- Who may receive the information
- Purpose of the use or disclosure
- Expiration date of authorization
- How long the data will be retained with identifiers
- Individual's signature and date
- Right to revoke authorization
- Right to refuse to sign authorization (if this happens, the individual may be excluded from the research and any treatment associated with the research)
- That information disclosed to another entity in accord with an authorization may no longer be protected by the rule.

2. Waiver of Authorization for Research

The Institutional Review Board uses the following criteria in approving requests for a waiver of authorization for research:

- The use or disclosure of protected health information must involve no more than minimal risk to the privacy, safety, and welfare of the individual
- The research could not practicably be conducted without the waiver or alteration
- The research could not practicably be conducted without access to the protected health information.

The Institutional Review Board must also consider if the researcher has provided:

- An adequate plan to protect the identifiers from improper use or disclosure
- An adequate plan to destroy the identifiers at the earliest opportunity, unless retention of identifiers is required by law or is justified by research or health issues
- Adequate written assurance that the PHI will not be used or disclosed to a third party except as required by law or permitted by an authorization signed by the research subject.

E. Information Needed for Review by the IRB

Detailed information is needed about the types of information investigators will use in their research, how it will be used, who will have access to it, and when it will be destroyed. Specifically, researchers should address:

- What risks are posed by the use of the data and how have they been minimized?
- What is the justification for access to the data and why are they necessary to conduct the research?
- What plan does the researcher have to protect identifiers from improper use or disclosure?
- What is the researcher's plan to destroy the identifiers? If it is not possible to destroy the identifiers, what is the health, legal, or scientific justification?
- Has the researcher provided adequate written assurance that the PHI will not be used or disclosed to a third party except as required by law or permitted by an authorization signed by the research subject?

Researchers requesting waivers of authorization will need to explain that the use or disclosure poses no more than minimal risk to the subject; that the research could not practicably be conducted without the waiver; and that the research could not practicably be conducted without access to the protected health information. The researcher must explain:

- How the use of PHI involves no more than minimal risk to individuals
- Why such a waiver will not adversely affect privacy rights or welfare of individuals in the study
- Why the study could not practicably be conducted without a waiver

- Why it is necessary to access and use protected health information to conduct this research
- How the risks to privacy posed by use of PHI in this research are reasonable in relation to the anticipated benefits
- The plan to protect identifiers from re-disclosure
- The plan to destroy identifiers. Provide a date by which this will take place. If identifiers must be retained, provide the reason (scientific, health, or other) why this is necessary
- Confirm that the PHI will not be reused or disclosed to anyone else.

F. Human Subjects' Rights

1. Right to an Accounting

When a research subject signs an authorization to disclose PHI, the covered entity is not required to account for the authorized disclosure. An accounting is not required when the disclosed PHI was contained in a limited data set or is released to the researcher as the de-identified data. However, an accounting is required for research disclosures of identifiable information obtained under a waiver or exception of authorization. Research subjects may request an accounting of disclosures going back for up to six years.

2. Right to Revoke Authorization

A research subject has the right to revoke his or her authorization unless the researcher has already acted in reliance on the original authorization. Under the authorization revocation provision, covered entities may continue to use or disclose PHI collected prior to the revocation as necessary to maintain the integrity of the research study. Examples of permitted disclosures include submissions of marketing applications to the FDA, reporting of adverse events, accounting of the subject's withdrawal from the study, and investigation of scientific misconduct.

G. Subject Recruitment

1. Recruitment is Subject to the General Authorization Requirements

The Privacy Rule classifies recruitment as "research" rather than as health care operations or marketing. Because development or use of research databases falls within the definition of "research," a covered entity may disclose PHI in a database to sponsors for subject recruitment only after an authorization from the research subject or a waiver from the Institutional Review Board has been obtained.

2. Requirements to Disclose PHI Contained in a Limited Data Set or as De-Identified Data

It is easier to create databases of potential subjects' limited data sets to verify feasibility to conduct a clinical trial or to perform epidemiological research.

3. Limitations on Use of PHI in a Limited Data Set for Subject Recruitment

The PHI may not be used to contact subjects, and, because telephone numbers, internet provider addresses, and email addresses are not part of a limited data set, this information may not be collected by researchers from prospective subjects.

4. Recruiting Subjects Identified using their PHI

When researchers want to approach potential subjects to participate in a study who they have identified using PHI under a waiver of authorization, they must use an approach method that has been approved in advance by the IRB. Examples include using an intermediary such as the patient's primary care provider or a member of the medical staff actually caring for that patient, or sending the potential subject a letter signed by the patient's provider.

H. Requirements for Security of Protected Health Information under the Health Insurance Portability and Accountability Act (HIPAA)

All investigators performing human subject research that involves access to Protected Health Information (PHI) are required to comply with both the Privacy Rule and Security Rule of the Health Insurance Portability and Accountability Act (HIPAA).

The Office of Research and Sponsored Programs ensures that researchers utilizing PHI are able to adequately safeguard those data. No one conducting human subjects research may handle or have access to PHI unless and until they complete the CITI Health Information Privacy and Security (HIPS) training. Therefore, investigators who create, use or otherwise obtain individually identifiable health information are asked to:

1. Complete the Health Information Privacy and Security (HIPS) training module at https://www.citiprogram.org/ , REQUIRED TRAINING,
2. Undergo a data security assessment conducted by the Information Technology Services (ITS). (The Office of Research and Sponsored Programs will inform ITS when such protocols are submitted; ITS will contact investigators directly to schedule assessment).

Only those computer terminals conforming to the Institute's HIPAA Rule Security Standards may be used for the creation, receipt, or maintenance of PHI.

With these provisions in mind, the Albany State University IRB requires that investigators who create, use or otherwise obtain PHI provide more detailed information about data storage, security, re- disclosure and destruction; and provide more information to research subjects in the consent and authorization process about how information about them will be used.

It is a violation of this policy for any person performing work with PHI for Albany State University as an employee or independent contractor to fail to comply with any Privacy and/or Security Rule obligation for which they are responsible, regardless of whether such failure is intentional or not.

1. HITECH Act of 2009

On April 17, 2009, the Department of Health and Human Services (HHS) issued guidance specifying the technologies and methodologies that render protected health information unusable, unreadable, or indecipherable to unauthorized individuals, as required by the Health Information Technology for Economic and Clinical Health (HITECH) Act passed as part of the American Recovery and Reinvestment Act of 2009 (ARRA). This guidance was developed through a joint effort by the Office of Civil Rights, the Office of the National Coordinator for Health Information Technology, and the Centers for Medicare and Medicaid Services.

Two breach notification regulations are forthcoming – one to be issued by HHS for covered entities and their business associates under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (Sec. 13402 of HITECH) and one to be issued by the Federal Trade Commission (FTC) for vendors of personal health records and other non-HIPAA covered entities (Sec. 13407 of HITECH). If the entities subject to the regulations apply the technologies and methodologies specified in the guidance to secure information, they will not be required to provide the notifications required by the regulations in the event the information is breached.

2. Strengthened Enforcement Measures

Perhaps the most significant feature of the HITECH Act is the strengthening of HIPAA enforcement measures. Whereas the Office of Civil Rights (OCR) and the Department of Justice were the only HIPAA enforcement authorities previously, the Act authorizes state's Attorneys General to enforce HIPAA violations in federal court. Should the Department of Justice not pursue criminal penalties for a violation that constitutes criminal behavior, the Office of Civil Rights is now authorized to pursue civil penalties for the same violation.

The Act includes new civil and criminal penalties for employees, with monetary fines being returned to OCR for future enforcement purposes and, eventually, to compensate victims. Civil monetary penalties for willful neglect violations were previously maxed at $25,000; the Act tiers civil monetary penalties with a maximum of $1.5 million.

XX. Projects Conducted by Multiple Faculty, or at Multiple Sites, or by Subrecipients

This Policy XX. Does Not Apply When a DoD Agency Is the Sponsor*.*

The Department of Defense (DoD) agencies, including DoD, Air Force, Army, Navy, Marines, Coast Guard, and others, will not award funds for human research work unless the center grant/contract Principal Investigator is named as a member of the research team in the human

research protocol. In most cases, the center grant/contract Principal Investigator may be named as co-Principal Investigator in the research protocol. He must also complete the required CITI modules that other members of the protocol research team must complete. The center grant/contract Principal Investigator must also submit the "umbrella form" to the Office of Research and Sponsored Programs.

The Institutional Review Board recognizes that large program or center grants may fund multiple projects conducted by multiple Albany State University faculty or entirely at other research sites and that have no direct involvement of the grant's Principal Investigator. The following policy has been established to facilitate IRB approvals in such cases.

A. Program or Center "Umbrella" Grants that Fund Projects Conducted by Multiple Faculty Members at Albany State University

If the program/center grant Principal Investigator has absolutely no involvement in the human research supported by the grant and conducted by other Albany State University faculty members, he should prepare an "umbrella" form listing those faculty members and their protocols that will be supported. Submission of this information will facilitate the IRB's compliance with the federal regulations requiring approval of the research involving humans. Completed umbrella forms (located in the forms and template section of IRBNet.org)should be forwarded to the Office of Research and Sponsored Programs. The umbrella grant Principal Investigator shall have no further obligations for complying with the regulations governing human subjects protections, other than to inform the Office of Research and Sponsored Programs when the umbrella grant funds additional projects to other Albany State University faculty. *There is one exception*:

1. IRB Responsibilities of Albany State University Faculty Whose Human Subjects Research Is Funded By an Umbrella Grant

Faculty members whose human research activities are funded by the umbrella grant are responsible for securing Albany State University's IRB approval for their human subjects research prior to its initiation. Their protocols shall indicate funding by the umbrella grant, and they shall provide their IRB protocol titles and protocol numbers to the umbrella grant Principal Investigator.

B. Program or Center "Umbrella" Grants That Fund Projects Conducted at Non-Albany State University Sites and the Albany State University Principal Investigator Has No Direct Interaction with Human Subjects

This guidance is for situations in which the subrecipient(s)'s Institutional Review Board is registered with the Office for Human Research Protections and holds a current Federalwide Assurance.

The Umbrella may be applicable when a Program or Center grant to an Albany State University Principal Investigator will fund multi-site research involving human subjects with which the Albany State University PI will have no direct interaction, even if he receives de-identified human subjects data from the other sites.

The umbrella form and subrecipient(s)'s letter of IRB approval must be submitted to the Office of Research and Sponsored Programs. If it determines that an Inter-institutional IRB Authorization agreement (IIA) is required, Albany State University Office of Research and Sponsored Programs will coordinate with the subrecipient(s)'s IRB to secure the IIA.

Upon receipt of the completed umbrella form, subrecipient(s)' IRB approval(s), and, if necessary, the IIA, the Office of Research and Sponsored Programs will issue a letter to the Albany State University Principal Investigator documenting that Institutional Review Board approval has been secured. Should he learn that adverse events occur at the other site, the Albany State University PI shall bring those to the attention of the Albany State University IRB. He shall also inform the IRB if he has a conflict of interest, in which case assistance will be provided to ensure the conflict is appropriately managed.

C. Program or Center "Umbrella" Grants That Fund Projects Conducted at Non-Albany State University Sites and the Albany State University Umbrella Grant Principal Investigator has Direct Interaction with Human Subjects

This guidance is for situations in which the subrecipient(s)'s Institutional Review Board is registered with the Office for Human Research Protections and holds a current Federalwide Assurance.

In the event that the human research is to be conducted in part by Albany State University investigator(s) and in part by a subrecipient, the Albany State University investigator must submit to the Office of Research and Sponsored Programs for IRB review a protocol clearly describing the work to be conducted by the subrecipient and that to be conducted by Albany State University investigator(s). The umbrella form and subrecipient(s)'s letter of IRB approval must be included. If it determines that an Inter-institutional IRB Authorization agreement (IIA) is required, the Albany State University Office of Research and Sponsored Programs will coordinate with the

subrecipient(s)'s IRB to secure the IIA.

In these cases, the Albany State University investigator will serve as Principal Investigator. The PI shall also inform the IRB if he has a conflict of interest, in which case assistance will be provided to ensure the conflict is appropriately managed. No subaward will be issued by Albany State University's Office of Research and Sponsored Programs until the subrecipient's IRB and the Albany State University IRB have approved the work.

D. Other Projects Subbed to Non-Albany State University Sites Wanting to Rely on the Albany State University Institutional Review Board

In some cases, the subrecipient institution, regardless of whether it has its own OHRP-approved Assurance, may wish to rely on a review by the Albany State University IRB. Inter-Institutional Agreements (IIAs) are established on a case-by-case basis and only with the approval of the Associate Vice President of the Office of Research and Sponsored Programs. When appropriate, the Office of Research and Sponsored Programs will execute an IIA describing the subrecipient's reliance upon the Albany State University IRB.

The Albany State University IRB will follow written procedures for reporting its findings and actions to appropriate officials at the relying institution. Relevant minutes of IRB meetings shall be made available to the relying institution upon request.

The relying institution's researchers must present documentation of having completed the required training in human research participant protections or, within thirty days of the execution of the IIA, satisfactorily complete the training provided by the Albany State University IRB. The relying institution will promptly and immediately forward to the Albany State University IRB any information regarding safety, adverse events, or other relevant data. The relying institution will also provide to the Albany State University IRB any relevant correspondence between itself and the sponsor or the Office for Human Research Protections. The relying institution remains responsible for ensuring compliance with the Albany State University IRB's determinations and policies and with the terms of its OHRP approved Assurance.

XXI. Research by Non-Albany State University Personnel or Entities Enrolling Albany State University Faculty, Staff, or Students

Occasionally, non-Albany State University personnel or other entities will collect data from faculty, staff, and/or students on campus. The determination as to whether the Albany State University IRB needs to review the proposed activity depends on whether Albany State University is *engaged* in the research.

A. Albany State University *is* Engaged in the Research

If Albany State University is engaged in the study, IRB review is required. An institution is considered *engaged* [45CFR46.102(d)(6)] in non-exempt human subjects research when the involvement of their employees or agents in that project includes any of the following:

- Institutions that receive an award through a grant, contract, or cooperative agreement directly from HHS for the nonexempt human subjects research (i.e. awardee institutions), even where all activities involving human subjects are carried out by employees or agents of another institution.

- Institutions whose employees or agents intervene for research purposes with any human subjects of the research by performing invasive or noninvasive procedures. Examples of invasive or noninvasive procedures include drawing blood; collecting buccal mucosa cells using a cotton swab; administering individual or group counseling or psychotherapy; administering drugs or other treatments; surgically implanting medical devices; utilizing physical sensors; and utilizing other measurement procedures.

- Institutions whose employees or agents intervene for research purposes with any human subject of the research by manipulating the environment. Examples of manipulating the environment include controlling environmental light, sound, or temperature; presenting sensory stimuli; and orchestrating environmental events or social interactions.

- Institutions whose employees or agents interact for research purposes with any human subject of the research. Examples of interacting include engaging in protocol dictated communication or interpersonal contact; asking someone to provide a specimen by voiding or spitting into a specimen container; and conducting research interviews or administering questionnaires.

- Institutions whose employees or agents obtain the informed consent of human subjects for the research.

- Institutions whose employees or agents obtain for research purposes identifiable private information or identifiable biological specimens from any source for the research. It is important to note that, in general, institutions whose employees or agents obtain identifiable private information or identifiable specimens for non-exempt human subjects research are considered engaged in the research, even if the institution's employees or agents do not directly interact or intervene with human subjects. In general, obtaining identifiable private information or identifiable specimens includes, but is not limited to observing or recording private behavior; using, studying, or analyzing for research purposes identifiable private information or identifiable specimens provided by another institution; and using, studying, or analyzing for research purposes identifiable private

information or identifiable specimens already in the possession of the investigators. In general, private information or specimens are considered individually identifiable [as defined in §45CFR46.102(f)) when they can be linked to specific individuals by the investigator either directly or indirectly through coding systems.

B. Albany State University *Is Not* Engaged in the Research

In cases where Albany State University is not engaged in the research and where no Albany State University facilities or personnel are being used for data collection, review by the Albany State University IRB is not required. For example, marketing research firms may send email to Albany State University students, inquiring about their vacation preferences. If the email addresses are not provided by any Albany State University office, and if there are no Albany State University - associated research personnel, the IRB will not review the study.

In cases where Albany State University faculty, staff, or students are conducting human subjects research at Albany State University *strictly in their capacity as students at another institution*, they must obtain IRB approval from the institution where they have matriculated but the Albany State University will not review the study.

Albany State University would not be considered engaged in research when Albany State University employees:

- Inform prospective subjects about the availability of the research
- Provide prospective subjects with information about the research (which may include a copy of the relevant informed consent document and other IRB approved materials) but do not obtain subjects' consent for the research or act as representatives of the investigators
- Provide prospective subjects with information about contacting investigators for information or enrollment
- Seek or obtain the prospective subjects' permission for investigators to contact them and/or
- Permit use of Albany State University facilities for intervention or interaction with subjects by investigators from another institution.

XXII. Visiting Researchers Participating in Protocols at Albany State University

Albany State University celebrates and fosters collaborative relationships with non-Albany State University researchers and scientists who visit the Institute and who may wish to participate in research projects at Albany State University. In order to ensure appropriate protections for those visitors and for Albany State University faculty and staff, this policy has been developed:

Any non-Albany State University personnel wishing to participate as a researcher on a study involving human subjects must complete a VISITING SCHOLAR AGREEMENT with the Albany State University Office of Research and Sponsored Programs, and must either be named in the original protocol application or be added by amendment to an existing protocol prior to participation in the protocol. The Visiting Scholar's current CV or completed credentials form must be submitted to the Office of Research and Sponsored Programs, and the Visiting Scholar must satisfactorily complete the required CITI training modules. Upon approval by the IRB, such Visiting Scholars may serve as co-investigators working with Albany State University Principal Investigators who are responsible for conducting the research and ensuring compliance with the approved protocol.

The Albany State University has set forth specific requirements that must be met in order for the title of Principal Investigator. These requirements apply not only in regard to IRB protocols, but also for protocols involving rDNA, and for serving as a PI on a sponsored project.

XXIII. Investigator's Responsibilities When Conducting Research Activities Subject to DHHS

Investigators who involve human subjects in their research have several specific responsibilities, some institutional, some regulatory, as indicated below:

A. Investigator Responsibilities Required by Albany State University's Institutional Review Board

All investigators at Albany State University must comply with these *Policies and Procedures* when conducting research involving human subjects. Investigators must:

1. Obtain approval from the Albany State University Institutional Review Board before undertaking research with human subjects.
2. Receive a written letter of approval from the Office of Research and Sponsored Programs to document that IRB review occurred and approval was given. (This document is frequently required by the funding sponsor and by publishers prior to publication in refereed journals).
3. Conduct every aspect of the project as approved by the Albany State University IRB.
4. Seek IRB review and approval prior to revising the protocol. (The only exception to this policy is in situations where changes in protocol are required to eliminate apparent, immediate hazards to the subject).
5. Promptly report any unanticipated problems involving risks to subjects or others.
6. Assume full responsibility for selecting subjects in strict accordance with the inclusion/exclusion criteria outlined in the application materials.

7. Use only Albany State University IRB-approved, forms in the consent process.
8. Comply with the applicable DHHS and FDA regulations, including the investigator responsibilities specified by both agencies.

B. Investigator Responsibilities Required by DHHS Regulations at §45CFR46

1. IRB Review and Approval

Investigators are responsible for obtaining IRB approval before beginning any human subjects research (§45CFR46.109(a) and (d)). Investigators are responsible for providing the IRB with sufficient information and related materials about the research (e.g., grant applications, research protocols, sample consent documents) so that the IRB can fulfill its regulatory obligations, including making the required determinations under §45CFR46.111 and, if applicable, subparts B, C and D. Investigators should follow institutional *Policies and Procedures* for IRB review that are required by HHS regulations at §45CFR46.103(b)(4).

Investigators play a crucial role in protecting the rights and welfare of human subjects and are responsible for carrying out sound ethical research consistent with research plans approved by an IRB. Along with meeting the specific requirements of a particular research study, investigators are responsible for ongoing requirements in the conduct of approved research.

2. Informed Consent

Investigators are responsible for obtaining and documenting the informed consent of research subjects or their legally authorized representatives, unless the IRB approves a waiver of informed consent, or a waiver of documentation of informed consent, respectively (§45CFR46.116, §45CFR46.117). Investigators must give a copy of the informed consent document to each research subject (or the subject's legally authorized representative), and keep the signed original or a copy of it for their records (§45CFR46.117(a); §45CFR46.115(b)). When the documentation requirement is waived, the IRB may require investigators to provide subjects with a written statement regarding the research (§45CFR46.117(c)).

3. Amendments

Investigators are responsible for obtaining prior approval from the IRB for any modifications of the previously approved research, including modifications to the informed consent process and document, except those necessary to eliminate apparent immediate hazards to subjects (§45CFR46.103(b)(4)). If investigators wish to modify an ongoing IRB-approved research study, they must submit a request to the IRB and receive IRB approval before implementing the proposed modification, unless the change is designed to eliminate an apparent immediate hazard to subjects (§45CFR46.103(b)(4)). If the investigators change the research in order to eliminate apparent immediate hazards to subjects without prior IRB approval, they should report those changes promptly to the IRB. The HHS protection of human subjects regulations allow for expedited review and approval of requests for minor changes in previously approved studies (§45CFR46.110(b)(2)).

4. Amendments that Render Exempt Research Nonexempt

Investigators should consult with the Associate Vice President of the Office of Research and Sponsored Programs whenever questions arise about whether planned changes to an exempt study [defined at §45CFR46.101(b)] might make that study nonexempt human subjects research. The designated entity at Albany State University for making a determination of exemption is the Institutional Review Board. If a determination of exemption is made by an authorized member of the IRB, the Office of Research and Sponsored Programs will issue a letter of exemption.

Investigators at Albany State University do not have the authority to make an independent determination that human subjects research is exempt.

5. Progress Reports and Continuing Review

Investigators are responsible for ensuring that progress reports and requests for continuing review and approval are submitted to the IRB in accordance with the policies, procedures, and actions of the IRB as referenced in the institution's OHRP-approved Federalwide assurance (§45CFR46.103(b)(4), §45CFR46.109(e).

Investigators are responsible for fulfilling requirements associated with continuing review in time for the IRB to carry out review prior to the expiration date of the current IRB approval. Investigators are responsible for submitting all required materials and information for the IRB to meet its regulatory obligations, and should follow the institutional policies and procedures for continuing IRB review of research that are required by HHS regulations at §45CFR46.103(b)(4) and referenced in the institution's OHRP-approved Federalwide assurance. OHRP guidance regarding continuing review is available at http://www.hhs.gov/ohrp/policy/continuingreview2010.html

If IRB approval of a specific study expires before continuing review and approval occur, investigators must stop all research activities involving human subjects related to that study (§45CFR46.103(b)), except where they judge that it is in the best interests of already enrolled subjects to continue to participate. When investigators make this judgment, they must promptly notify the IRB (§45CFR46.103(b)(5)). When the IRB reviews the investigator's decision, it may decide whether it is in the best interests of already enrolled subjects to continue to participate in the research by considering the best interests of subjects either one at a time or as a group. If an IRB determines that it is not in the best interests of already enrolled subjects to continue to participate, investigators must stop all human subjects research activities, including intervening or interacting with subjects, or obtaining or analyzing identifiable private information about human subjects (§45CFR46.103(b)). Investigators may resume the human subjects research activity once continuing review and approval by the IRB has occurred.

6. Continuing Review When Data Collection Is Completed

If all research-related interventions or interactions with human subjects have been completed,

and all data collection and analysis of *identifiable private information* described in the IRB-approved research plan have been finished, then the research study should be closed.

If data analysis will continue, even though the study is closed to enrollment, investigators are required to obtain continuing approval *in certain cases*. When identifiable private information is being analyzed, the study must remain open and undergo continuing review by the IRB.

IRB review is not required for data analysis ONLY when data are not identifiable personal information. Identifiable personal information can be rendered unidentifiable by stripping all identifiers and destroying all codes and links to coded identities. There must be no remaining link to personal information.

Study Status	**Identifiable Personal Information?**	**Continuing Review Requirements**
Continuing data analysis under the original research intent of the approved protocol	YES	Expedited 8*, under additional risk have been identified; submit continuing application
Continuing data analysis under the original research intent of the approved protocol	NO	Expedited 8*, unless additional risks have been identified. Expedited 8*, if original review was by Full Board. Submit continuing application
Data analysis under new research intent	YES	Expedited or full board, depending on the data type
Data analysis under new research intent	NO	Exempt 4

*Per §45CFR46.110 (F), under Expedited Category (8), an expedited review procedure may be used for the 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.

Once a study has been completed, investigators must submit a study closure report describing disposition of subject data. Data, including identifiable private data, may be retained by investigators, if consistent with the IRB-approved research plan. Investigators must continue to honor any data confidentiality assurances, and identifiable private health data must be secured in accordance with guidance in Section XX of these policies,

"Health Insurance Portability and Accountability Act (HIPAA) for Protected Health Information."

Investigators also should honor any other commitments that were agreed to as part of the approved research, for example, providing information about the study results to research subjects, or honoring commitments for compensation to research subjects for research participation.

7. Records the Investigator Must Keep

The HHS protection of human subjects regulations require institutions to retain records of IRB activities and certain other records frequently held by investigators for at least three years after completion of the research (§45CFR46.115(b)).

Documentation of the informed consent of the subjects - either the signed informed consent form or the short form and the written research summary - are records related to conducted research [§45CFR46.115(b)] that *must be retained by investigators for at least three years after completion of the research*, unless the IRB waived the requirement for informed consent or the requirement for documentation of informed consent (§45CFR46.117).

Investigators must retain the records in hardcopy, electronic or other media form accessible for inspection and copying by authorized representatives of HHS at reasonable times and in a reasonable manner (§45CFR46.115(b)). Retention of multiple copies of each record is not required. Investigators should follow the institution's *Policies and Procedures* for retaining records. If investigators who have been designated to retain records on behalf of the institution leaves that institution, the investigators and the institution should identify the successor responsible for maintaining those institutional records, either at the original institution or wherever the records are relocated, for the period of time required under HHS regulations at §45CFR46.115(b). Other regulations or policies may apply to the retention of records, including study data.

8. Additional DHHS Regulatory Requirements

In certain circumstances, investigators are responsible for meeting the following additional regulatory requirements:

- Providing to the IRB prompt reports of any unanticipated problems involving risks to subjects or others §45CFR46.103(b)(5);
- Providing to the IRB prompt reports of serious or continuing non-compliance with the regulations or the requirements or determinations of the IRB (§45CFR46.103(b)(5)); and

C. Conflict of Interest

A conflict of interest occurs when there is a divergence between an individual's private interests and his or her professional obligations to the Institute, such that an independent observer might reasonably question whether the individual's professional actions or decisions are influenced by considerations of personal gain, financial or otherwise. A conflict of interest depends on the situation, and not on the character or actions of the individual.

Conflicts of interest are common and practically unavoidable in a modern research university. At the Albany State University, conflicts of interest can arise out of the fact that the research mission of the Institution foster the transfer of knowledge gained through research and scholarship to the private sector. Two important means of accomplishing this mission include faculty consulting and the commercialization of technologies derived from faculty research. It is appropriate that faculty be rewarded for their participation in these activities through consulting fees and sharing in royalties resulting from the commercialization of their work. These rewards may be misunderstood or misconstrued and must therefore be carefully managed and appropriately disclosed.

Investigators who have a substantial financial interest in the outcome of the research, and those whose family members have a substantial financial interest in the outcome of the research, must, during the consent process, disclose the conflict to potential subjects. This includes providing a written disclosure on the consent form to explain and document the disclosure.

An appropriately managed conflict that is fully disclosed to participants does not always negatively affect recruitment. Appropriately managed conflicts are registered with the Albany State University. Questions should be forwarded to the Office of Research and Sponsored Programs.

There will be cases in which the Office of Research and Sponsored Programs has a financial interest in the research project, and in those cases, disclosure must likewise be made and documented during the consent process.

Finally, no investigator who is a member of the reviewing IRB participates in the review of any study on which he has a potential conflict of interest or is named on the research team.

XXIV. Amendments and Exceptions

A. Amendments and Other Proposed Changes

All *amendments* to protocols must be approved by the IRB before implementation of the revised study or use of a revised consent/permission/assent form. *All proposed changes* to procedures, recruitment, risk/benefit, personnel on the research team, funding sources, and any other aspect of the study are to be submitted to the IRB for review via IRBNet *prior to their implementation*.

In accord with §21CFR56.110(b), the IRB utilizes expedited review procedures to review minor changes in ongoing previously-approved research during the period for which approval is authorized. An expedited review may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB.

When a proposed change in a research study is not minor (e.g., procedures involving increased risk or discomfort are to be added), then the IRB must review and approve the proposed change at a convened meeting before the change can be implemented. The only exception is a change necessary to eliminate apparent immediate hazards to the research subjects [§21CFR56.108(a)(4)]. In such a case, the change must be reported to the IRB promptly. The IRB will then review the change to determine that it is consistent with ensuring the subjects' continued welfare.

1. Consent Addendum

Changes to consent/permission/assent forms may be required as a result of an amended protocol, or subsequent to review of adverse events (i.e., addition to the risks section of the consent form). The revised version should be used to consent new subjects for enrollment in the study. *However, in order to inform subjects who are already enrolled in the study of the changes to the study, the following format should be used.* If the study involves minors, an additional addendum, directed to the parent(s), and a revised assent form should be drafted as well. A sample follows.

Albany State University
Addendum to Consent Form

Project Title:

Investigators:

You have already agreed to be a volunteer in the research study referenced above. The consent form that you signed (attached) stated that you would be told of any new information that might affect your willingness to continue in this study.

This addendum serves to tell you that *…(e.g., your participation will be extended another 3 Weeks….OR…An additional 3 tsp. of blood will be taken at your 4th visit…. …etc.).*

(If applicable, explain why the change is being implemented, and provide details regarding relevant changes to risks, benefits, etc. that occur as a result of the revised protocol.)
You are reminded that:

- All other information from the original consent form remains unchanged,
- Your participation in this study continues to be voluntary. You do not have to be in this study if you don't want to be.
- You have the right to change your mind and leave the study at any time without giving any reason, and without penalty.
- Any new information that may make you change your mind about being in this study will be given to you.
- You will be given a copy of this consent addendum to keep.
- You do not waive any of your legal rights by signing this consent form.

If you have any questions about the study, you may contact [Dr. P. Investigator], at telephone (XXX) XXX-XXXX.

If you have any questions about your rights as a research subject, you may contact:

Office of Research Sponsored Programs
Albany State University
(229) 430-3690

If you sign below, it means that you have read (or have had read to you) the information given in this consent form addendum, and you would like to continue to be a volunteer in this study.

Subject Name

_____
Subject Signature Date

B. Protocol Exceptions

A *protocol exception* differs from an amendment in that an exception involves a single subject (or, very rarely, a small number of subjects) and does not constitute failure to comply with the approved protocol. An exception is not a permanent change to the research protocol and must

be approved by the IRB prior to implementation. Exceptions generally involve the enrollment of a subject who does not meet the approved inclusion criteria. Enrollment of such subjects requires justification, including convincing evidence that participation is in the best interest of that subject.

If the study involves an investigational drug, device, or biologic, prior approval by the sponsor is also required. If the research involves an investigational device *and* the exception may affect the scientific soundness of the research plan or the rights, safety, or welfare of the subjects, Food and Drug Administration (FDA) pre-approval is required *[§21CFR812.150 (4)].*

The PI is responsible for obtaining prior approval from the IRB for exceptions. Protocol exceptions may be submitted online via IRBNet and, if applicable, documentation of sponsor and FDA approval must be uploaded with the exception request. If appropriate, information sheets for subjects and/or revised consent or informational scripts must be submitted.

XXV. Protocol Deviations

A protocol deviation is defined as any change to, or departure from, the approved protocol that is not approved by the IRB prior to its initiation or implementation, OR any deviation from standard operating procedures, Good Clinical Practices (GCPs), federal regulations, or institute policies.

A. Protocol Deviations

The PI must report a major protocol deviation to the Office of Research and Sponsored Programs as soon as possible after becoming aware that it occurred, but always within seven days of its occurrence.

1. Major Protocol Violations

Violations meeting any of the following criteria are considered major protocol violations:

- A *serious failure* by the study team to comply with the protocol, standard operating procedures, good clinical practices, or with federal, state or local regulations. Such violations may not be intentional. *(Serious failure is non-compliance that adversely affects the rights and welfare of subjects or places them at increased risk of harm).*
- *Continuing failure* of the study team to comply with the protocol, standard operating procedures, good clinical practices, or with federal, state or local regulations. Such violations may not be intentional. (*Continuing failure is a pattern of non-compliance that is willful or that indicates a lack of knowledge that may increase the likelihood of an adverse effect on the rights and welfare of subjects or may place them at an increased risk of harm*.

- Subject safety or risk/benefit ratio is impacted by the violation, even if actual harm does not result.
- The violation significantly damages the completeness, accuracy and reliability of the data collected;

Regardless of their potential impact on subject safety or on the risk/benefit ratio of the protocol, these are considered major protocol violations and require immediate reporting to the Office of Research Compliance:

- Consenting not done in conformance with the approved plan (subjects not consented, or consented after study began);
- Inclusion or exclusion criteria not followed;
- Dosing errors.

2. Minor Protocol Deviations

Minor protocol deviations are just that—minor. They do not constitute a serious failure to comply with the protocol, standard operating procedures, good clinical practices, or with federal, state or local regulations. Minor protocol deviations do not constitute a continuing failure to comply, nor do they impact subject safety or substantively alter the risk/benefit ratio. Subject safety or risk/benefit ratio is not impacted by the violation, and the minor violation does not significantly damage the completeness, accuracy and reliability of the data collected.

Minor deviations must be reported to the Office of Research and Sponsored Programs within 30 days of their occurrence.

XXVI. Adverse Events and Unanticipated Problems

Federal regulations at §21CFR56.108(b)(1) and at §45CFR46.103(b)(5) require the IRB to follow written procedures for ensuring prompt reporting to the IRB of any unanticipated problems involving risk to human subjects or others.

Guidance from the Office for Human Research Participants (OHRP) states that, before research is approved and the first subject enrolled, the investigator(s) and the IRB should give appropriate consideration to the spectrum of adverse events that might occur in subjects. In particular, in order to make the determinations required for approval of research under HHS regulations at §45CFR46.111(a)(1), (2), and (6), the IRB needs to receive and review sufficient information regarding the risk profile of the proposed research study, including the type, probability, and expected level of severity of the adverse events that may be caused by the procedures involved in the research. The investigator also should describe how the risks of the research will be minimized.

A. Adverse Events

The FDA defines an adverse event as *any undesirable experience associated with the use of a medical product in a patient*. The HHS regulations at §45CFR46 do not define or use the term *adverse event*, nor is there a common definition of this term across government and non-government entities. The Office for Human Research Protections (OHRP) utilizes this definition: *An adverse event is "Any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research (modified from the definition of adverse events in the 1996 International Conference on Harmonization E-6 Guidelines for Good Clinical Practice)."*

Adverse events encompass both physical and psychological harms. They occur most commonly in the context of biomedical research, but they can also occur in social and behavioral research.

An *adverse event* may be both serious and unanticipated.

1. Serious Adverse Events

A *serious adverse event* is one that is fatal, life-threatening, persistent, significantly disabling or incapacitating, requires inpatient hospitalization or prolongation of hospitalization, results in congenital anomaly or defect, and/or that is a significant medical incident. (A significant medical incident is considered a serious, study-related adverse event because it may jeopardize the subject's health and may require medical or surgical intervention to prevent a poor outcome.)

The FDA requires that serious events be reported when the patient outcome is:

- **Death:** Report if the patient's death is suspected as being a direct outcome of the adverse event.
- **Life-Threatening:** Report if the patient was at substantial risk of dying at the time of the adverse event or it is suspected that the use or continued use of the product would result in the patient's death. *Examples: Pacemaker failure; gastrointestinal hemorrhage; bone marrow suppression; infusion pump failure which permits uncontrolled free flow resulting in excessive drug dosing.*
- **Hospitalization (initial or prolonged):** Report if admission to the hospital or prolongation of a hospital stay results because of the adverse event. *Examples: Anaphylaxis; pseudo membranous colitis; or bleeding causing or prolonging hospitalization.*
- **Disability:** Report if the adverse event resulted in a significant, persistent, or permanent change, impairment, damage or disruption in the patient's body function/structure, physical activities or quality of life. *Examples: Cerebrovascular accident due to drug-induced hypercoagulability; toxicity; peripheral neuropathy.*

- **Congenital Anomaly:** Report if there are suspicions that exposure to a medical product prior to conception or during pregnancy resulted in an adverse outcome in the child. *Examples: Vaginal cancer in female offspring from diethylstilbestrol during pregnancy; malformation in the offspring caused by thalidomide.*
- **Requires Intervention to Prevent Permanent Impairment or Damage:** Report if you suspect that the use of a medical product may result in a condition which required medical or surgical intervention to preclude permanent impairment or damage to a patient. *Examples: Acetaminophen overdose-induced hepatotoxicity requiring treatment with acetylcysteine to prevent permanent damage; burns from radiation equipment requiring drug therapy; breakage of a screw requiring replacement of hardware to prevent malunion of a fractured long bone..*

2. Unanticipated Adverse Events

An *unanticipated adverse event* is one that results from a study intervention and was not expected or anticipated. Expected adverse events that occur with greater frequency or severity than expected may be characterized as unanticipated adverse events.

3. Unanticipated Adverse Device Effects (UADEs)

The Food & Drug Administration (FDA) investigational device exemption (IDE) regulations define an *unanticipated adverse device effect (UADE)* as *"any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects." (*§21CFR812.3(s))

4. When Adverse Events Must Be Reported

Investigators are required to *report via IRBNet to the Institutional Review Board within ten days of its occurrence* any serious problem, serious adverse event, or other outcome that occurs more frequently or with greater severity than anticipated. Further, if any event(s) cause the suspension, whether temporary or permanent, of a research study involving human subjects, the IRB must be informed within ten days. Such reports to the IRB must describe the adverse events' relevance and significance to the study and whether there is a change in the risk of participation.

When the ASU PI is managing a study site on an NIH-supported multi-center clinical trial, in lieu of receiving individual adverse event reports from each of the clinical sites, the ASU IRB should receive from the investigator a written summary report whenever a data safety monitoring board (DSMB) review has taken place. All other adverse events are to be reported within thirty calendar days via IRBNet.

Adverse events are to be reported to the ASU IRB via IRBNET. Very serious and unanticipated events may be immediately reported by telephone to the Office of Research and Sponsored Programs at 229-430-3690. Investigators are responsible for the accurate documentation, investigation and follow-up of all possible study-related adverse events.

a. PI-Initiated Studies

When the investigator is the study sponsor--that is, when he is the holder of the Investigational New Drug (IND) or Investigational Device Exemption (IDE)—he is responsible for reporting serious adverse events directly to the IRB and to the Food and Drug Administration (FDA). FDA requires use of the Form #3500a (Mandatory Medwatch Form).

b. Industry Sponsored Studies

When the study is industry-sponsored, the PI will also be required to report serious and unanticipated adverse events and problems to the sponsor, as well as to the ASU IRB. This form may also be used to voluntarily report serious adverse events, potential and actual medical product errors, and product quality problems associated with the use of FDA-regulated drugs, biologics, devices and dietary supplements. Study sponsors may have different reporting processes.

Unanticipated Adverse Device Effects (UADEs) must be reported to the IRB and the sponsor within 10 working days after the investigator first learns of the effect (§812.150(a)(1)). Sponsors must immediately evaluate reports of an UADE and report the results to the FDA, all reviewing IRBs, and participating investigators within 10 working days after first receiving notice of the effect (§812.46(b), 812.150(b)(1)).

B. Unanticipated Problems

An unanticipated problem is an event that was not anticipated or foreseen, involves risk to subjects and, in the judgment of the investigator, was related to or caused by the research activity. The loss of a laptop computer containing confidential information about subjects is an example of an unanticipated problem. In such cases, while subjects may not be physically harmed, the potential breach of confidentiality may cause them anxiety or embarrassment.

1. Requirement for Investigators to Report Unanticipated Problems

Serious unanticipated problems must be reported to the Office of Research and Sponsored Programs by the Principal Investigator within ten working days of their occurrence. Very serious and unanticipated events may be immediately reported by telephone to the Office of Research and Sponsored Programs at 229-436-3690. Other unanticipated problems should be reported within thirty days. Any protocol deviation to mitigate immediate risk or potential harm should also be reported. These reports may be submitted online via IRBNet.

Such reports must include a complete description of what happened, when and where the event took place, and any resulting harm or injury to a subject or others. Principal Investigators must report to the Office of Research and Sponsored Programs any injury to a human subject; unanticipated problems; new information that affects risk/benefit, and any evidence of research misconduct involving risks to research subjects. Reports of unanticipated problems should explain why the event represents a problem for the study and why it was unanticipated.

2. Requirement for Investigators to Monitor Problems

The Principal Investigator must monitor anticipated problems, subject complaints and any other issues that do not constitute an unanticipated problem requiring reporting to the IRB. These events should be recorded in a log maintained by the PI or research staff. The PI should consider whether such problems, complaints, or issues necessitate modification of the consent document or other protocol amendment.

C. Institutional Review Board Response to Reports of Adverse Events and Unanticipated Problems

Serious adverse events that occur on-site will be reviewed by the full committee at a convened meeting. Those occurring at another center conducting the study (i.e., in the case of multicenter studies) will be reviewed by the IRB in a timely manner.

The IRB may suspend or terminate approval of research at its site when there is unexpected serious harm to subjects. Such action shall be with the majority vote of IRB members at a convened meeting with a quorum. The Institutional Official will be immediately informed when the IRB makes such a determination. The Principal Investigator will also be immediately informed and will be provided a written statement of the action and the reasons for it. The IRB will also inform the appropriate Department or Agency head, the Office for Human Research Protections and the FDA, if an investigational new drug or device is involved. The IRB will communicate concerns to the sponsor of the study if it believes that the safety of study participants is in jeopardy.

The IRB Chair and the Institutional Official shall each have independent authority to suspend a study immediately when, in their judgment, human subjects are at risk of immediate harm. Such actions shall be reported to the IRB at the next convened meeting, when the Board will determine whether such suspended study may continue.

These actions and IRB deliberations shall be documented in the meeting minutes and be retained in accordance with records requirements.

D. Incidental Findings

Incidental findings are possible medical abnormalities that may have clinical implications and are observed in the course of research studies but are unrelated to the topic under study. Examples might include:

- A study involving fractionation of normal human blood suggests a potential infection
- A baseline study of mental status indicates a psychiatric condition
- A screening protocol for an exercise intervention identifies a cardiac insufficiency
- A brain imaging study of depressed individuals reveals a potential structural abnormality (From *Nature*, Vol. 433. January, 2005, p. 185.).

No National Institutes of Health (NIH) policies/guidance specifically address incidental findings, however, NINDS, NIDA, NIBIB, NIMH, NIA and Stanford University sponsored a meeting in 2005 on "Detection and Disclosure of Incidental Finding in Neuroimaging Research." See more information at http://www.ninds.nih.gov/news_and_events/proceedings/ifexecsumma ry.htm.

At this point, the NIH Office of Extramural Research (OER) suggests that investigators who propose studies that may result in incidental findings describe their plans for addressing incidental findings in the Human Subjects section of their applications as follows:

- How observed incidental findings will be handled by research staff, and
- How plans for handling incidental findings will be presented to potential participants during the informed consent process.

More details are available at http://grants.nih.gov/grants/policy/hs/faqs_aps_hsp.htm#342 .

XXII. Institutional Review Board Responsibilities and Approval Processes

In keeping with its charge to safeguard the rights and welfare of human participants in research, the Institutional Review Board has several specific responsibilities, and processes in place to ensure that the IRB is in compliance with those requirements. Among the most important IRB responsibilities are initial protocol review, continuing protocol review, reporting findings & actions, determining review frequency, when to require outside verification of no changes since previous review, reporting proposed changes, and reporting unanticipated problems and continuing non-compliance to the Institutional Official, the Office for Human Research Protections, the Food and Drug Administration, National Institutes of Health, and so on. Those IRB processes are described here.

A. Initial Protocol Review

The Albany State University Institutional Review Board reviews protocols in accordance with the FDA and HHS requirements and as described in these policies. The components of a protocol application are described in section IX of these *Policies and Procedures*: "Procedures for Obtaining Institutional Review Board Approval."

The IRB has authority to approve, to require modifications in (to secure approval), or to disapprove all research activities covered by this policy. Research that has been approved by the Albany State University IRB may be subject to further appropriate review and approval by officials of the institution. However, those officials may not approve research if it has not been approved by the Albany State University IRB.

Protocols are submitted online via www.IRBNet.org to the Office of Research and Sponsored Programs. The IRBNet system logs in the protocol, assigns it a unique identifying number, and adds the protocol to the agenda for the next convened meeting of the IRB. If the study qualifies for exempt or expedited review, the Compliance Officer will forward the protocol and all other supporting documentation to members of the IRB in order for a review to be conducted. Where applicable, approvals of protocols, amendments, and/or continuing review applications must be given by a voting member of the IRB.

1. Requirements for Approval

In order to approve a research activity, the Albany State University IRB must determine that all of the following requirements are satisfied:

- No Albany State University IRB members will participate in the review of any study on which they are an investigator or co-investigator or where a potential for personal conflict of interest exists.
- Risks to subjects are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and, whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
- Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects and the importance of the knowledge that may reasonably be expected to result.
- Selection of subjects is equitable, in relation to the purposes of the research and the setting in which the research will be conducted.

- Informed consent is appropriately obtained. The IRB shall require that information given to subjects as part of informed consent is in accordance with §46.116. The IRB may require that information, in addition to that specifically mentioned in §46.116, be given to the subjects when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of subjects. The IRB shall require documentation of informed consent or may waive documentation in accordance with §46.117. To ensure PI compliance with IRB policy regarding consent, the IRB may request a redacted copy of signed consent forms used to enroll subjects. An IRB shall notify investigators and the institution in writing of the outcome of the review, which may be to approve or disapprove the proposed research activity, or to require modifications to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.
- Where appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
- Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
    - Where some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as minors, persons with acute or severe physical or mental illness, or persons who are economically or educationally disadvantaged, appropriate additional safeguards have been included in the study to protect the rights and welfare of these subjects.

2. Review for Scientific Merit

While federal regulations governing Institutional Review Boards do not clearly require IRB review of the scientific validity of an investigator's research design, the IRB determines whether risks to subjects are reasonable in relation to the importance of the knowledge that may reasonably be expected to result. The (then) Office for Protection from Research Risks issued guidance stating that *one of the ethical justifications for research involving human subjects is the social value of advancing scientific understanding and promoting human welfare by improving health care. But if a research study is so methodologically flawed that little or no reliable information will result, it is unethical to put subjects at risk or even to inconvenience them through participation in such a study*" (OPRR, 1993: 41).

With this guidance in mind, the Albany State University IRB generally leaves thorough scrutiny of the research design to the peer review process, if the project will receive funding from an external agency. The proposals of investigators not submitting to external agencies may be examined more closely for research design flaws and, depending on their seriousness, these flaws may need to be corrected before IRB approval is granted.

3. IRB Determination Regarding Risk

The IRB must determine that the following requirements are satisfied prior to issuing approval for proposed research involving human subjects.

a. Risks to subjects are minimized: (i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
b. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies that subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

4. Determining Review Frequency

At the time of initial review, the IRB determines whether an independent data and safety monitoring board or committee is required, and also sets a date for reevaluating the research project. The IRB may determine that certain protocols necessitate review more frequently than every twelve months. Such protocols typically pose a higher risk of harm to subjects and/or involve a vulnerable population or very sensitive topic; these protocols generally undergo full board review. Concerns about the Principal Investigator's compliance can also prompt a requirement for more frequent review. The IRB shall determine at the time of review whether a shorter period of approval is appropriate, and the IRB will establish the required reporting schedule at approval. At its discretion, the IRB may require the investigator to report on progress at intervals of the board's choosing.

IRB approval periods are granted on the basis of degree of risk associated with the particular protocol, but never for a period longer than one year minus one day. During the course of a study, unexpected side effects may occur or knowledge resulting from another research project may become available. The IRB may then need to reassess the balance of risks to benefits. In light of the reassessment, the IRB may require that the research be modified or halted altogether. Alternatively, special precautions or criteria for inclusion may be relaxed. Between IRB reviews, it is largely the researchers' responsibility to keep the IRB informed of significant findings that affect the risk/benefit ratio. In larger studies or clinical trials, a data and safety monitoring committee may be responsible for keeping the IRB up-to-date. Even isolated incidents of unanticipated adverse reactions must be reported to the IRB. The IRB must then decide whether the research should be modified or been terminated. In addition, a report from one research activity may sometimes be relevant to the evaluation of another. In such cases, the IRB may set an approval period of a few weeks or months, instead of one year minus one day.

5. Review Lead-Time Considerations

The length of time required for IRB review of a protocol is necessarily dependent on the review category. Exempt category projects are generally reviewed within 1-2 weeks of receipt date by the Compliance Officer. Protocols reviewed under expedited procedures are sent to board members on a regular basis. Review is completed generally within three weeks of receipt date. Protocols requiring full board review at a convened meeting of the IRB must be submitted by the deadline.

For protocols supporting a funded project, IRB materials should be submitted far enough in advance of the grant submission deadline to allow for two successive meetings of the IRB. Consultation with the Compliance Officer early in the planning stages is recommended in order to facilitate the coordination of the various deadlines to which the research activity may be subject for review. There are separate campus committees that are federally and/or state mandated to review research for compliance with regulations that govern involvement of, for example, animal subjects, recombinant DNA, and radioisotopes.

6. IRB Disapproval of Protocols

If the IRB does not approve a human subjects research activity, the board shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing within 14 calendar days of receipt of written notification. If the investigator is not satisfied with the decision subsequently reached by the Albany State University IRB, he or she may request re-review by the Albany State University IRB whenever significant changes are made to the research protocol or significant new information becomes available.

While all reviewers may exercise all authority of the IRB to review projects qualifying for expedited or exempt review, no individual member, including the Chair, may disapprove a research protocol. Any proposed disapproval is to be referred to the full board for review and disposition. Disapproval of a research protocol must be determined by a majority vote at a convened meeting of the full board where a quorum is present.

7. Review by Institution

Research covered by this policy that has been approved by the IRB may be subject to further review and approval or disapproval by officials of the institution. However, those officials may not approve the research involving human subjects if it has not been approved by an IRB. *An IRB disapproval cannot be overruled by any institutional officer or official.*

B. Continuing Review Procedures

The federal regulations require that Institutional Review Boards reevaluate research projects at intervals appropriate to the degree of risk but not less than once a year. Periodic review of the research activity is necessary to determine whether the risk/benefit ratio has shifted, whether there are unanticipated findings involving risks to subjects, and whether any new information regarding the risks and benefits should be provided to subjects. It is important to note that the risk/benefit ratio may change over time.

1. Automated Notification of Pending Expiration

Approximately 60 days prior to the end of the approval period, investigators will receive an automated email reminding them to submit continuation materials for the next approval period. A second automated email notice is sent about a month prior to expiration. The investigator is strongly urged to be aware of application deadlines and review lead-time considerations to ensure uninterrupted coverage of project approval. Continuations requiring full board review must be submitted with sufficient lead time.

2. Materials Required for Continuing Review

Progress Report: The progress report comprises a major portion of the continuation application. The progress report summarizes project activities over the past approval period; states number of subjects participating; describes adverse events, new information learned, results of research, and any publications. It further summarizes adverse events and unanticipated problems. In many cases, it is sufficient for the Principal Investigator to provide a brief statement that there have been no unanticipated problems and that adverse events have occurred at the expected frequency and level of severity as documented in the research protocol, the informed consent document, and any investigator brochure.

Consent/Permission/Assent form(s) *to be used for the upcoming approval period.* The Principal Investigator is to provide clean, unstamped copies of all consent documents to be utilized in the renewal period. Once reviewed and approved, the IRB will date-stamped these with the new approval period.

Signatures: The continuation application must be submitted through IRBNet. As with original protocols, continuation applications must have the electronic signatures of the principal investigator, Chair of the department, Dean of the college or the Provost and VPAA. In the case of undergraduate or graduate student researcher, their advisor will be listed as the principal investigator on the submitted protocol.

3. Review Lead-Time Considerations

Continuing reviews are as rigorous as original protocol reviews, so investigators should plan on an equivalent amount of time to obtain continuing approval. As always, investigators are reminded to submit continuation materials well in advance of meeting dates when full board review is required.

4. Maximum Number of Continuing Reviews

A research project may be renewed a maximum of four times, after which a new, complete application must be submitted to the IRB for review, incorporating all amendments, updated consent, permission, and assent forms, funding information, etc. that have occurred since the study's inception.

Studies closed to enrollment but with ongoing data analysis after four renewals are not subject to the requirement for a rewrite of the protocol. The IRB will review such continuations in accordance with the process described herein.

5. Expiration of Approvals

When IRB approval expires, all activities involving human subjects must be stopped immediately, *including data analysis,* except in extraordinary cases involving an intervention that must continue for subject safety. Expired IRB protocols may only continue after the IRB reviews and approves a continuation application. If no continuation application is received within thirty days after expiration, the protocol will be closed by the Office of Research Sponsored Programs. The investigator will have to submit an entirely new protocol if he wishes to take up that same work in the future.

6. Outside Verification That No Material Changes Have Occurred Since Previous Review

During the continuing review process, the Principal Investigator is asked to specify what changes, if any, have occurred since the previous IRB review. If deemed appropriate, the Office of Research and Sponsored Programs and/or IRB members may perform a compliance audit to ascertain the degree of compliance.

7. Determining Which Studies Need Verification from Other Sources

The IRB generally relies on the Principal Investigator with an approved protocol to carry out the research as described to, and approved by, the IRB. Sometimes circumstances cause the IRB to require verification from sources other than the investigators regarding information related to the conduct of the study. Such circumstances might include an allegation of investigator misconduct, complaint from a subject, report filed by a third party whistleblower or a random compliance audit by the Office of Research Sponsored Programs.

8. Ensuring that Changes in Approved Research Are Not Initiated without IRB Review and Approval

Investigators must obtain prior IRB approval for any changes in study procedures, except where necessary to eliminate immediate hazards to the participants. (If changes are implemented to eliminate hazards, the IRB must be notified no later than the next business day).

To ensure compliance, the Office of Research and Sponsored Programs informs investigators of this requirement in written IRB approval letters. Investigators also are so informed during required training before they may initiate any study involving human subjects. The Office of Research and Sponsored Programs may conduct random audits of investigator's study records to assess compliance.

9. Reporting IRB Findings and Actions to the Institutional Official

In cases where a previously approved research study is suspended or terminated by the IRB for reasons other than simple expiration of the approval period, the Institutional Official is notified by the Office of Research and Sponsored Programs. Such terminations, suspensions, and other findings and actions are provided in writing to investigators and, in some cases, to their department heads and/or Deans.

10. Reporting Unanticipated Problems, Continuing Non-Compliance, Suspensions and Terminations to Oversight Agencies

Cases of serious or continuing non-compliance; unanticipated problems involving risks to participants or others; and suspension or termination of IRB approval must be reported to federal oversight agencies. The Office of Research and Sponsored Programs prepares such written notification for submission by the Institutional Official to the Office for Human Research Protections, National Institutes of Health, the Food and Drug Administration, and/or the funding agency(ies), as appropriate.

C. Monitoring and Observation of Research by the IRB

The IRB has the authority to inspect records, and to observe (or have a third party observe) the consent process and any research activity that it approves (§45CFR46.109(e). Depending upon the risks of the research and the likelihood that the research could involve risks to subjects that are unforeseeable, the IRB must ensure, if appropriate, that the research includes adequate provisions for monitoring the data collected to ensure the safety of subjects (§45CFR46.111(a)(6)). Such provisions typically would include the following:

- The type of data or events that are to be captured under the monitoring provisions.
- The entity responsible for monitoring the data collected, including data related to unanticipated problems and adverse events, and their respective roles (e.g., the investigators, the research sponsor, a coordinating or statistical center, an independent medical monitor, and/or some other entity).
- The time frames for reporting adverse events and unanticipated problems to the monitoring entity.
- The frequency of assessments of data or events captured by the monitoring provisions.
- Definition of specific triggers or stopping rules that will dictate when some action is required.
- As appropriate, procedures for communicating to the IRB(s), the study sponsor, the investigator(s), and other appropriate officials the outcome of the reviews by the monitoring entity.
- Monitoring provisions should be tailored to the expected risks of the research; the type of subject population being studied; and the nature, size (in terms of projected subject enrollment and the number of institutions enrolling subjects), and complexity of the research protocol.

XXVIII. Non-Compliance

Non-compliance is generally defined as a serious and/or continuing failure by the Principal Investigator or research team to comply with the approved protocol, standard operating procedures, good clinical practices, with federal, state or local regulations, or with Institute policy, including these *Policies & Procedures*. Such violations may or may not be intentional.

A. Responsibility for Proper Conduct of Research Studies Involving Human Subjects

The ultimate responsibility for the conduct of a research project involving human subjects belongs to the Principal Investigator (PI). The Principal Investigator and all other members of the research team must comply with these *Policies and Procedures* and with appropriate federal regulations governing human subjects' protections and with the Albany State University Federalwide Assurance. Research projects must be conducted in accordance with protocols as approved by the Institutional Review Board (IRB) and as outlined in these *Policies and Procedures*.

B. Allegations of Non-compliance

Allegations of non-compliance in a human subjects study should be brought to the attention of the IRB Chair, the Office of Research and Sponsored Programs, or the AVP ORSP. If an alleged non-compliance has caused, or may cause, injury or any other risks to subjects or others, the study shall be immediately suspended at the direction of the Institutional Official, and an inquiry and review by the full IRB or a subset of the IRB shall be ordered.

C. Full Board Review of Allegation of Non-compliance

In the event that a review of non-compliance by the full IRB is warranted, the Office of Research and Sponsored Programs and Chair of the IRB shall notify the IRB and appoint a subcommittee of IRB members to conduct an investigation which will focus on the protection of study subjects. The Institutional Official will be kept informed and may participate in the investigation.

D. IRB Procedures for Resolution of Alleged Non-Compliance

The following points outline the procedures for resolving alleged noncompliance:

1. When a potential non-compliance is reported, the Office of Research and Sponsored Programs will compile appropriate information from the complainant, the protocol file and other sources, and present concerns to the IRB Chair and the Institutional Official.

2. The IRB Chair or Associate Vice President of Research and Sponsored Programs will contact the Principal Investigator for the purpose of fact-finding, to determine whether the alleged non-compliance is intentional, unintentional, or the result of mistake or oversight.
3. If the initial discussion does not result in resolution of the matter, the allegation will be presented at the next IRB meeting by the IRB Chair or Office of Research and Sponsored Programs.
4. An audit of study records may be called by the IRB or Institutional Official. Such audit shall be conducted by an audit team appointed by the IRB Chair, and shall include a subset of IRB members and at least one or Associate Vice President of Research.

In order to make a finding of non-compliance, the IRB must determine that:

1. There were violations of institutional *Policies and Procedures*, the state and/or federal laws or regulations governing research with human subjects, good clinical practices, or Institute policy; and/or
2. There was a material failure to follow the approved protocol; and/or
3. The alleged non-compliance resulted in otherwise unanticipated problems involving risks to subjects.

If any of these are confirmed either through discussions with the investigator or by audit finding, the IRB must then determine whether the non-compliance is serious or continuing. A *serious compliance failure* may adversely affect the rights and welfare of subjects or places them at increased risk of harm. C*ontinuing failure* is a pattern of noncompliance that is willful or that indicates a lack of knowledge that may increase the likelihood of an adverse effect on the rights and welfare of subjects or may place them at an increased risk of harm.

In the event that non-compliance results from administrative oversight that is self-reported by the PI or other individual, the Office of Research and Sponsored Programs shall compile the appropriate information and present the concerns to the IRB Chair and the Institutional Official. The Office of Research and Sponsored Programs will work with the reporting party to correct the non-compliance.

E. Possible Outcomes of Non-compliance Inquiries and Investigations

Serious or continuing failure to comply with these requirements may result in study suspension and, in egregious cases, study termination, return of sponsor funding and the matter being reported to federal agencies and the sponsor. Investigators may also be required to destroy data.

The Principal Investigator is provided written notification of determinations made, with copies to the departmental Chair or Dean, the Institutional Official, Associate Vice President of Research and Sponsored Programs and others as appropriate. Should protocol suspension or termination result, the Office of Research Sponsored Programs will be notified in cases where there is external funding. The Office of Research and Sponsored Programs, in collaboration with the Institutional Official, shall determine whether notification of federal regulatory agencies is also warranted.

Should there be an appearance of research misconduct, the Institute's procedures governing research misconduct will be implemented. Inquiries or investigations into research misconduct do not preclude IRB review and actions.

Confidentiality will be strictly observed during any inquiry and investigation, and due process for the Principal Investigator and members of the research team will be ensured.

F. Guidance on Reporting Incidents (non-compliance) to the Office for Human Research Protections

The Associate Vice President of Research and Sponsored Programs will be responsible for reporting incidents of non-compliance to the Office for Human Research Protections.

June 20, 2011 THIS GUIDANCE REPLACES OHRP'S MAY 27, 2005 GUIDANCE ENTITLED "GUIDANCE ON REPORTING INCIDENTS TO OHRP" This guidance has been updated to clarify what information regarding serious or continuing noncompliance by the institutional review board needs to be reported, to include an e-mail address to report incidents to OHRP, and to update OHRP's contact information.

Scope: This document provides guidance about procedures institutions may use to file incident reports with OHRP. Incident reports include reports of unanticipated problems involving risks to subjects or others; serious or continuing noncompliance with Department of Health and Human Services (HHS) regulations at 45 CFR part 46 or the requirements or determinations of the institutional review board (IRB); and suspension or termination of IRB approval. In particular, OHRP offers guidance on the following topics:

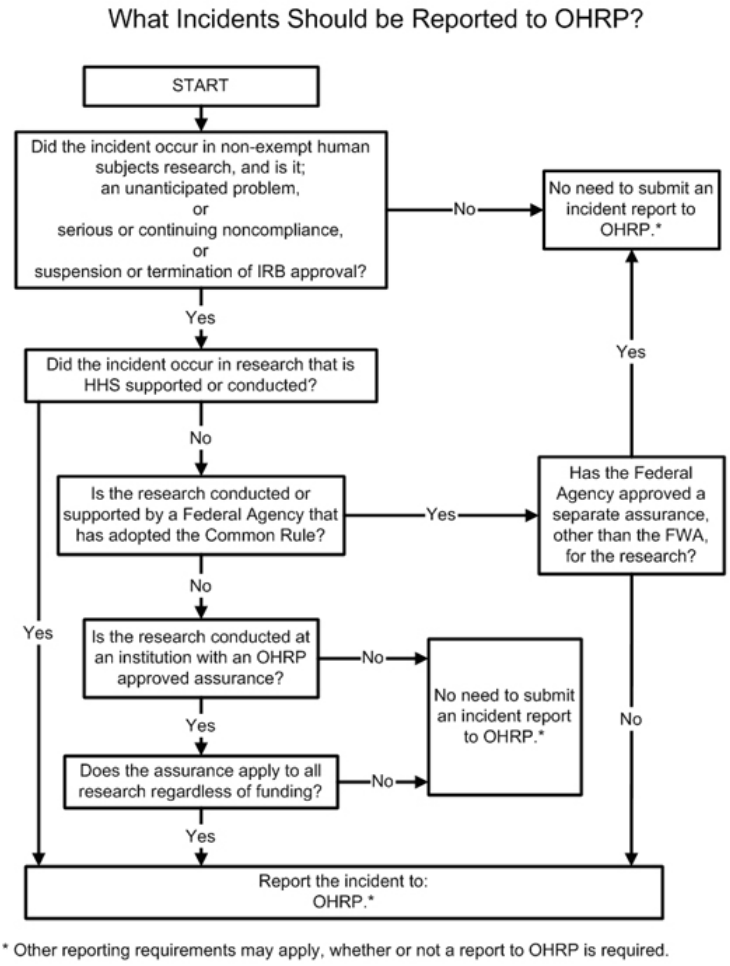
I. Applicability of incident reporting requirements;
II. Information to be included in incident reports;
III. Time frame for reporting incidents;
    - OHRP focus on corrective actions when reviewing incident reports;
    - OHRP's response to incident reports;
IV. Where to send incident reports; and
V. Additional guidance.

Guidance:

I. Applicability of incident reporting requirements

In general, these reporting requirements apply to all nonexempt human subjects research that is: (a) conducted or supported by HHS; (b) conducted or supported by any non-HHS federal department or agency that has adopted the Common Rule and is covered by a Federalwide Assurance (FWA) determined to be appropriate for such research; or (c) covered by an FWA, regardless of funding source.

Federal departments or agencies other than HHS that have adopted the Common Rule may determine that the FWA is not appropriate for certain research that they conduct or support. OHRP notes that these incident reporting requirements are **not** applicable to such research. In such cases, the institution should contact the non-HHS department or agency that supports the research about reporting requirements. See the decision chart below.



II. Information to be included in incident reports

To fulfill the regulatory requirements for reporting incidents, OHRP would consider it acceptable for an institution to comply with written procedures specifying that the following information be included in an incident report submitted to OHRP:

A. For unanticipated problems involving risks to subjects or others:

- Name of the institution (e.g., university, hospital, foundation, school, etc) conducting the research;
- Title of the research project and/or grant proposal in which the problem occurred;
- Name of the principal investigator on the protocol;
- Number of the research project assigned by the IRB and the number of any applicable federal award(s) (grant, contract, or cooperative agreement);
- A detailed description of the problem; and
- Actions the institution is taking or plans to take to address the problem (e.g., revise the protocol, suspend subject enrollment, terminate the research, revise the informed consent document, inform enrolled subjects, increase monitoring of subjects, etc.).

B. For serious or continuing noncompliance:

- Name of the institution (e.g., university, hospital, foundation, school, etc) conducting the research;
- Title of the research project and/or grant proposal in which the noncompliance occurred, or, for IRB or institutional noncompliance, the IRB or institution involved;
- Name of the principal investigator on the protocol, if applicable;
- Number of the research project assigned by the IRB and the number of any applicable federal award(s) (grant, contract, or cooperative agreement);
- A detailed description of the noncompliance; and
- Actions the institution is taking or plans to take to address the noncompliance (e.g., educate the investigator, educate all research staff, educate the IRB or institutional official, develop or revise IRB written procedures, suspend the protocol, suspend the investigator, conduct random audits of the investigator or all investigators, etc.).

C. For suspension or termination:

- Name of the institution (e.g., university, hospital, foundation, school, etc.) conducting the research;
- Title of the research project and/or grant proposal that was suspended or terminated;
- Name of the principal investigator on the protocol;
- Number of the research project assigned by the IRB that was suspended or terminated and the number of any applicable federal award(s) (grant, contract, or cooperative agreement);
- A detailed description of the reason for the suspension or termination; and

- The actions the institution is taking or plans to take to address the suspension or termination (e.g., investigate alleged noncompliance, educate the investigator, educate all research staff, require monitoring of the investigator or the research project, etc.)

III. Time frame for reporting incidents

The regulations at 45 CFR 46.103(a) and (b)(5) do not specify a time frame for reporting, except to say this must be done "promptly." For a more serious incident, this may mean reporting to OHRP within days. For a less serious incident, a few weeks may be sufficient. It may be appropriate to send an initial report, and indicate that a follow-up or final report will follow by the earlier of:

- a specific date; or
- when an investigation has been completed or a corrective action plan has been implemented.

IV. OHRP focus on corrective actions when reviewing incident reports

When reviewing a report of an unanticipated problem, OHRP assesses most closely the adequacy of the actions taken by the institution to address the problem. Likewise, when reviewing reports of noncompliance or suspension or termination of IRB approval, OHRP assesses most closely the adequacy of the corrective actions taken by the institution. In particular, OHRP assesses whether or not the corrective actions will help ensure that the incident will not happen again, with the investigator or protocol in question, with any other investigator or protocol, or with the IRB. Therefore, OHRP recommends that, when appropriate, corrective actions be applied institution-wide.

Reference:

Georgia Technology Institute. (2011). *Research Integrity Assurance.* Retrieved November 2011, from Gearogia Tech: http://researchintegrity.gatech.edu/about-irb/irb-policies-and-procedures/