Texas A&M International University

Institutional Review Board

Policy and Procedures Manual

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1. General Overview

1.1 Institutional Oversight of TAMIU's Federwide Assurance

A. It is the policy of Texas A&M International University's (TAMIU) – Institutional Review Board (IRB) – to uphold its Assurance with the Office for Human Research Protections (OHRP).

B. A copy of TAMIU's Federalwide Assurance (FWA)[1] will be maintained in the Office of Graduate Studies and Research and will be available to the TAMIU community. TAMIU's assurance (see Appendix 1) is based on the following principles:

1. Safeguarding the rights and welfare of human participants in research and other research activities. TAMIU's IRB policies and procedures are designed to protect the rights and welfare of human participants and are effectively applied in compliance with its FWA.(1)
2. TAMIU's staff and students, which comprise its schools, departments, divisions, and facilities are subject to the FWA (1) and this policy. This includes any research for which an Assurance or another formal agreement (e.g., Authorization Agreement (2) or Cooperative Research Project) (3), (4) identifies the TAMIU Institutional Review Board (IRB) as the IRB of Record. (5)
3. TAMIU agrees to uphold the ethical principles of the Belmont Report [6] and apply Department of Health and Human Services (DHHS) regulations, including Subparts A, B, C, & D (7) to all proposed research involving human participants regardless of sponsorship. The ethical principles set forth in the Belmont Report (6) are:
    a. Respect for Persons: Recognition of the personal dignity and autonomy of individuals and special protection of those persons with diminished autonomy;
    b. Beneficence: Obligation to protect persons from harm by maximizing anticipated benefits and minimizing possible risk of harm; and
    c. Justice: Fairness in the distribution of research benefits and burdens.
4. TAMIU further agrees to apply additional regulations such as, the U.S. Food and Drug Administration Human Subject Regulations, (8) and the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (9), when applicable, to research involving human participants under review.

C. Additionally TAMIU's IRB is subject to the guidelines set forth in Texas A&M University System (TAMUS) Policy 15.99.01: Use of Human Participants in Research (Appendix 2).

D. Structure of the IRB.

1. The IRB Committee is appointed as TAMIU Institutional Committees. As such, the IRB Committee serves TAMIU as a whole, rather than a particular school or department, and any institution for which the TAMIU IRB is designated as the IRB of Record (7) in a FWA (1) filed with Office for Human Research Protection (OHRP) (10) with a corresponding Authorization Agreement. (10)

2. TAMIU's Assurance requires that each IRB Committee be approved and registered with OHRP. (10)

E. IRB Authority: Research covered by this policy that has been approved by an IRB may be subject to further appropriate review and approval or disapproval by officials of the institution. However, those officials may not approve the research if it has not been approved by an IRB. (11, 12)

1. TAMIU's Federalwide Assurance – see appendix
2. OHRP Website - Assurances
3. 45 CFR 46.114
4. 21 CFR 56.114
5. TAMIU IRB Policy 2.5
6. Belmont Report
7. 45 CFR 46
8. 21 CFR 50, 21 CFR 56, 21 CFR 312, 21 CFR 812
9. Health Insurance Portability and Accountability Act of 1996
10. DHHS - Office for Human Research Protections
11. 45 CFR 46.112
12. 21 CFR 56.112

1.2 Purpose of the Institutional Review Board (IRB)

The purpose of the TAMIU IRB is to:
1. Review all human research occurring at TAMIU in compliance with its Federalwide Assurance and System Policy. (1,2)
2. Serve as a HIPAA Privacy Board for TAMIU. (3)

1. TAMIU's Federalwide Assurance – see appendix
2. TAMUS System Policy 15.99.01 – see appendix
3. Health Insurance Portability and Accountability Act of 1996

1.3 Codes of Research Ethics

Codes of research ethics have been developed, in part to address the disregard for human safety and dignity that these research projects reflect. The Nuremberg Code of 1947 was the first international code of research ethics. Its first principle is "The voluntary consent/authorization of the human subject is absolutely essential." The accompanying text made it clear that this voluntary consent/authorization should also be informed consent/authorization: "...the person involved ... should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision." This principle of "free and informed consent/authorization" remains the basic foundation of ethical research with human participants.

Another early code was the Helsinki Declaration, adopted by the World Medical Assembly at its meeting in Helsinki, Finland in 1964. Its second principle, "The design and performance of each experimental procedure involving human subjects should be clearly formulated in an experimental protocol which should be transmitted for

consideration, comment and guidance to a specially appointed committee independent of the investigator and the sponsor..." established the concept of ethical review.

The first ethical code covering social and behavioral research was a set of 10 ethical principles adopted by the American Psychological Association in 1972, which has been updated effective June, 2003. The bases for these principles were critical incidents. Psychologists were asked to submit examples of research that they deemed unethical or of questionable ethics. The committee charged with developing ethical standards for psychological research then developed principles that would guide the conduct of researchers when conducting research that could pose ethical problems. The American Psychological Association's principles were the first to recognize the principle of confidentiality. Principle 10 states: "Information obtained about the research participants during the course of an investigation is confidential. When the possibility exists that others may obtain access to such information, ethical research practice requires that this possibility, together with the plans for protecting confidentiality, be explained to the participants as a part of the procedure for obtaining informed consent/authorization."

Most professional organizations have ethical codes, and most require authors of manuscripts submitted to the journals of these organizations to state that they have followed these ethical principles in their research.

The U. S. Department of Health, Education, and Welfare issued ethical guidelines in 1971, which were codified into Federal Regulations in 1974. However, the primary impetus for current government ethical regulation began with the establishment of a National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research under the aegis of the Department of Health, Education, and Welfare in 1974. The Commission was charged with identifying the basic ethical principles that should underlie research with human subjects. The report of the Commission, called The Belmont Report because it was based on deliberations held at the Smithsonian Institution's Belmont Conference Center, was published in 1978. The Belmont Report identified three basic ethical principles. They are:

(1) Respect for Persons (autonomy): This principle acknowledges the dignity and freedom of every person. It requires obtaining informed consent/authorization from all potential research subjects (or their legally authorized representatives).
(2) Beneficence: This principle requires that researchers maximize benefits and minimize harms or risks associated with research. Research-related risks must be reasonable in light of expected benefits.
(3) Justice: This principle requires the equitable selection and recruitment and fair treatment of research subjects.

These three principles were the underpinnings of both an early (1980) version of a Common Federal Policy for the Protection of Human Research Subjects and the current version of that policy. The current version has been adopted by sixteen federal departments and agencies, including the Department of Health and Human Services, the National Science Foundation, the Department of Education, and the Central Intelligence Agency. The Food and Drug Administration (FDA) has concurred with the

Federal Policy and has made changes in its IRB and informed consent/authorization regulations so that they correspond to the Federal Policy. This Federal Policy, sometimes called the Common Rule, is codified as the Common Federal Policy for the Protection of Human Subjects and was published in the Federal Register in 1991. It is referred to as 45 CFR 46 and its regulations underlie the decisions of IRBs. The regulations further require that each institution at which federally funded research is conducted adhere to the principles of The Belmont Report and set forth in writing its ethical principles, policies, and procedures. This institution's agreement to abide by the Belmont Report and by 45 CFR 46 (called a Federal Wide Assurance or FWA) is approved by the federal agency that oversees ethical issues in human research.

1.4 Activities Subject to IRB Jurisdiction

A. It is the policy of Texas A&M International University's – Institutional Review Board (IRB) – to have jurisdiction over all human subjects research subject to TAMIU's Federalwide Assurance.

B. Jurisdiction of the IRB:

1. All research (1) projects involving human subjects (2) fall under the jurisdiction of the IRB. This includes any clinical investigation under the jurisdiction of the Food and Drug Administration. (3) (**NOTE:** TAMIU IRB currently does not review any FDA regulated research (4))

C. Review and Approval of Human Subjects Research

1. No intervention or interaction with human subjects in research, including advertising, recruitment, and/or screening, may begin until the IRB has reviewed and approved the research. (5, 6)
2. It is the responsibility of the IRB Chairperson or his/her designee or the full IRB to determine what activities constitute "human subjects research".
3. TAMIU's Federalwide Assurance (7) with the Federal government and TAMU System Policy defines it's jurisdiction over the review of human subjects research. Regardless of sponsorship, the IRB must review all human subjects research when TAMIU's IRB is the IRB of Record. (8, 9)

D. Failure to Submit a Project for IRB Review

If research involving human subjects is conducted without prior IRB review and approval, the matter will be referred to the IRB in accordance with IRB Policy Section 9. (10)

1. 45 CFR 46.102(d)
2. 45 CFR 46.102(f)
3. 21 CFR 56.102 (c)
4. TAMIU IRB Policy 3.11
5. 45 CFR 46.101(a)(2)
6. 21 CFR 56.103 (c)
7. TAMIU's Federalwide Assurance – see appendix
8. IRB Policy 1.1
9. TAMUS System Policy 15.99.01 – see appendix
10. IRB Policy Section 9

1.5 Revision and Maintenance of IRB Policy and Procedures

It is the policy of Texas A&M International University that the TAMIU IRB is responsible to maintain policies and procedures for conducting research activities under its jurisdiction as defined by Federal and State law and TAMU System Policy. (1, 2, 3)

1. 45 CFR 46.103 (b)(4) and (5)
2. 21 CFR 56.108 (a) and (b)
3. TAMUS System Policy 15.99.01 – see appendix

1.6 Definitions

Administrative Hold: An action initiated by the Investigator in response to an IRB request to place specific research activities on hold temporarily to allow for additional information to be obtained.

Adverse event: 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).

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

Authorization Agreement: A contract or agreement that establishes standards for human subjects research as approved by the Office for Human Research Protection (OHRP).

Children: Federal regulations define children as persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.

Continuing Non-compliance: A pattern of repeated actions or omissions taken by an Investigator that indicates a deficiency in the ability or willingness of an Investigator to comply with Federal regulations, TAMIU IRB Policy, or determinations or requirements of the TAMIU IRB.

Continuing Review: Periodic review of research activities at intervals appropriate to the degree of risk, but not less than once per year. The criteria for approval is defined by Federal regulations.

Cooperative Research Project: Research Projects which involve more than one institution as defined by Federal regulations. In the conduct of cooperative research projects, each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with this policy. With the approval of the department or

agency head, an institution participating in a cooperative project may enter into a joint review arrangement, rely upon the review of another qualified IRB, or make similar arrangements for avoiding duplication of effort.

Data Use Agreement: An agreement between TAMIU and the recipient of the Public Health Information (PHI). This agreement establishes who is permitted to use or receive the limited data set; and provides that the limited data set recipient will safeguard the data.

De-Identified Health Information: Health information that has been stripped of all 18 identifiers as defined by HIPAA so that the information could not be traced back to an individual. De-identified data also pertains to health information that has been assigned and retains a code or other means of identification provided that:

Designated Record Set: A group of records maintained by TAMIU that includes medical and billing records about an individual for the purpose of treatment, payment, or provision of health care. Research records that are not contained in the participants medical record are not likely to be part of the designated record set.

DHHS: The Department of Health and Human Services.

Ex Officio/Administrative Member: Ex officio and administrative members on the IRB Committees may include persons who are automatically members by virtue of the position held. These individuals do not have voting privileges and do not count toward quorum.

Exempt Review: Studies determined by the IRB to meet the exempt criteria as defined by the Federal regulations. Exempt studies do not require periodic review by the IRB unless a change in the project is planned.

Expedited Review: Studies determined by the IRB to meet the expedited criteria as defined by the Federal regulations.

External adverse event: From the perspective of one particular institution engaged in a multicenter clinical trial, external adverse events are those adverse events experienced by subjects enrolled by investigators at other institutions engaged in the clinical trial.

Federalwide Assurance (FWA): A contract or agreement that establishes standards for human subjects research as approved by the Office for Human Research Protection (OHRP).

Fetus: The product of conception from implantation until delivery.

Food and Drug Administration (FDA): The office responsible for implementing regulations governing the use of investigational drugs, biologics, devices and radiological procedures including radioactive drugs in clinical investigations with

humans. The FDA is the federal oversight agency responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation. The FDA is also responsible for advancing the public health by helping to speed innovations that make medicines and foods more effective, safer, and more affordable; and helping the public get the accurate, science-based information they need to use medicines and foods to improve their health.

Full Committee Review: Studies reviewed by the full, convened IRB Committee with a recorded vote and corresponding minutes to document the discussion.

Greater than Minimal Risk: Where the research involves greater than minimal risk to subjects, the mechanism of obtaining local research context differs depending on whether the local research context involves intervention or interaction with subjects and whether the principal risk associated with the local research context is limited to the potential harm resulting from a breach of confidentiality (see also Minimal Risk).

Guardian: An individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care.

HIPAA Authorization: A customized document/form, that gives permission to use specified protected health information (PHI) for a specific purpose, or to disclose PHI to a third party specified by the Investigator other than for treatment, payment or healthcare operations.

Human Subjects: A living individual about whom an Investigator (whether professional or student) conducting research obtains data through intervention or interaction with an individual or with his/her identifiable private information or an individual who is or becomes a participant in research, either as a recipient of the test article or as a control.

Human Subjects Research: Any research that involves humans as subjects or any clinical investigation (see Human Subjects).

Informed Consent: An individuals voluntary agreement, based upon adequate knowledge and understanding of relevant information, to participate in research.

IRB of Record: An IRB is considered the IRB of Record when it assumes IRB responsibilities for another institution and is designated to do so through an approved Assurance with OHRP. An IRB Authorization Agreement is required, designating the relationship, for TAMIU to serve as the IRB of Record.

Legally Authorized Representative: An individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subjects participation in the procedures involved in the research.

Limited Data Set: Protected health information that excludes direct identifiers of the individual or of relatives, employers, or household members of the individual, with the exception of city, state, ZIP code, elements of dates, and other numbers, characteristics, or codes not listed as direct identifiers.

Minimal Risk: The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. An example of minimal risk is the risk of drawing a small amount of blood from a healthy individual for research purposes (because the risk of doing so is no greater than the risk of doing so as part of a routine physical examination).

Modification: Any change to an IRB-approved study protocol regardless of the level of review it receives initially.

Neonate: A newborn.

Nonviable Neonate: A neonate after delivery that, although living, is not viable.

Non-Affiliated Member: Any IRB member who is not a current or former employee or student of Texas A&M International University or the Texas A&M University System and who does not have an immediate family who is a current or former employee or student of Texas A&M International University or the Texas A&M University System.

Non-Scientific Member: Any IRB member who does not have a terminal degree in a medical or scientific field.

Not Less Than Once Per Year: All research proposals, with the exception of exempt proposals, must receive IRB continuing review at a minimum of once every 365 days, per Federal regulations. There are no exceptions or grace periods allowed.

Office for Human Research Protection (OHRP): The office under the Department of Health and Human Services responsible for implementing DHHS regulations (45 CFR 46) governing biomedical and behavioral/social science research involving human subjects.

Parent: A child's biological or adoptive parent.

Possibly related to the research: There is a reasonable possibility that the adverse event, incident, experience or outcome may have been caused by the procedures involved in the research (modified from the definition of associated with use of the drug in FDA regulations at 21 CFR 312.32(a)).

Pregnancy: Encompasses the period of time from implantation until delivery. A woman shall be assumed to be pregnant if she exhibits any of the pertinent presumptive signs

of pregnancy, such as a missed menses, until the results of a pregnancy test are negative or until delivery.

Preparatory to Research: Any action taken in assessing the research question or hypothesis, such as accessing medical records, querying of databases for any type of individually identifiable health information, or any activity where PHI is accessed to prepare a research protocol.

Prisoner: Prisoner means any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.

Protected Health Information (PHI): PHI is individually identifiable health information that is or has been collected or maintained by the covered entity in the course of providing healthcare that can be linked back to the individual participant. PHI is individually identifiable health information that is transmitted by, or maintained in, electronic media or any other form or medium. This information must relate to 1) the past, present, or future physical or mental health, or condition of an individual; 2) provision of health care to an individual; or 3) payment for the provision of health care to an individual. If the information identifies or provides a reasonable basis to believe it can be used to identify an individual, it is considered individually identifiable health information. See Part II, 45 CFR 164.501.

Research: A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

Scientific Member: Any IRB member who has a terminal degree in a medical or scientific field.

Serious adverse event: Any adverse event temporally associated with the subject's participation in research that meets any of the following criteria:
(1) results in death;
(2) is life-threatening (places the subject at immediate risk of death from the event as it occurred);
(3) requires inpatient hospitalization or prolongation of existing hospitalization;
(4) results in a persistent or significant disability/incapacity;
(5) results in a congenital anomaly/birth defect; or
(6) any other adverse event that, based upon appropriate medical judgment, may jeopardize the subject's health and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition (examples of such events include allergic bronchospasm requiring intensive treatment in the emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse).

(Modified from the definition of serious adverse drug experience in FDA regulations at 21 CFR 312.32(a).)

Serious Non-compliance: (i) the conduct of any non-exempt research involving human subjects without IRB review and approval; (ii) enrollment of any human subject in a research study involving greater than minimal risk without informed consent; or (iii) implementation of substantive modifications involving possible risks to human subjects or others without IRB review and approval.

Suspension for Cause: An action initiated by the IRB to stop temporarily some or all research procedures pending future action by the IRB or by the Investigator or his/her study personnel.

Termination for Cause: An action initiated by the IRB to stop permanently some or all research procedures.

Unanticipated Problem Involving Risk to Subjects or Others (UPIRTSO): Any incident, experience, or outcome that meets all of the following criteria:
(1) unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;
(2) related or possibly related to a subject's participation in the research; and
(3) suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) related to the research than was previously known or recognized.

Unexpected adverse event: Any adverse event occurring in one or more subjects in a research protocol, the nature, severity, or frequency of which is not consistent with either:
(1) the known or foreseeable risk of adverse events associated with the procedures involved in the research that are described in (a) the protocol–related documents, such as the IRB-approved research protocol, any applicable investigator brochure, and the current IRB-approved informed consent document, and (b) other relevant sources of information, such as product labeling and package inserts; or
(2) the expected natural progression of any underlying disease, disorder, or condition of the subject(s) experiencing the adverse event and the subject's predisposing risk factor profile for the adverse event.
(Modified from the definition of unexpected adverse drug experience in FDA regulations at 21 CFR 312.32(a).)

Written Consent Form: A written consent document that includes the elements of informed consent required by Federal regulations.

2. Institutional Review Board

2.1 Regulations Governing the IRB

A. TAMIU IRB is subject to federal regulations as indicated in its Federalwide Assurance (1) and associated Federal Regulations (2).

B. TAMIU IRB is subject to TAMU System Policy 15.99.01 (3).

C. Currently TAMIU IRB does not review any research under the FDA (4, 5).

1. TAMIU's Federalwide Assurance – see appendix
2. TAMUS System Policy 15.99.01 – see appendix
3. 45 CFR 46
4. 21 CFR 56.102 (c)
5. TAMIU IRB Policy 3.11

2.2 Composition of the IRB

A. It is the policy of TAMIU – Institutional Review Board (IRB) – that each IRB will have membership as defined by Federal regulations.

B. Each IRB will have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB will be 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 will be 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 will therefore include persons knowledgeable in these areas. If an IRB regularly reviews research that involves a vulnerable category of subjects, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, consideration will be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these subjects.

C. Every nondiscriminatory effort will be made to ensure that no IRB consists entirely of men or entirely of women, including consideration of qualified persons of both sexes, so long as no selection is made to the IRB on the basis of gender. No IRB will consist entirely of members of one profession.

D. Each IRB will include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas (non-scientific member – preference will be given to individuals in disciplines/careers that do not normally conduct human research).

E. Each IRB will include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution (non-affiliated member).

F. No IRB will have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB. The IRB member with a conflict of interest must be absent during final deliberations and votes. The absence must be noted in the IRB minutes.

G. An IRB may, at its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. These individuals will not vote with the IRB (Ex Officio and Administrative Members). (1, 2)

1. 45 CFR 46.107
2. 21 CFR 56.107

2.3 IRB Committee Members/ Appointment of Committee

A. The TAMIU IRB Committee shall be appointed by and serve at the discretion of the Provost or their designated representative. Currently TAMIU has one IRB and thus its membership will be subject to the following additional provisions to facilitate the review process:

1. The TAMIU IRB shall consist, whenever possible, of at least one faculty member from each College or School within TAMIU. The majority of the IRB members shall be from the tenure/tenure-track faculty members. Currently the IRB is composed of eight or nine members – five being quorum.
2. Federal regulations divide research into Social Sciences, Biomedical and Educational. The TAMIU IRB shall have on its committee at a minimum two individuals with expertise in each of these three areas. One of the biomedical experts will be a medical doctor or equivalent.
3. The TAMIU IRB shall have on its committee at least one individual with experience in research involving children.
4. The TAMIU IRB shall have on its committee at least one individual who has experience with the local community, preferably a priest/minister/rabbi.
5. The TAMIU IRB shall have two non-scientific members.
6. At least two members of the TAMIU IRB must be fluent in Spanish.

B. Each member of the committee will be appointed for a term of three years. A single member can serve multiple consecutive terms by mutual agreement between the Provost (or their designee) and the individual.

C. The Chair of the IRB shall be appointed by the Provost from among the tenured/tenure-track faculty at TAMIU. The Chair of the IRB shall be appointed for a term of three years. The chair may serve multiple consecutive terms by mutual agreement between the Provost (or their designee) and the faculty member.

D. The IRB Chair will be responsible for notifying OHRP of changes in the composition of the IRB. Until the paperwork is filed with OHRP appointment to the IRB is not official, and the new IRB member may not vote, or officially review protocols. The IRB Chair will notify OHRP within seven business days of the Provost or their designee informing the IRB Chair in writing of changes in composition of the IRB.

2.4 Signatory Authority & Duties of the IRB Chair

A. The Chair of the IRB shall have signatory power for review and actions taken by the IRB.

B. In the absence of the Chair of the IRB, the IRB faculty member who has served on the committee the longest will have signatory power for review and actions taken by the IRB.

C. The IRB Chair shall be notified within five business days of the actions taken by representatives of the IRB committee.

D. Duties of the IRB Chair are:

1. Maintain an up to date FWA on file with the OHRP.
2. Maintain an up to date IRB composition on file with the OHRP.
3. Maintain IRB records at TAMIU (See IRB Policy 3.7 and 6.1).
4. Convene meetings of the IRB at least twice per year, or more often (up to monthly) as needed to conduct IRB business.
5. Inform the Investigator and Institutional Officials (the Provost or their designee) of findings and actions of the IRB, and meeting dates.
6. Review once per year the OHRP website for regulatory changes, or updated guidance.
7. Maintain a list of current active protocols approved by the IRB, a list of approved modifications, and a list of events (adverse events, complaints, unanticipated events, and reports of noncompliance). These lists shall be made available to the entire IRB at full meetings, or upon request of any IRB member or the Institutional Official or their designee.
8. Once per year, in January, the IRB Chair shall submit a report to the Provost or their designee a listing all protocols reviewed during the past year by the IRB, including a summary of any modifications and events and IRB response to those events.
9. Training new members of the IRB regarding TAMIU specific IRB procedures.

2.5 IRB of Record and Cooperative Research

A. The TAMIU IRB may serve as the IRB of Record for an external site engaged human research being conducted when representatives of TAMIU serve as the primary PI for a multi-center study.

B. IRB of Record – TAMIU's IRB may serve as the IRB of Record as set forth in this policy. A 'coordinating center' of a multi-center trial is responsible for assuring that IRB approval is granted at the participating sites prior to the initiation of the research at that

site. TAMIU's IRB is not necessarily the IRB of Record for other participating sites unless it has agreed to do so in accordance with IRB Policy 1.1 (1). The coordinating center assumes responsibility for assuring that the participating sites have received IRB approval.

C. Authorization Agreements and Cooperative Research Projects - An Authorization Agreement (2) or an agreement entered into as part of a cooperative research project (3, 4) are the only methods by which TAMIU's IRB will serve as the IRB of Record for a site which is not covered by TAMIU's FWA. (5) This agreement will outline specific responsibilities for each party entering into the agreement.

D. All Cooperative Research agreements are subject to approval of the Provost.

1. IRB Policy 1.1
2. OHRP Website - Assurances
3. 45 CFR 46.114
4. 21 CFR 56.114
5. TAMIU's Federalwide Assurance

3. IRB Review Procedures

3.1 Institutional Review Board Committee Review Responsibilities

A. It is the policy of TAMIU's – Institutional Review Board (IRB) – to review all human subjects research activities under TAMIU's IRB jurisdiction in compliance with TAMIU's Federalwide Assurance and TAMU System Policy (1,2).

B. Overview of IRB review of human research

1. The IRB will review and have authority to approve, require modifications in (to secure approval), or disapprove all human research activities covered by this policy, and all research falling under HIPAA (1, 2, 3).
2. The IRB will require that information given to subjects as part of informed consent is in accordance with IRB Policy 4.1 (4). The IRB may require that information, in addition to that specifically mentioned in IRB Policy 4.1 (4) 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.
3. The IRB will require documentation of informed consent or may waive documentation in accordance with IRB Policy 4.2 (5) and 4.3 (6). In cases where the requirement for documentation of informed consent is waived; the IRB may require the Investigator to provide subjects with a written statement regarding the research.
4. The IRB will notify Investigators and the institution in writing of its decision to approve or disapprove the proposed research activity or of modifications required to secure IRB approval of the research activity (deferral) (7). If the IRB decides to disapprove a research activity, it will 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.
5. The IRB will conduct continuing review of research covered by this policy at intervals appropriate to the degree of risk, but not less than once per year, and will have authority to observe or have a third party observe the consent process and the research (8,9).

C. Overview of the review procedure – applies to all requests submitted to the IRB, initial proposals, continuing review, modifications, etc. (In this section the term "proposal" applies to all of these requests):

1. In general the signed original of investigator submitted proposals should be submitted directly to the IRB Chair. If submitted directly to an IRB member, that IRB member should make a working copy and forward the original to the IRB chair. The IRB chair will assign a unique file number – generally the date in the format of YYYY-MM-DD.
2. An IRB member should review the proposal within seven business days for completeness, essentially conducting an initial review to the extent possible from the original protocol. The IRB member will inform the investigator and the IRB Chair of the results of that initial review, ie if the application is complete or incomplete – if incomplete what additional information is needed.

a. If the protocol is incomplete it shall be deferred until it is complete.
b. Upon receipt of required modifications, or investigators response, the IRB should conduct an initial review of the proposal within seven business days as described above.

3. If the application is complete the IRB member will determine if the research falls under the category of Exempt, Expedited, or Full Review (See IRB Policy 3.3, 3.4, and 3.5 (9, 10, 11).
4. Exempt Review should be conducted by the IRB member, and the IRB chair informed – See IRB Policy 3.3 (9) – Exempt Review should be done within seven days of receipt of the complete protocol.
5. Expedited Review should be conducted by two IRB members, at least one of which should have general expertise in that area of research (The three designated areas are Social Science/Behavioral, Educational, Biomedical) – See IRB Policy 3.4 (10). Expedited Review should be done within seven days of receipt of the complete protocol.
6. Full Review should be conducted for protocols that do not fit into the Exempt or Expedited Category, or by request of the IRB members/chair.
7. Particularly in the case of vulnerable populations it may be necessary to seek review from an outside reviewer. If an outside reviewer is sought the investigator should be informed of the status of the protocol. The confidentiality of the outside reviewer should be respected. If the outside reviewer fails to respond in 14 days another outside reviewer should be sought.
8. Once a protocol is complete and is reviewed the investigator and the institutional officer (or their designee) should be informed in writing within five business days of the findings of the IRB – See IRB Policy 3.7 (12). This is done by the IRB Chair – See IRB Policy 2.4 (13).
9. The original signed protocol, copies of IRB Review Forms, written correspondence between the investigator and the IRB should be forwarded to the IRB Chair for record keeping – See IRB Policy 6.1 (14).

D. Initial Review Materials should include the following as appropriate (all reviewers should receive a complete copy of the following):

1. Protocol
2. Consent Document and/or Assent Document
3. Grant Application
4. Investigator Brochure if used
5. Recruitment materials – including seen or heard, eg. Summaries of radio interviews
6. Survey instruments, etc used
7. A summary of correspondence between the IRB and investigator.

1. TAMIU's Federalwide Assurance – see appendix
2. TAMUS System Policy 15.99.01 – see appendix
3. See IRB Policy 8.1, 8.2
3. IRB Policy 4.1
4. IRB Policy 4.2
5. IRB Policy 4.3

6. IRB Policy 3.2
7. 45 CFR 46.109
8. 21 CFR 56.109
9. IRB Policy 3.3
10. IRB Policy 3.4
11. IRB Policy 3.5
12. IRB Policy 3.7
13. IRB Policy 2.4
14. IRB Policy 6.1

3.2 IRB Committee Determinations/Motions

A. It is the policy of TAMIU's Institutional Review Board (IRB) – to render determinations as defined by Federal regulations. Federal regulations allow research to be approved, or disapproved. In addition the TAMIU IRB will use designations of approved pending specific modifications, deferred, tabled, and withdrawn.

B. Approved - An approval is granted if the research activity meets the criteria for approval as defined in IRB Policy 3.6(1) and no changes to the research application are recommended. The date of IRB approval is the start date for one year until continuing review.

C. Approved pending specific modifications – The IRB may approve research pending specific modifications only if the modifications do not substantially change the level of risk or the nature of the proposal. If there is not sufficient information to approve the research then it must be deferred or disapproved. Note that the date of IRB approval pending specific modifications is the start date for one year until continuing review. The formal letter of approval should not be sent and the research may not begin until the specific modifications to the protocol are made.

1. OHRP Guidance on this - 2002: Only when the convened IRB stipulates specific revisions requiring simple concurrence by the investigator may the IRB Chair or another IRB member designated by the Chair subsequently approve the revised research protocol on behalf of the IRB under an expedited review procedure.
2. OHRP Guidance on this – 2007: OHRP notes that when the convened IRB requests substantive clarifications or modifications regarding the protocol or informed consent process/documents that are directly relevant to the determinations required by the IRB under HHS regulations at 45 CFR 46.111 (see IRB Policy 3.6A-C (1)), IRB approval of the proposed research must be deferred, pending subsequent review by the convened IRB of responsive material (2).

D. Deferred - A deferral is granted if the research activity does not meet the criteria for approval as defined in IRB Policy 3.6 (1), and the Board requires modifications in the research to secure approval. The application may subsequently be approved if the modifications have been made by the Investigator or the Investigator has justified to the satisfaction of the IRB that the modifications do not need to be made.

1. New Studies: The application may be reconsidered upon re-submission after the requested changes have been made to the study or the Investigator has justified to the satisfaction of the IRB why the changes do not need to be made.

2. Modifications: The change cannot be implemented, and the Board expects the research will continue as previously approved.

E. Disapproved - A disapproval is granted if the research activity does not meet the criteria for approval as defined in IRB Policy 3.6 (1). Research can only be disapproved at full committee meetings. If the IRB disapproves a research activity, it will include in its written notification a statement of the reason(s) for its decision and give the Investigator an opportunity to respond in person or in writing, at the discretion of the IRB.

1. New Studies: The application may be reconsidered as a new submission after substantial changes have been made to the study.
2. Modifications: The change cannot be implemented, and the Board expects the research will continue as previously approved (3, 4).

F. Tabled Due to Lack of Time - A study will be tabled if the Committee is unable to review it due to lack of time. The study will then be placed on a future agenda.

1. IRB Policy 3.6
2. OHRP Guidance on Written IRB Procedures see Appendix
2. 45 CFR 46.109(a)
3. 21 CFR 56.109(a)

3.3 IRB Review of Human Subjects Research – Exempt

A. It is the policy of TAMIU's Institutional Review Board (IRB) – that all human subjects research activities under its jurisdiction be reviewed to determine whether the research meets one or more of the exemption categories as defined by Federal regulations.

B. Exempt Eligibility - The IRB may determine a research activity to be exempt where the only involvement of human subjects will be in one or more of the following categories **provided that NO prisoners are involved in the study**:

45 CFR 46.101(b)(1) - Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (a) research on regular and special education instructional strategies, or (b) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. **Applies to children.**

45 CFR 46.101(b)(2) - Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior, unless: (a) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (b) 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. **For children see Section H below.**

45 CFR 46.101(b)(3) - Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or

observation of public behavior that is not exempt under paragraph (2)(b) of this section, if: (a) the human subjects are elected or appointed public officials or candidates for public office; or (b) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter. **Applies to children.**

45 CFR 46.101(b)(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. **Applies to children.**

45 CFR 46.101(b)(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: (a) public benefit or service programs; (b) procedures for obtaining benefits or services under those programs; (c) possible changes in or alternatives to those programs or procedures; or (d) possible changes in methods or levels of payment for benefits or services under those programs. **Applies to children.**

45 CFR 46.101(b)(6) - Taste and food quality evaluation and consumer acceptance studies, (a) if wholesome foods without additives are consumed or (b) if a food is consumed that contains a food ingredient at or below the level and use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture. **Applies to children.**

C. Only the IRB may determine which activities qualify for an exempt review. Investigators do not have the authority to make an independent determination that research involving human subjects is exempt and must contact the IRB concerning the status of proposed research or changes in ongoing research.

D. Modifications - Certain changes may disqualify the research from exempt status. Therefore, any significant changes to an exempt study must be submitted to the IRB for review and approval prior to implementation.

E. All research that has been determined to be exempt by the IRB may still be subject to other applicable TAMIU institutional policies and procedures.

F. Exempt research activities are subject to the same subject protections and ethical standards as outlined in The Belmont Report (1).

G. These exemptions do not apply to research involving prisoners (2, 3). For prisoners see IRB Policy 5.2 (3).

H. Research Involving Children

1. The exemptions at 45 CFR 46.101(b)(1), (b)(3), (b)(4), (b)(5) and (b)(6) are applicable to research involving children (4).
2. The exemption at 45 CFR 46.101(b)(2) only applies to research involving children for research involving observation of public behavior when the Investigator does **not** participate in the activities being observed. The exemption does not apply where the research involves survey or interview procedures or **any** direct interaction with the participants being observed (4, 5).

I. Any tenured/tenure-track faculty member of the IRB may determine that a study meets the qualifications for Exempt Review, and conduct the review. That faculty member shall notify the IRB Chair via e-mail or in writing within five business days. The IRB member shall inform the IRB Chair under which federal category exemption was granted.

1. Belmont Report
2. 45 CFR 46.101, footnote 1
3. IRB Policy 5.2
4. 45 CFR 46.101, footnote 1; 45 CFR 46.401(b)
5. IRB Policy 5.3

3.4 IRB Review of Human Subjects Research – Expedited

A. It is the policy of TAMIU's Institutional Review Board (IRB) – to permit the use of expedited review procedures for eligible human subjects research activities, as defined by Federal regulations.

B. Eligibility for Expedited Review - The IRB may use an expedited review procedure to review either or both of the following:

1. Research that involves no more than minimal risk, and which appears on the following list: Expedited Review Categories (1)
2. Minor changes in previously approved research during the period (of one year or less) for which approval is authorized. (2, 3)

C. Expedited Review may **not** be used when:

1. identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects financial standing, employability, insurability, reputation, or be stigmatizing, **unless** reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.
2. the research is classified.

D. Expedited Review - The review may be carried out by two faculty members of the IRB. At least one of the reviewers should be in the subject area of the research being conducted (Social Science, Education, or Biomedical).

1. The reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research.

2. A research activity may be disapproved only after review in accordance with the non-expedited procedure set forth in IRB Policy 3.5 (4, 5, 6).
3. Specific documentation of which expedited review category was used should be kept with the approved protocol.
4. Specific documentation of review shall be made using the "IRB Review Form".
5. For criteria for approval, and specific procedures for documentation of IRB decisions see IRB Policy 3.6, and 3.7 (7, 8).

E. IRB Oversight of Expedited Review.

1. If the IRB Chair did not participate in the Expedited Review the IRB Chair should be notified by e-mail or in writing within five business days. The category used for expedited review must be indicated. The completed IRB Review Form must be submitted to the IRB Chair.
2. All IRB members shall be advised of research proposals which have been approved under expedited review (9, 10). At each Full Committee meeting the entire committee will be notified of all research proposals approved since the last meeting.

1. Expedited Review Categories as defined by OHRP – see Appendix
2. 45 CFR 46.110(a), (b)
3. 21 CFR 56.110(a), (b)
4. 45 CFR 46.110(b)
5. 21 CFR 56.110(b)
6. IRB Policy 3.5
7. IRB Policy 3.6
8. IRB Policy 3.7
9. 45 CFR 46.110(c)
10. 21 CFR 56.110(c)

3.5 IRB Review of Human Subjects Research – Full Committee

A. It is the policy of TAMIU's Institutional Review Board (IRB) – to review all human subjects research activities according to applicable criteria, as defined by Federal regulations.

B. Full Committee Eligibility - Studies not qualifying for IRB review through an expedited review procedure will be reviewed by a fully convened IRB.

C. Full Committee Review

1. At a minimum of one week prior to the Full Committee Meeting the agenda, and protocols being reviewed (including initial review and correspondence) shall be submitted to the entire IRB committee.
2. Research will be reviewed at convened meetings at which the majority of IRB members are present, including at least one member whose primary concerns are in non-scientific areas. Quorum is defined as a simple majority, including at least one non-scientific member, and excluding anyone with conflict of interest. No one with conflict of interest may be present at the meeting during final deliberations and votes. Only IRB members designated with OHRP may vote.

Others who may attend the meeting:

a. Provost or their designee (ex officio – non-voting)

b. External Reviewers/Experts on Research Area (non-voting). An IRB may, at its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. These individuals will not vote with the IRB (Ex Officio and Administrative Members). (1, 2)

c. Investigator at the discretion of the IRB – only to answer questions concerning their protocol.

d. In general others should not attend the meeting. The meetings are confidential by nature.

3. One or more members of the IRB will be asked to review the protocol in detail prior to the meeting. They will present the protocol for review at the meeting.

4. Each item on the "IRB Review Form" shall be discussed and a summary for each item will be documented in the meeting minutes.

5. In order for the research to be approved, it must receive the approval of the majority of those members present at the meeting (3, 4).

6. For criteria for approval, and specific procedures for documentation of IRB decisions see IRB Policy 3.6, and 3.7 (5, 6).

D. Scheduling of Full Committee Review

1. The IRB Chair shall be responsible for scheduling meetings. In general the IRB will convene meetings only as needed to conduct Full Review, or at least twice per year.

2. Once a protocol needing Full Review is submitted an IRB meeting will be convened within 30 days (if possible) of receiving a complete IRB protocol.

3. It is preferred, in order to facilitate the review process, that IRB members receive the protocol and forward comments, concerns, questions to the IRB Chair prior to the meeting. These comment, concerns, and questions can by submitted anonymously to the investigator by the IRB Chair. The investigator may submit a written response prior to the meeting, or at the discretion of the IRB attend a portion of the meeting. The Investigator may not be present during final deliberations, and voting.

1. 45 CFR 46.107
2. 21 CFR 56.107
2. 45 CFR 46.108 (b)
3. 21 CFR 56.108 (c)
4. IRB Policy 3.6
5. IRB Policy 3.7

3.6 IRB Approval of Research

A. It is the policy of TAMIU's Institutional Review Board (IRB) – to review and approve research in accordance with the criteria as defined by Federal regulations.

B. Criteria for IRB Approval of Research

1. Risks to subjects are minimized by:

a. using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and
b. whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes;

2. 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. In evaluating risks and benefits, the IRB Committee should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB Committee should not consider possible long-range effects of applying knowledge gained in the research (e.g., the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility;
3. Selection of subjects is equitable considering the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations and the potential need for additional protections, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons;
4. Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by Federal and State regulations and Institutional polices and procedures including the IRB;
5. Informed Consent will be appropriately documented, in accordance with, and to the extent required by the Federal and State regulations and Institutional policies and procedures including the IRB;
6. When appropriate, the research plan makes adequate provisions for monitoring the data collected to ensure the safety of subjects;
7. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data (1, 2).

C. There are adequate provisions to protect the rights and welfare of vulnerable populations from coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons. The IRB Committee must determine if additional safeguards need to be included in the study to protect the rights and welfare of these subjects (3, 4). See IRB Policy 5.1, 5.2, 5.3, and 5.4 (5, 6, 7, 8).

D. The IRB shall consider the local context of the research prior to approval. See IRB Policy 3.15 (9).

E. Determining the Interval for Continuing Review - At the time of initial approval the full IRB or expedited review committee determine the interval for continuing review will be not less than once per year. In making this determination, the full board or expedited review committee will consider the factors specified in sections B and C of this policy and may also consider factors such as:

1. Research conducted internationally;
2. Previous Administrative Holds or Suspensions of the research due to compliance, record-keeping or other concerns; and/or
3. Recommendations from other Institutional committees (10, 11)
4. Protocols with a high risk to benefit ratio.

1. 45 CFR 46.111(a)
2. 21 CFR 56.111(a)
3. 45CRF 46.111(b)
4. 21 CFR 56.111(b)
5. IRB Policy 5.1
6. IRB Policy 5.2
7. IRB Policy 5.3
8. IRB Policy 5.4
9. IRB Policy 3.15
10. 45 CFR 46.103(b)(4)(ii)
11. 21 CFR 56.108(a)(2)

3.7 Documentation of IRB Determinations

A. It is the policy of TAMIU's Institutional Review Board (IRB) – to prepare and maintain documents of IRB activities and notify Investigators of IRB decisions as defined by Federal regulations

B. The IRB will prepare and maintain adequate documentation of IRB review/continuing review of each proposal/adverse event, including the following:

1. Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, continuing review reports submitted by Investigators, and reports of injuries to subjects.
2. Copies of "IRB Review Forms" for proposals undergoing expedited and/or non-expedited review. The IRB review form should document IRB findings, including *protocol-specific* information justifying each finding. Including, but not limited to:
    a. Review of the informed consent document (if applicable) as indicated in IRB Policy 4.1, 4.2, 4.3, and 4.4 (1, 2, 3, 4).
    b. If a waiver of informed consent is granted this form must document the four findings indicated in IRB Policy 4.3.B.2 (6, 7).
    c. Approving a procedure involving pregnant women, human fetuses, or neonates as indicated in IRB Policy 5.1 (8).
    d. Approving research involving prisoners as indicated in IRB Policy 5.2 (9).
    e. Approving research involving children as indicated in IRB Policy 5.3 (10).
    f. Approving research involving vulnerable populations as indicated in IRB Policy 5.4 (11).
    g. Approving research involving preK-12 schools as indicated in IRB Policy 3.14 (12).
    h. Approving recruitment and advertising as indicated in IRB Policy 3.12 (13).
    i. Approving research involving payment to subjects as indicated in IRB Policy 3.13 (14).
    j. Determinations regarding risk and approval period (6).

k. When approving research for which the IRB is geographically removed as indicated in IRB Policy 3.15 (15).

3. Documentation of categories used for exempt or expedited review.
4. Copies of all correspondence between the IRB and the investigators.
5. Minutes of the IRB meetings.

C. Minutes of the IRB meetings should be in sufficient detail to:

1. Show attendance at the meetings, documenting quorum, and if quorum was maintained throughout the meeting. If any IRB member has a conflict of interest in reviewing a protocol their absence must be noted in the minutes.
2. A list of studies that had been reviewed, submitted since the last IRB meeting, and the status of those proposals.
3. A list of modifications that had been reviewed or submitted since the last IRB meeting, and the status of those requests.
4. A list of events (adverse events, unanticipated events or findings of non-compliance), if any, since the last IRB meeting, and their current status/recommended responses.
5. Actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining.
    a. Format recommended by OHRP (6):
    Total = 15; Vote: For=14, Opposed=0, Abstain=1
6. The basis for requiring changes in or disapproving research.
7. Demonstrate meaningful review of each proposal including a written summary of the discussion of controverted issues and their resolution. The minutes should reflect separate deliberations, actions, and votes for each protocol undergoing initial and continuing review by the convened IRB (6). The IRB minutes should document IRB findings, including *protocol-specific* information justifying each finding. Including, but not limited to:
    a. Review of the informed consent document (if applicable) as indicated in IRB Policy 4.1, 4.2, 4.3, and 4.4 (1, 2, 3, 4).
    b. If a waiver of informed consent is granted this form must document the four findings indicated in IRB Policy 4.3.B.2 (6, 7).
    c. Approving a procedure involving pregnant women, human fetuses, or neonates as indicated in IRB Policy 5.1 (8).
    d. Approving research involving prisoners as indicated in IRB Policy 5.2 (9).
    e. Approving research involving children as indicated in IRB Policy 5.3 (10).
    f. Approving research involving vulnerable populations as indicated in IRB Policy 5.4 (11).
    g. Approving research involving preK-12 schools as indicated in IRB Policy 3.14 (12).
    h. Approving recruitment and advertising as indicated in IRB Policy 3.12 (13).
    i. Approving research involving payment to subjects as indicated in IRB Policy 3.13 (14).
    j. Determinations regarding risk and approval period (6).
    k. When approving research for which the IRB is geographically removed as indicated in IRB Policy 3.15 (15).

D. The IRB will notify Investigators and the Institution (the Provost or their designee) in writing of its decision to approve, defer, or disapprove the proposed research activity or of modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, it will include in its written notification a statement of the reason(s) for its decision and give the Investigator an opportunity to respond in person or in writing (16, 17). In general this should be done within five business days of review of the proposal.

E. For information pertaining to IRB Records. See IRB Policy 6.1 (18).

1. IRB Policy 4.1
2. IRB Policy 4.2
3. IRB Policy 4.3
4. IRB Policy 4.4
6. OHRP Guidance on Written Procedures – see Appendix
7. IRB Policy 4.3.B.2
8. IRB Policy 5.1
9. IRB Policy 5.2
10. IRB Policy 5.3
11. IRB Policy 5.4
12. IRB Policy 3.14
13. IRB Policy 3.12
14. IRB Policy 3.13
15. IRB Policy 3.15
16. 45 CFR 46.109(d)
17. 21 CFR 56.109(e)
18. IRB Policy 6.1

3.8 Modifications to Previously Approved Research

A. It is the policy of TAMIU's Institutional Review Board (IRB) – to review all requests for modifications to previously approved research and exempt research.

B. For previously approved research: Proposed changes in a research activity during the period for which IRB approval has already been given must be promptly reported in writing to the IRB Chair or their designee. Such changes may not be initiated without IRB review and approval is given in writing except when necessary to eliminate apparent immediate hazards to the subject (1, 2). Requests for modifications will be treated in the same manner as initial proposals, except as indicated below.

C. Modifications eligible for Expedited Review - The IRB may use an expedited review procedure to review either or both of the following:

1. Research that involves no more than minimal risk, and which appears on the following list: Expedited Review Categories (3)
2. Minor modifications in previously approved research during the period (of one year or less) for which approval is authorized (4, 5).

D. Exempt research - Certain changes may disqualify the research from exempt status. Therefore, any proposed changes to an exempt study should be submitted to the IRB for review and approval prior to implementation (6).

E. Re-consent or Notification of Participants - The IRB will determine whether the changes to the research require a change in the consent documents and therefore warrant re-consenting of currently enrolled participants or notification of participants who have completed research interventions. The IRB will ensure that the consent documents contain the information required in accordance with IRB Policy 4.1 (7, 8, 9).

F. If the modification requires review by a full meeting of the IRB, quorum must be present as in any other protocol (10).

G. OHRP recommends that each revision to a research protocol be incorporated into the written protocol. This practice ensures that there is only one complete protocol with the revision dates noted on each revised page and the first page of the protocol itself. This procedure is consistent with the procedure used for revised and approved informed consent documents which then supersede the previous one (10).

1. Whenever reasonable the IRB will make handwritten note of revisions to the protocol, including date of revision, on the original protocol itself. The date of the revision should be noted on the top of the page of each revised page, and on the top of the first page of the protocol. The written request for revision shall be dated and attached to the back of the protocol.
2. The IRB may require, at its discretion, the investigator to submit an updated protocol document.

H. IRB Oversight of Expedited Review.

1. If the IRB Chair did not participate in the Expedited Review of the modification the IRB Chair should be notified by e-mail or in writing within five business days. The category used for expedited review must be indicated. The complete modification must be submitted to the IRB Chair.
2. All IRB members shall be advised of modifications to research proposals which have been approved under expedited review (11, 12). At each Full Committee meeting the entire committee will be notified of all modifications to research proposals approved since the last meeting.

1. 45 CFR 46.103(b)(4)(iii)
2. 21 CFR 56.108(a)(4)
3. Expedited Review Categories – see Appendix
4. 45 CFR 46.110(a), (b)
5. 21 CFR 56.110(a), (b)
6. IRB Policy 3.3 (C, D)
7. 45 CFR 46.116 (a), (b)
8. 21 CFR 50.25 (a), (b)
9. IRB Policy 4.1
10. OHRP Guidance on Written IRB Procedures – see Appendix
11. 45 CFR 46.110(c)
12. 21 CFR 56.110(c)

3.9 IRB Continuing Review

A. It is the policy of TAMIU's Institutional Review Board (IRB) – that research activities be periodically reviewed at intervals appropriate to the degree of risk, but not less than once per year, as required by the Federal regulation and TAMU System Policy (1, 2, 3, 4, 5). The criteria for approval will be the same as set forth in IRB Policy 3.6 (6). The IRB will determine the interval for continuing review of research as set forth in IRB Policy 3.6 (6).

B. Additional considerations for proposals undergoing continuing review (7):

1. When conducting continuing review, the IRB needs to determine whether any new information has emerged – either from the research itself or from other sources – that could alter the IRB's previous determinations, particularly with respect to risk to subjects. Special attention should be paid to any reports of adverse events.
2. A "Continuing Review Form" status report shall be prepared including information indicated on the OHRP Guidance on Continuing Review.
3. The informed consent document(s) must be reviewed for:
    a. accuracy and completeness
    b. that any new findings that may affect the willingness of the subject to continue to participate are reflected in the updated document.

C. In general continuing review should involve the same level of review as the initial protocol. There are some exceptions, particularly in the case of studies which are no longer enrolling subjects. For selection of review category see IRB Policy 3.3, 3.4, and 3.5 (8, 9, 10). In addition, during continuing review the primary reviewer shall be provided with all documents pertaining to the initial review, and subsequent modifications. The IRB Chair or designated member should review the continuing review and above-mentioned original documentation.

D. There is no grace period for continuing review (7). If the proposal is not submitted, or not approved by one year from the last full review of the proposal then the study must cease until it is re-approved. Enrollment of new subjects can not occur after expiration of the approved proposal.

E. Some protocols may require verification from sources other than the investigator that no material changes have occurred since previous IRB review. Including, but not limited to:

1. Protocols involving much more than minimal risk.
2. Protocols involving investigators with clear conflict of interest.
3. Protocols involving investigators with a documented history of noncompliance.

1. 45 CFR 46.109 (e)
2. 45 CFR 46.110 (b)(2)
3. 21 CFR 56.109 (f)
4. 21 CFR 56.110 (b)(2)
5. TAMUS System Policy 15.99.01 – see appendix

6. IRB Policy 3.6
7. OHRP Guidance on Continuing Review - see Appendix
8. IRB Policy 3.3
9. IRB Policy 3.4
10. IRB Policy 3.5

3.10 Reporting Unanticipated Problems Involving Risk to Subjects or Others

A. It is the policy of TAMIU's Institutional Review Board (IRB) – to require that Investigators promptly report any unanticipated problems involving risk to subjects or others (UPIRTSO). Once reported, TAMIU's IRB will determine what constitutes an unanticipated problem involving risks to subjects or others (UPIRTSO) and will report to appropriate institutional officials, OHRP, and other relevant Federal agencies as set forth in IRB Policy 9.3 (1, 2, 3, 4).

B. Unanticipated Problem Involving Risk to Subjects or Others (UPIRTSO):
OHRP Definition of Unanticipated Problems:
OHRP considers *unanticipated problems*, in general, to include any incident, experience, or outcome that meets **all** of the following criteria:

1. unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;
2. related or possibly related to participation in the research (in this guidance document, possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and
3. suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized (4).

C. Unanticipated Problems include adverse events (in which there is a direct physical or psychological harm to the subject - see Part C), and any problem or event that

1. problems/events that may have adversely affected the rights, safety, or welfare of the subjects or others, or substantially compromise the research data
2. unexpected: problems/events are those that are not already described as potential risks in the consent form, not listed in the Investigators Brochure, or not part of an underlying disease. A problem/event is unanticipated when it was unforeseeable at the time of its occurrence. A problem/event is unanticipated when it occurs at a increased frequency or at a increased severity than expected AND
3. at least possibly related to participation in the research.

Clearly not all unanticipated events have a direct physical or psychological harm to the subject. A specific example sited by OHRP as an unanticipated event that is not an adverse event is theft of a laptop containing unencrypted data about the subjects in the study (4). This is an unanticipated problem that must be reported.

D. Adverse Events may occur in any study. Adverse events are defined as:

1. 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).
2. Adverse events encompass both physical and psychological harms. They occur most commonly in the context of biomedical research, although on occasion, they can occur in the context of social and behavioral research.

E. Evaluating if an Adverse Event qualifies as an unanticipated problem. Clearly not all adverse events are unanticipated. For example, a participant becoming upset because a study asked questions that were offensive is not unanticipated in a study about sexual attitudes.

1. In evaluation whether the adverse event qualifies as an unanticipated problem the following three questions should be asked, if the answer to all three is yes then it is an unanticipated problem and must be reported:
    a. Is the adverse event unexpected? (for a definition see below)
    b. Is the adverse event related or possibly related to participation in the research?
    c. Does the adverse event suggest that the research places subjects or others at a greater risk of harm than was previously known or recognized?
2. OHRP defines unexpected adverse event as: Any adverse event occurring in one or more subjects participating in a research protocol, the nature, severity, or frequency of which is not consistent with either:
    a. the known or foreseeable risk of adverse events associated with the procedures involved in the research that are described in (a) the protocol related documents, such as the IRB-approved research protocol, any applicable investigator brochure, and the current IRB-approved informed consent document, and (b) other relevant sources of information, such as product labeling and package inserts; or
    b. the expected natural progression of any underlying disease, disorder, or condition of the subject(s) experiencing the adverse event and the subject's predisposing risk factor profile for the adverse event.
3. Unexpected adverse events should be distinguished from expected adverse events. Most adverse events are expected.
4. Assessing whether an adverse event is related or possibly related to participation in research. Adverse events may be caused by one or more of the following:
    a. the procedures involved in the research;
    b. an underlying disease, disorder, or condition of the subject; or
    c. other circumstances unrelated to either the research or any underlying disease, disorder, or condition of the subject.

In general, adverse events that are determined to be at least partially caused by (a) would be considered related to participation in the research, whereas adverse events determined to be solely caused by (b) or (c) would be considered unrelated to participation in the research.

5. Assessing whether an adverse event suggests that the research places subjects or others at a greater risk of harm than was previously known or recognized. The first step in assessing whether an adverse event meets the third criterion for an unanticipated problem is to determine whether the adverse event is *serious*. OHRP defines serious adverse event as any adverse event that:

a. results in death;

b. is life-threatening (places the subject at immediate risk of death from the event as it occurred);

c. results in inpatient hospitalization or prolongation of existing hospitalization;

d. results in a persistent or significant disability/incapacity;

e. results in a congenital anomaly/birth defect; or

f. based upon appropriate medical judgment, may jeopardize the subject's health and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition (examples of such events include allergic bronchospasm requiring intensive treatment in the emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse).

6. OHRP considers adverse events that are unexpected, related or possibly related to participation in research, and serious to be the most important subset of adverse events representing unanticipated problems because such events always suggest that the research places subjects or others at a greater risk of physical or psychological harm than was previously known or recognized and routinely warrant consideration of substantive changes in the research protocol or informed consent process/document or other corrective actions in order to protect the safety, welfare, or rights of subjects.

7. Adverse events that are not serious in nature may still warrant modification of the protocol, consent form, etc. in order to protect the safety, welfare, or rights of subjects or others. Adverse events that are not serious in nature do not need to be reported to OHRP.

F. Procedure for reporting unanticipated problems:

1. The Investigator should inform the IRB of any Unanticipated Problems Involving Risk to Subjects or Others. In addition the Investigator should inform the IRB of any complaints received from subjects. In cases in which the subject, or others, submit a complaint to the IRB the IRB will contact the Investigator.

2. An IRB Adverse Event Report Form is available to facilitate this process. This form includes the following required information:

a. appropriate identifying information for the research protocol, such as the title, investigator's name, and the IRB project number;

b. a detailed description of the adverse event, incident, experience, or outcome;

c. an explanation of the basis for determining that the adverse event, incident, experience, or outcome represents an unanticipated problem; and

d. a description of any changes to the protocol or other corrective actions that have been taken or are proposed in response to the unanticipated problem (if appropriate).

3. Adverse events and unanticipated problems should be reported within 10 business days. If the adverse event is serious (See section E.5) then it should be reported within 5 business days.
4. The IRB member/chair will inform the entire committee and Institutional Official (or their designee) of the adverse event, including any information provided by the investigator.
5. Depending on the nature of the event/complaint the issue will be addressed by the IRB Chair, entire IRB committee, and/or Institutional Official (or their designee). Part C, D and E of this policy shall be used in evaluating the event/complaint. For further guidance see the OHRP Guidance in the Appendix (4).
6. If after evaluation of the report it is found that the unanticipated problem needs to be reported to OHRP, it should be reported to Institutional officials, OHRP, and other agencies (if applicable) within 30 days.
6. Irrespective of the resolution, the entire IRB shall be informed at the next meeting of the report, and any response by the IRB.

G. Response to Unanticipated Problems Involving Risk to Subjects or Others. Possible responses include, but are not limited to:

1. No response – minor issues only, not really an unanticipated problem.
2. changes to the research protocol initiated by the investigator prior to obtaining IRB approval to eliminate apparent immediate hazards to subjects;
3. modification of inclusion or exclusion criteria to mitigate the newly identified risks;
4. implementation of additional procedures for monitoring subjects;
5. suspension of enrollment of new subjects;
6. suspension of research procedures in currently enrolled subjects;
7. modification of informed consent documents to include a description of newly recognized risks; and
8. provision of additional information about newly recognized risks to previously enrolled subjects.

1. 45 CFR 46.103 (b)(5)
2. 21 CFR 56.108 (b)(1)
3. IRB Policy 9.3
4. OHRP Guidance on Reviewing and Reporting Unanticipated Problems Involving Risks to Subjects or Others and Adverse Events

3.11 Investigational Drugs, Biologics, and Devices

A. It is the policy of TAMIU's Institutional Review Board (IRB) – to whenever possible enter into a cooperative research agreement for research falling under FDA regulations, this includes investigational drugs, biologics, and device (1). This does not include routine medical procedures (blood draws, magnetic resonance imaging, etc.)

B. Currently TAMIU IRB does not review any research under the FDA, nor is it authorized to under its Federalwide Assurance (1, 2).

1. 21 CFR 56.102 (c)
2. TAMIU's Federalwide Assurance – see appendix

3.12 Recruitment and Advertising

A. It is the policy of TAMIU's Institutional Review Board (IRB) – That all recruiting and advertising materials must be approved by the IRB. When advertising is to be used, the IRB must review the information contained in the advertisement and the mode of its communication to determine that the procedure for recruiting participants is not coercive and does not state or imply a certainty of favorable outcome or other benefits beyond what is outlined in the consent document and the protocol.

B. Any advertisement to recruit participants shall be limited to the information the prospective participants need to determine their eligibility and interest.

C. Advertising materials shall not include the following:

1. claims, either explicit or implicit, that the intervention is safe or effective for the purposes under investigation;
2. claims, either explicit or implicit, that the test article is known to be equivalent or superior to any other drug, biologic, device or intervention;
3. promise of "free medical treatment," when the intent is only to say that participants will not be charged for taking part in the investigation;
4. an emphasis on the payment or the amount to be paid, by such means as larger or bold type.

D. The IRB has the authority to approve whether compensation information shall be included in the advertisement.

E. Employees as Participants - No researcher may give an indication that an employee is required or shall consent to participate as a research subject. No coercion or inference that employment status could be affected with respect to participation in research activities is allowed.

F. Students as Participants - Prior to enrollment in a course where students may be requested to participate as research subjects, students shall be informed of the possibility. The course syllabus shall clearly describe proposed participation in research activities for course credit and include an alternative means of earning the course credit. Any IRB concerns regarding the use of students will promptly be forwarded to the Office of the Provost.

3.13 Payment to Subjects

A. It is the policy of TAMIU's Institutional Review Board (IRB) – That all payment to subjects shall be considered compensation for time and inconvenience **ONLY**.

B. The IRB must determine that the risks to subjects are reasonable in relation to anticipated benefits and that the consent document contains an adequate description of the study procedures as well as the risks and benefits. Payment/gifts or other non-

monetary renumeration to research subjects for participation in studies is not considered a benefit.

C. The amount and schedule of all payments shall be presented to the IRB at the time of initial review. The IRB shall review both the amount of payment and the proposed method and timing of disbursement to determine that neither are coercive nor present undue influence.

D. Timing of Payments - Payment(s) shall be made to the subject as the study progresses and shall not be contingent upon the subject completing the entire study.

E. Disclosure of Payments - All information concerning payment, including the amount and schedule of payment(s) shall be set forth in the informed consent document.

F. Alterations in Payments - Any alterations in human research subject payment or revising of the payment schedule must be reported to the IRB prior to implementation as an amendment.

G. Finder's Fees - The IRB does not allow the use of any form of compensation to individuals (including faculty, staff, students, family members, etc.) who identify and/or recruit subjects for participation in a research study.

H. Documentation of Payments - The PI must keep documentation of payment(s) made to each subject in study files. All records shall be made accessible for inspection and copying by TAMIU IRB, authorized TAMIU representatives, as well as federal regulatory officials.

3.14 Research occurring at schools (Pre-K through 12th Grade)

A. It is the policy of TAMIU's Institutional Review Board (IRB) that all research occurring at schools (Pre-K through 12th Grade) be first approved by that schools IRB before consideration by/approval by TAMIU IRB. Exceptions may be made in the case of grant applications, or at the discretion of the IRB, however no subjects may be enrolled until this requirement is satisfied.

B. If at any time the schools IRB should withdraw approval to conduct research the TAMIU IRB must be informed by the investigator.

3.15 Knowledge of Local Context

A. It is the policy of TAMIU's Institutional Review Board (IRB) – to obtain sufficient knowledge of the local research context to fulfill its responsibilities under its FWA, regardless of the geographical location of the research.

B. TAMIU's IRB must fulfill the responsibilities under the regulations and its FWA (1) with the Federal government to ensure that the IRB has sufficient knowledge of local context of the research regardless of its geographical location (2).

C. When TAMIU's IRB is either geographically removed from the site in which the research will be conducted, the TAMIU IRB is serving as another institution's IRB of Record, or when the research involves a distinct subject population, the IRB must demonstrate that it has obtained the necessary information about the local research context through compliance with required standards.

1. When the IRB expands or limits its jurisdiction through the use of an Authorization Agreement (3) or Cooperative Research Project (4), TAMIU's IRB has a responsibility to ensure that the particular characteristics of the local research context are considered either:
    a. Through knowledge of the local research context by the reviewing IRB; or
    b. Through subsequent review by appropriate designated institutional officials, such as the Chairperson and/or other members of its local IRB.

1. TAMIU's Federalwide Assurance
2. 45 CFR 46.103(d), OPRR Guidance Dated August 1998 and July 2000
3. OHRP Website - Assurances
4. IRB Policy I.A

4. Informed Consent Process

4.1 Legally Effective and Prospectively Obtained Informed Consent

A. It is the policy of TAMIU's Institutional Review Board (IRB) – that no Investigator involves a human being as a subject in research unless the Investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative, unless the IRB has granted a waiver of the informed consent requirement.

B. Except as provided elsewhere in this policy, no Investigator may involve a human being as a subject in research covered by this policy unless the Investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An Investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence (1, 2).

B. Basic elements of informed consent (except as provided in IRB Policy 4.3 (3)) in seeking informed consent the following information shall be provided to each subject:

1. 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;
2. A description of any reasonably foreseeable risks or discomforts to the subject;
3. A description of any benefits to the subject or to others which may reasonably be expected from the research;
4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
6. For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
7. 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; and
8. 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 (4, 5).

C. Additional elements of informed consent - When appropriate, one or more of the following elements of information shall also be provided to each subject:

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; and
6. The approximate number of subjects involved in the study.
7. The amount of payment, if any, and the proposed method and timing of disbursement (6, 7).

1. 45 CFR 46.116
2. 21 CFR 50.20
3. IRB Policy 4.3
4. 45 CFR 46.116 (a)
5. 21 CFR 50.25 (a)
6. 45 CFR 46.116 (b)
7. 21 CFR 50.25 (b)

4.2 Documentation of Informed Consent for Human Subjects Research

A. It is the policy of TAMIU's Institutional Review Board (IRB) – that informed consent is documented as determined in the IRB review and approval process.

B. Except as provided below, informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form (1, 2).

C. Except as provided below, the consent form may be either of the following:

1. A written consent document that embodies the elements of IRB Policy 4.1 (3). This form may be read to the subject or the subject's legally authorized representative, but in any event, the Investigator shall give either the subject or the representative adequate opportunity to read it before it is signed; (4, 5) or
2. A short form consent document stating that the elements in IRB Policy 4.1 (3) 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 will approve a written summary of what is to be said to the subject or the representative. Only the short form consent itself is to be signed by the subject or the representative. However, the witness shall sign both the short form consent 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 consent (6, 7).

D. Verbal Consent - The IRB may waive the requirement for the Investigator to obtain a signed consent form for some or all subjects if it finds either:
1. 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
2. That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent form is normally required outside of the research context. In cases in which the documentation requirement is waived, the IRB may require the Investigator to provide subjects with a written statement regarding the research (8). This waiver provision does not apply to research regulated by the FDA.

E. Minimal Risk Surveys of Adults. For surveys that are minimal risk, completion of the survey is often considered consent.

1. 45 CFR 46.117 (a)
2. 21 CFR 50.27 (a)
3. IRB Policy 4.1
4. 45 CFR 46.117 (b)(1)
5. 21 CFR 50.27 (b)(1)
6. 45 CFR 46.117 (b)(2)
7. 21 CFR 50.27 (b)(2)
8. 45 CFR 46.117 (c)

4.3 Waiver of Informed Consent for Human Subjects Research

A. It is the policy of TAMIU's Institutional Review Board (IRB) – to grant a waiver from informed consent for research as defined by Federal regulations (1, 2).

B. Waiver of informed consent - The IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in IRB Policy 4.1 (3) or waive the requirement to obtain informed consent provided the IRB finds and documents that:

1. The research or demonstration project is to be conducted by or subject to the approval of State or Local government officials and is designed to study, evaluate, or otherwise examine:
   a. public benefit or service programs;
   b. procedures for obtaining benefits or services under those programs;
   c. possible changes in or alternatives to those programs or procedures; or

d. possible changes in methods or levels of payment for benefits or services under those programs; and

2. The research could not practicably be carried out without the waiver or alteration (4). (This waiver provision does not apply to research regulated by the FDA).

a. An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in IRB Policy 4.1 (3) or waive the requirements to obtain informed consent provided the IRB finds and documents that:

i. The research involves no more than minimal risk to the subjects;

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

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

iv. Whenever appropriate, the subjects will be provided with additional pertinent information after participation (1)

1. 45 CFR 46.116 (d)
2. 21 CFR 50.24
3. IRB Policy 4.1
4. 45 CFR 46.116 (c)

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

A. It is the policy of TAMIU's Institutional Review Board (IRB) – that adequate provisions are made for soliciting permission of each child's parents or guardian and the assent of each child for the participation in research, when in the judgment of the IRB the children are capable of providing assent, unless the IRB has granted a waiver of the permission and / or assent requirements as defined by Federal regulations.

B. In addition to the determinations required under IRB Policy 5.3 (1) the IRB will determine that adequate provisions are made for soliciting the assent of the children, when in the judgment of the IRB the children are capable of providing assent. In determining whether children are capable of assenting, the IRB will take into account the ages, maturity, and psychological state of the children involved. This judgment may be made for all children to be involved in research under a particular protocol, or for each child, as the IRB deems appropriate. If the IRB determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research, the assent of the children is not a necessary condition for proceeding with the research. Even where the IRB determines that the subjects are capable of assenting, the IRB may still waive the assent requirement under circumstances in which consent may be waived in accord with IRB Policy 4.3 (2).

C. In addition to the determinations required under IRB Policy 5.3 (1) the IRB will determine, in accordance with and to the extent that consent is required by IRB Policy 4.1 (3) or 4.3 (2) that adequate provisions are made for soliciting the permission of each child's parents or guardians. Where parental permission is to be obtained, the IRB may find that the permission of one parent is sufficient for research to be conducted in accordance with IRB Policy 5.3.B.1, or 5.3.B.2 (4). Where research is covered by IRB Policy 5.3.B.3 or 5.3.B.4 (5) and permission is to be obtained from parents, both parents must give their permission unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

D. In addition to the provisions for waiver contained in IRB Policy 4.3 (2), if the IRB determines that a research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children), it may waive the consent requirements in IRB Policy 4.1 (3) and Section C of this policy, provided an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted, and provided further that the waiver is not inconsistent with Federal, State, or Local law. The choice of an appropriate mechanism would depend upon the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and their age, maturity, status, and condition.

D. Permission by parents or guardians shall be documented in accordance with and to the extent required by IRB Policy 4.2 (6). In addition, given the local research context, for research done using children from South Texas, the parental consent forms will be required to be available in both English and Spanish, unless there is a clear reason that only one language should be used.

E. When the IRB determines that assent is required, it will also determine whether and how assent must be documented, and in what language(s) (7).

1. IRB Policy 5.3
2. IRB Policy 4.3
3. IRB Policy 4.1
4. IRB Policy 5.3.B.1, 5.3.B.2
5. IRB Policy 5.3.B.3, 5.3.B.4
6. IRB Policy 4.2
7. 45 CFR 46.408

5. Vulnerable Populations

5.1 Special Categories of Research: Pregnant Women, Human Fetuses and Neonates

A. It is the policy of TAMIU's Institutional Review Board (IRB) – to review research involving pregnant women, human fetuses, and neonates and approve only research which satisfies the requirements of 45 CFR 46 Subpart B (1) and other applicable Federal, State, and Local laws (2, 3).

B. Research involving pregnant women or fetuses - Pregnant women or fetuses may be involved in research if all of the following conditions are met:

1. Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on nonpregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses; and
2. 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 that the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means; and
3. Any risk is the least possible for achieving the objectives of the research; and
4. 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 IRB Policy 4.1 (4); and
5. 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 IRB Policy 4.1 (4), 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; and
6. Each individual providing consent under (B.4) or (B.5) above, is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate; and
7. For children who are pregnant, assent and permission are obtained in accord with the provisions of IRB Policy 4.4 (5); and
8. No inducements, monetary or otherwise, will be offered to terminate a pregnancy; and
9. 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
10. Individuals engaged in the research will have no part in determining the viability of a neonate (6).

C. Research Involving Neonates of uncertain viability and nonviable neonates may be involved in research if all of the following conditions are met:

1. Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to neonates; and
2. Each individual providing consent under paragraph B.4 or B.5 of this section is fully informed regarding the reasonably foreseeable impact of the research on the neonate; and
3. Individuals engaged in the research will have no part in determining the viability of the neonate; and
4. The requirements of paragraph D or E of this section have been met as applicable.

D. Neonates of uncertain viability. Until it has been ascertained whether or not a neonate is viable, a neonate may not be involved in research covered by this policy unless the following additional conditions have been met:

1.The IRB determines that:

a. The research holds out the prospect of enhancing the probability of survival of the neonate to the point of viability, and any risk is the least possible for achieving that objective; or

b. The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means and there will be no added risk to the neonate resulting from the research.

2. The legally effective informed consent of either parent of the neonate, or if neither parent is able to consent because of unavailability, incompetence, or temporary incapacity, the legally effective informed consent of either parent's legally authorized representative is obtained in accord with IRB Policy 4.1 (3) except that the consent of the father or his legally authorized representative need not be obtained if the pregnancy resulted from rape or incest.

E. Nonviable neonates. After delivery a nonviable neonate may not be involved in research covered by this policy unless all of the following additional conditions are met:

1. Vital functions of the neonate will not be artificially maintained; and
2. The research will not terminate the heartbeat or respiration of the neonate; and
3. There will be no added risk to the neonate resulting from the research; and
4. The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means; and
5. The legally effective informed consent of both parents of the neonate is obtained in accord with IRB Policy 4.1 (3), except that the waiver and alteration provisions of IRB Policy 4.3 (7) do not apply. However, if either parent is unable to consent because of unavailability, incompetence, or temporary incapacity, the informed consent of one parent of a nonviable neonate will suffice to meet the requirements of this paragraph, except that the consent of the father need not be obtained if the pregnancy resulted from rape or incest. The consent of a legally authorized representative of either or both of the parents of a nonviable neonate will not suffice to meet the requirements of this paragraph.

F. Viable neonates. A neonate, after delivery, that has been determined to be viable may be included in research only to the extent permitted by and in accord with the requirements of 45 CFR 46 Subparts A (8) and D (9, 10).

G. Research involving, after delivery, the placenta, the dead fetus, or fetal material.

1. Research involving, after delivery, the placenta; the dead fetus; macerated fetal material; or cells, tissue, or organs excised from a dead fetus, shall be conducted only in accord with any applicable Federal, State, or Local laws and regulations regarding such activities.
2. If information associated with material described in paragraph G.1 of this section is recorded for research purposes in a manner that living individuals can be identified, directly or through identifiers linked to those individuals, those individuals are research subjects and all IRB policies are applicable (11).

H. Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of pregnant women, fetuses, or neonates. Research that the IRB does not believe meets the requirements of this policy:

1. The IRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses, or neonates; and
2. The Secretary of DHHS, after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, ethics, law) and following opportunity for public review and comment, including a public meeting announced in the Federal Register, has determined either:
    a. That the research, in fact, satisfies the conditions of 45 CFR 46.204 6 as applicable; or
    b. The following:
        i. The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses, or neonates; and
        ii. The research will be conducted in accord with sound ethical principles; and
        iii. Informed consent will be obtained in accord with the informed consent provisions of 45 CFR 46 Subpart A 8 and other applicable subparts of 45 CFR 46 (12).

I. Exemption from Review. The exemptions from IRB review listed at IRB Policy 3.3 (13) may be applied to research involving pregnant women, human fetuses, and neonates (14, 15).

1. 45 CFR 46 Subpart B
2. 45 CFR 46.203
3. 21 CFR 56.111 (b)
4. IRB Policy 4.1
5. IRB Policy 4.4
6. 45 CFR 46.204

7. IRB Policy 4.3
8. 45 CFR 46 Subpart A
9. 45 CFR 46.205
10. 45 CFR 46 Subpart D
11. 45 CFR 46.206
12. 45 CFR 46.207
13. IRB Policy 3.3
14. 45 CFR 46.101(b)
15. 45 CFR 46.201 (b)

5.2 Special Categories of Research: Prisoners

A. It is the policy of TAMIU's Institutional Review Board (IRB) – to review and approve all research involving prisoners with additional ethical and regulatory considerations applicable to prisoners under 45 CFR 46, Subpart C (1), and other applicable Federal, State, and Local laws (2).

B. Composition of Institutional Review Boards where prisoners are involved - In addition to satisfying the requirements of IRB Policy 2.2 (3), the Institutional Review Board, carrying out responsibilities under this part with respect to research covered by this policy, will also meet the following specific requirements:

1. A majority of the Board (exclusive of prisoner members) will have no association with the prison(s) involved, apart from their membership on the Board.
2. At least one member of the Board will be a prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity, except that where a particular research project is reviewed by more than one Board only one Board need satisfy this requirement (4).

C. Additional duties of the IRB where prisoners are involved.

1. In addition to all other responsibilities in this section, the IRB will review research covered by this policy and approve such research only if it finds that:
   a. The research under review represents one of the categories of research permissible under Section D of this policy.
   b. Any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired;
   c. The risks involved in the research are commensurate with risks that would be accepted by nonprisoner volunteers;
   d. Procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the principal investigator provides to the IRB justification in writing for following some other procedures, control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project;
   e. The information is presented in language which is understandable to the subject population;

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

g. Where the IRB finds there may be a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact.

2. The IRB will carry out such other duties as may be assigned by the Secretary of DHHS.

3. The institution will certify to the Secretary of DHHS, in such form and manner as the Secretary may require, that the duties of the IRB under this section have been fulfilled (5).

D. Permitted research involving prisoners - Biomedical or behavioral research may involve prisoners as subjects only if:

1. TAMIU has certified to the Secretary of DHHS that the IRB has approved the research under this policy; and

2. In the judgment of the Secretary of DHHS the proposed research involves solely the following:

a. Study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk for prisoners and no more than inconvenience to the subjects;

b. Study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;

c. Research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults) provided that the study may proceed only after the Secretary of DHHS has consulted with appropriate experts including experts in penology, medicine, and ethics, and published notice, in the Federal Register, of his/her intent to approve such research; or

d. Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject. In cases in which those studies require the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups which may not benefit from the research, the study may proceed only after the Secretary of DHHS has consulted with appropriate experts, including experts in penology, medicine, and ethics, and published notice, in the Federal Register, of the intent to approve such research (6).

e. Research that has as its sole purpose:

i. To describe the prevalence or incidence of a disease by identifying all cases, or

ii. To study potential risk factor associations for a disease (7, 8).

E. Exemption from review of research involving prisoners is not allowed (9).

1. 45 CFR 46 Subpart C
2. 21 CFR 56.111 (b)
3. IRB Policy 2.2
4. 45 CFR 46.304
5. 45 CFR 46.305
6. 45 CFR 46.306
7. 45 CFR 46.101(i)
8. Waiver of the Applicability of Certain Provisions of Department of Health and Human Services Regulations for Protection of Human Research Subjects for Department of Health and Human Services Conducted or Supported Epidemiologic Research Involving Prisoners as Subjects, 68 FR 36929
9. 45 CFR 46.101(i), Footnote 1

5.3 Special Categories of Research: Children

A. It is the policy of TAMIU's Institutional Review Board (IRB) – to review research involving children and approve only research which satisfies the requirements of 45 CFR 46 Subpart D (1) and other applicable Federal, State, and local laws (2, 3).

B. Categories of Research Involving Children

1. Research not involving greater than minimal risk: The IRB may approve research in which the IRB finds that no greater than minimal risk to children is presented, only if the IRB finds that adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians, as set forth in IRB Policy 4.4 (4, 5).
2. Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects: The IRB may approve research in which the IRB finds that greater than minimal risk to children is presented by an intervention or procedure that 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, only if the IRB finds that:
    a. The risk is justified by the anticipated benefit to the subjects;
    b. 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
    c. Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians, as set forth in IRB Policy 4.4 (5, 6).
3. Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition. The IRB may approve research in which the IRB finds that greater than minimal risk to children is presented by an intervention or procedure that does not hold out the prospect of direct benefit for the individual subject, or by a monitoring procedure which is not likely to contribute to the well-being of the subject, only if the IRB finds that:
    a. The risk represents a minor increase over minimal risk;
    b. The intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations;

c. The intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition; and

d. Adequate provisions are made for soliciting assent of the children and permission of their parents or guardians, as set forth in IRB Policy 4.4 (5, 7)

4. The IRB generally may not approve research that does not meet the requirements of sections B.1, B.2, or B.3 of this policy. However, if the research presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children, the IRB may approve the research if the following has occurred:

a. The IRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children; and

b. The Secretary of DHHS, after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, education, ethics, law) and following opportunity for public review and comment, has determined either:

i. That the research in fact satisfies the conditions of Sections B.1, B.2, or B.3 of this policy (45 CFR 46.404 (4);45 CFR 46.405 (6);45 CFR 46.406 (7)) as applicable, or

ii. the following:

1. The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children;

2. The research will be conducted in accordance with sound ethical principles;

3. Adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians, as set forth in IRB Policy 4.4 (5, 8).

C. Wards of the State or Other Agency.

1. Children who are wards of the state or any other agency, institution, or entity can be included in research approved under B.3 and B.4 of this policy only if the IRB finds and documents that such research is:

a. Related to their status as wards; or

b. Conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as participants are not wards.

2. If the research is approved under section C.1.a of this policy, the IRB will 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 Investigators, or the guardian organization (9).

D. Exemptions.

1. The exemptions specified in 45 CFR 46.101(b)(1), (b)(3), (b)(4), (b)(5) and (b)(6) are applicable to research involving children (see IRB Policy 3.3 (10)), Only the IRB may determine which activities qualify for an exempt review. Investigators do not have the authority to make an independent determination that research involving human subjects is exempt and must contact the IRB concerning the status of proposed research or changes in ongoing research.

2. The exemption at 45 CFR 46.101(b)(2) (see IRB Policy 3.3 (10)) only applies to research involving children for research involving observation of public behavior when the Investigator does **not** participate in the activities being observed. The exemption does not apply where the research involves survey or interview procedures or **any** direct interaction with the participants being observed (11).

1. 45 CFR 46 Subpart D
2. 45 CFR 46.403
3. 21 CFR 56.111 (b)
4. 45 CFR 46.404
5. IRB Policy 4.4
6. 45 CFR 46.405
7. 45 CFR 46.406
8. 45 CFR 46.407
9. 45 CFR 46.409
10. IRB Policy 3.3
11. 45 CFR 46.401 (b)

5.4 Special Categories of Research: Other Participants Who May Be Vulnerable to Coercion or Undue Influence

A. It is the policy of TAMIU's Institutional Review Board (IRB) – to ensure that additional safeguards have been included in the research to protect the rights and welfare of subjects who are likely to be vulnerable to coercion or undue influence. These subjects might include mentally disabled persons, or economically or educationally disadvantaged persons, or other persons as determined by the IRB (1, 2).

1. 45 CFR 46.111 (b)
2. 21 CFR 56.111 (b)

6. IRB Records and Documents

6.1 IRB Records

A. It is the policy of TAMIU's Institutional Review Board (IRB) – to prepare and maintain adequate documentation of IRB activities as defined by Federal regulations.

B. The IRB will prepare and/or maintain all of the following documents:

1. Copies of all research proposals reviewed, including scientific and scholarly evaluations, if any that accompany the proposals, approved sample consent documents, continuing review reports submitted by the Investigators and reports of injuries to subjects.
2. Minutes of IRB meetings that will be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution – See IRB Policy 3.7C (2).
3. Records of continuing review activities.
4. Copies of all correspondence between the IRB and the Investigators.
5. A list of IRB members in the same detail as described in 45 CFR 46.103(b)(3). (1)
    a. A list of IRB members identified by name; earned degrees; representative capacity; indications of experience such as board certifications, licenses, etc., sufficient to describe each member's chief anticipated contributions to IRB deliberations; and any employment or other relationship between each member and the institution; for example: full-time employee, part-time employee, member of governing panel or board, paid or unpaid consultant (1).
6. Written procedures for the IRB as required by 45 CFR 46.103(b)(4) and (b)(5). In addition the IRB should refer to "OHRP: Guidance on Written Procedures" for other recommendations.
    a. The procedures which the IRB will follow for conducting its initial review of research.
    b. The procedures which the IRB will follow for conducting its continuing review of research.
    c. The procedures which the IRB will follow for reporting its findings and actions to investigators and the institution.
    d. The procedures which the IRB will follow for determining which projects require review more often than annually.
    e. The procedures which the IRB will follow for determining which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review.
    f. The procedures which the IRB will follow for ensuring prompt reporting to the IRB of proposed changes in a research activity, and for ensuring that such changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject.

g. The procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, any Department or Agency head, and OHRP of: (a) any unanticipated problems involving risks to subjects or others; (b) any serious or continuing noncompliance with 45 CFR Part 46 or the requirements or determinations of the IRB; and (c) any suspension or termination of IRB approval.

7. Statements of significant new findings provided to subjects, as required by IRB Policy 4.1 (3).

C. The IRB records required by this policy shall be retained for at least 3 years.

D. Protocol Files

1. Each protocol file should be assigned a unique number. For convenience and tracking of review time each proposal will be assigned a number based on the date of receipt YYYY-MM-DD. If more than one proposal is received on a given day the additional proposal(s) will be assigned the following day(s) or by adding a,b,c,etc to the end of the date.
2. Each completed protocol file shall have
   a. A copy of the approval letter sent to the investigator and copied to the Provost or their designee.
   b. Documentation of review and/or a copy of the minutes where the protocol was reviewed.
   c. If exempt or expedited – documentation of the category used for exemption or expedited review.
   d. An original copy of the completed protocol and associated documents (including consent forms, assent forms, survey instruments, etc as appropriate).
   e. A copy of all written (electronic or paper) correspondence between the IRB and the investigator and/or institutional officials and/or others concerning the protocol.
   f. A copy of all requested modifications and IRB determinations based on these requests, including associated correspondence.
   g. Adverse events/complaints if reported, and documentation of IRB response to those events, including a copy of all associated correspondence.
   h. Compliance audit results if completed and associated correspondence.
   i. Completion reports if completed and associated correspondence.

E. Access to Documents

1. Certain IRB documents are privileged and confidential records, not subject to disclosure except to authorized TAMIU representatives, including IRB members, Compliance personnel, the Provost or their designee. Requests for authorization to access IRB records shall be made to the Office of the Provost.
2. All records must be accessible for inspection and copying by authorized representatives of FDA, OHRP or any authorized department or agency at reasonable times and in a reasonable manner (4, 5).

1. 45 CFR 46.103(b)(3)
2. IRB Policy 3.7c
3. IRB Policy 4.1
4. 45 CFR 46.115
5. 21 CFR 56.115

6.2 Research Records

A. It is the policy of TAMIU's Institutional Review Board (IRB) – that each investigator shall be responsible form maintaining records of all non-exempt research for a minimum of 3 years after the completion of research (1, 2).

B. If the investigator is a TAMIU student researcher, the records shall, in most cases, be maintained by that student's mentor upon completion of the research, for a minimum of 3 years.

C. If the non-exempt research is funded externally, or results of the non-exempt research are published, it is the responsibility of the investigator to be aware of, and maintain research records for the required amount of time by that funding agency or publisher/journal.

D. Access to Documents

1. Certain research records are privileged and confidential records, not subject to disclosure except to authorized TAMIU representatives, including IRB members, Compliance personnel, the Provost or their designee. Requests for authorization to access research records shall be made to the Office of the Provost.
2. All records must be accessible for inspection and copying by authorized representatives of FDA, OHRP or any authorized department or agency at reasonable times and in a reasonable manner (1, 2).

1. 45 CFR 46.115
2. 21 CFR 56.115

7. IRB Education and Training

7.1 Investigator, Study Personnel, IRB Committee Member and Staff Training

A. It is the policy of TAMIU's Institutional Review Board (IRB) – to ensure that research investigators, study personnel, IRB Committee members and staff maintain continuing knowledge of, and comply with the following: relevant ethical principles; relevant Federal regulations; written IRB policies and procedures; OHRP guidance; other applicable guidance, State and Local laws; and Institutional policies for the protection of human subjects.

B. All investigators conducting human research shall be required to review the Belmont Report in compliance with TAMIU's Federal Wide Assurance (1).

C. All investigators conducting expedited or non-exempt research will be required to undergo additional training designated by the Office of the Provost. (NOTE: Currently that training is CITI Program – http://www.citiprogram.org/). Annual retraining will be required.

1. All "investigators" that are directly involved in supervising the research will undergo Investigator training prior to enrolling subjects. This includes primary investigators, co-investigators, student investigators that are the primary researcher, and primary faculty mentors of those student investigators.
2. All "research assistants" that are directly involved with primary research data, or subjects must undergo Research Assistant/Student Assistant training before assisting with research. The primary investigator is required to maintain documents verifying that all "research assistants" were properly trained. (NOTE: if the research assistant ONLY has access to blinded data, and NO access to the subject identity/code then training is recommended but not required.)

D. All IRB members, and the IRB Chair, will be required to undergo IRB member training. IRB member training will consist of two components:

1. IRB members manual – This manual will contain the IRB policies and procedures manual, supporting documents, and IRB forms. The IRB Chair or their designee will review these policies with the IRB member when they join the committee.
2. IRB members will participate in IRB member training annually as designated by the Office of the Provost.

1. TAMIU's Federalwide Assurance – see appendix

8. Privacy and Confidentiality

8.1 Health Insurance Portability and Accountability Act (HIPAA) Policy

A. It is the policy of TAMIU's Institutional Review Board (IRB) – requires in its role as the Privacy Board for TAMIU, that research data be used, stored and/or disclosed only according to current HIPAA regulations. This Policy covers all Protected Health Information (PHI), that is created, used, or disclosed during research activities.

B. Texas A& M University System designates itself and its component institutions as an affiliated covered entity for purpose of administering the group health plans know as the A & M Care Plans. Additionally many faculty at TAMIU are engaged in clinical activities involving PHI.

C. When must use of PHI that is going to be used for research be reviewed by the IRB as the Privacy Board?
1. An investigator may always use or disclose for research purposes health information which has been de-identified (in accordance with 45 CFR 164.502(d), and 164.514(a)-(c) of the Rule) without regard to the provisions below. Note this de-identification means that the only geographic information known about a participant is the state, and the first three digits of the zip code if there are more than twenty thousand people living in that geographic area, in addition to many other requirements. See 45 CFR 64.514(a)-(c).
2. The de-identified information may be assigned code or other means of record identification to allow de-identified information to be re-identified, provided that, the key to such a code is not accessible to the Investigator requesting to use or disclose the de-identified health information and the code is not derived from or related to information about the individual and is not capable of being translated so as to identify the individual (15).
3. If health information is collected prospectively as part of a study for the purposes of that study only, then by definition it is not PHI. (Obviously medical information collected in a clinical setting as part of the study is also PHI – see part J below). The study must be reviewed by the IRB if it is human research, but it is not regulated by HIPAA requirements.
4. Access to most other health information falls under HIPAA privacy rules.

D. What is the purpose of the Privacy Rule?
The Privacy Rule also defines the means by which individuals will be informed of uses and disclosures of their medical information for research purposes, and their rights to access information about them held by covered entities. Where research is concerned, the Privacy Rule protects the privacy of individually identifiable health information, while at the same time ensuring that researchers continue to have access to medical information necessary to conduct vital research. Currently, most research involving human subjects operates under the Common Rule (45 CFR Part 46, Subpart A) and/or the Food and Drug Administration’s (FDA) human subject protection regulations (21 CFR Parts 50 and 56), which have some provisions that are similar to, but separate from, the Privacy Rule’s provisions for research. These human subject protection

regulations, which apply to most Federally-funded and to some privately funded research, include protections to help ensure the privacy of subjects and the confidentiality of information. The Privacy Rule builds upon these existing Federal protections. More importantly, the Privacy Rule creates equal standards of privacy protection for research governed by the existing Federal human subject regulations and research that is not.

E. How the Rule Works : In the course of conducting research, researchers may obtain, create, use, and/or disclose individually identifiable health information. Under the Privacy Rule, covered entities are permitted to use and disclose protected health information for research with individual authorization, or without individual authorization under limited circumstances set forth in the Privacy Rule. Described in Sections F- J.

F. Research Use/Disclosure Without Authorization. Except as set forth in this policy an investigator must obtain an authorization from each participant prior to use or disclosure for any research related purpose. To use or disclose protected health information without authorization by the research participant, an Investigator must comply with one of the following:

1. Documented Institutional Review Board (IRB) / Privacy Board Approval. Documentation that an alteration or waiver of research participants' authorization for use/disclosure of information about them for research purposes has been approved by an IRB or a Privacy Board. See 45 CFR 164.512(i)(1)(i). This provision of the Privacy Rule might be used, for example, to conduct records research, when researchers are unable to use de-identified information, and the research could not practicably be conducted if research participants' authorization were required.

a. A legally effective authorization for use of protected health information for research purposes requires documentation of **all** of the following:

i. identification of the IRB or Privacy Board and the date on which the alteration or waiver of authorization was approved;

ii. A statement that the IRB or Privacy Board has determined that the alteration or waiver of authorization, in whole or in part, satisfies the three criteria in the Rule;

iii. A brief description of the protected health information for which use or access has been determined to be necessary by the IRB or Privacy Board. It should identify the information in a specific and meaningful way;

iv. The name or other specific identification of the person(s), or class of persons, authorized to make the requested use of disclosure (for example research assistants);

v. A statement that the alteration or waiver of authorization has been reviewed and approved under either normal or expedited review procedures; and

vi. The signature of the chair or other member, as designated by the chair, of the IRB or the Privacy Board, as applicable.

b. The following three criteria must be satisfied and documented for an IRB or Privacy Board to approve a waiver of authorization under the Privacy Rule:

i. The use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements:

1. an adequate plan to protect the identifiers from improper use and disclosure;
2. an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and
3. adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of protected health information would be permitted by this Policy;

ii. The research could not practicably be conducted without the waiver or alteration; and

iii. The research could not practicably be conducted without access to and use of the protected health information (5).

c. When uses or disclosures of PHI are made pursuant to a waiver, the Investigator must make reasonable efforts to limit PHI to the minimum necessary to accomplish the intended purpose of the use or disclosure (6). When the Investigator makes the representations set forth in Section C.1 of this policy to obtain a waiver, the IRB will rely on the Investigator to ensure that the minimum necessary standard is met (7).

d. If the IRB grants a waiver and the Investigator discloses any PHI outside of TAMIU, the Investigator must record the following information for any PHI disclosed:

i. The date of the disclosure;

ii. The name of the entity or person who received the PHI and, if known, the address of such entity or person;

iii. A brief description of the PHI disclosed; and

iv. A brief statement of the purpose of the disclosure that describes the basis for disclosure(8).

G. Research Use or Disclosure of Limited Data Sets with a Data Use Agreement.
A data use agreement entered into by both the covered entity and the researcher, pursuant to which the covered entity may disclose a limited data set to the researcher for research, public health, or health care operations. See 45 CFR 164.514(e) (9). A limited data set excludes specified direct identifiers of the individual or of relatives, employers, or household members of the individual.

1. The data use agreement must:

a. Establish the permitted uses and disclosures of the limited data set by the recipient, consistent with the purposes of the research, and which may not include any use or disclosure that would violate the Rule if done by the covered entity;

b. Limit who can use or receive the data; and

c. Require the recipient to agree to the following:

i. Not to use or disclose the information other than as permitted by the data use agreement or as otherwise required by law;

ii. Use appropriate safeguards to prevent the use or disclosure of the information other than as provided for in the data use agreement;

iii. Report to the covered entity any use or disclosure of the information not provided for by the data use agreement of which the recipient becomes aware;

iv. Ensure that any agents, including a subcontractor, to whom the recipient provides the limited data set agrees to the same restrictions and conditions that apply to the recipient with respect to the limited data set; and

v. Not to identify the information or contact the individual.

2. When uses or disclosures of a Limited Data Set are made pursuant to a Data Use Agreement, the Investigator must make reasonable efforts to limit PHI to the minimum necessary to accomplish the intended purpose of the use or disclosure (10).

H. Research Use or Disclosure of Decedent's PHI without Authorization.

1. Except as set forth in Section E.2 below, an Investigator may use and disclose a decedent's PHI for research purposes without IRB review provided that all of the following criteria are satisfied:

a. The use or disclosure will be solely for research on the PHI of decedents;

b. The PHI for which use or disclosure is sought is necessary for research purposes; and

c. The Investigator has documentation of the death of the individuals whose PHI is being sought (11).

2. For PHI that is included in medical records at TAMIU, an Investigator may use and disclose a decedent's PHI for research purposes in accordance with this IRB Policy.

3. When uses or disclosures of a decedent's PHI are made without authorization, the Investigator must make reasonable efforts to limit PHI to the minimum necessary to accomplish the intended purpose of the use or disclosure (12).

I. Use and Disclosure of PHI without Authorization when it is Preparatory to Research.

1. An Investigator may use or disclose PHI without IRB review for activities preparatory to research if all of the following criteria are satisfied:

a. Use or disclosure is sought solely to review PHI as necessary to prepare a research protocol or for similar purposes preparatory to research;

b. No PHI is to be removed from TAMIU by the Investigator in the course of the review; and

c. The PHI for which use is sought is necessary for the research purposes (16).

2. When uses or disclosures are made without authorization preparatory to research, the Investigator must make reasonable efforts to limit PHI to the minimum necessary to accomplish the intended purpose of the use or disclosure (17).

3. This provision might be used, for example, to design a research study or to assess the feasibility of conducting a study. Preparatory to Research implies that it is not being used for publication purposes, only feasibility purposes.

J. Research Use/Disclosure With Individual Authorization. The Privacy Rule also permits covered entities to use or disclose protected health information for research purposes when a research participant authorizes the use or disclosure of information about him or herself. Today, for example, a research participant's authorization will typically be sought for most clinical trials and some records research. In this case, documentation of IRB or Privacy Board approval of a waiver of authorization is not required for the use or disclosure of protected health information. To use or disclose protected health information with authorization by the research participant, the covered entity must obtain an authorization that satisfies the requirements of 45 CFR 164.508. The Privacy Rule has a general set of authorization requirements that apply to all uses and disclosures, including those for research purposes. However, several special provisions apply to research authorizations:

1. Unlike other authorizations, an authorization for a research purpose may state that the authorization does not expire, that there is no expiration date or event, or that the authorization continues until the "end of the research study;" and
2. An authorization for the use or disclosure of protected health information for research may be combined with a consent to participate in the research, or with any other legal permission related to the research study.
3 Except as set forth in this Policy, the Investigator must obtain an authorization from each participant prior to the use or disclosure of PHI for any research related purpose (1).
4 A legally effective authorization must include the following:
   a. A description of the information to be used or disclosed that identifies the information in a specific and meaningful way;
   b. The name or other specific identification of the person(s), or class of persons, authorized to make the requested use of disclosure;
   c. The name or other specific identification of the person(s), or class of persons, to whom the Investigators may make the requested use or disclosure;
   d. A description of each purpose of the requested use or disclosure;
   e. An expiration date or an expiration event that relates to the individual or the purpose of the use or disclosure. The statement such as "end of research study" or "none" may be used when appropriate;
   f. A statement that the individual may revoke the authorization if requested in writing. However, the Investigator may continue to use and disclose, for research integrity and reporting purposes, any PHI collected from the individual, pursuant to such authorization before it was revoked;
   g. A statement that either: TAMIU may not condition treatment, payment or eligibility for benefits on whether the individual signs the authorization (for non-treatment studies) or TAMIU may condition the individual's research-related treatment on the provision of the authorization (for treatment studies);

h. A statement that information disclosed pursuant to the authorization could potentially be subject to redisclosure by the recipient and no longer be protected under HIPAA

i. The individual's right to revoke the authorization in writing, and the exceptions to the right to revoke and a description of how the individual may revoke the authorization

j. The consequences of an individual's refusal to sign. If there is none, state so; and

k. The individual's signature (or that of his/her legally authorized representative and a description of that representative's authority to act for the individual) and date (2).

l. A copy of the authorization form must be provided to the individual.

3. An authorization for the use or disclosure of PHI for a research study may be combined with any other type of written permission for the same research study (including the consent form for the research study) (3).

4. An Investigator may condition the provision of research-related treatment on provision of an authorization for the use or disclosure of PHI for the research (4). The research must state this clearly in the authorization form (see B.2.j above).

K Accounting for Research Disclosures. In general, the Privacy Rule gives individuals the right to receive an accounting of certain disclosures of protected health information made by a covered entity. See 45 CFR 164.528. This accounting must include disclosures of protected health information that occurred during the six years prior to the individual's request for an accounting, or since the applicable compliance date (whichever is sooner), and must include specified information regarding each disclosure. A more general accounting is permitted for subsequent multiple disclosures to the same person or entity for a single purpose. See 45 CFR 164.528(b)(3). Among the types of disclosures that are exempt from this accounting requirement are:

1. Research disclosures made pursuant to an individual's authorization;
2. Disclosures of the limited data set to researchers with a data use agreement under 45 CFR 164.514(e).

In addition, for disclosures of protected health information for research purposes without the individual's authorization pursuant to 45 CFR164.512(i), and that involve at least 50 records, the Privacy Rule allows for a simplified accounting of such disclosures by covered entities. Under this simplified accounting provision, covered entities may provide individuals with a list of all protocols for which the patient's protected health information may have been disclosed under 45 CFR 164.512(i), as well as the researcher's name and contact information. Other requirements related to this simplified accounting provision are found in 45 CFR 164.528(b)(4).

L. Participant's Access to Research Information.

Individuals who participate in research generally have a right to access their own PHI that is maintained in a Designated Record Set. However, an individual's access to PHI created or obtained in the course of research that involves treatment may be temporarily suspended for as long as the research is in progress, provided that the individual has agreed to the denial of access when consenting to participate in the

research study, and the Investigator has informed the individual that the right of access will be reinstated upon completion of the research (18).

M. Participant's Request to Revoke Research Authorization.
An individual may revoke his or her authorization at any time, provided that the revocation is in writing, except to the extent that the Investigator has taken action in reliance on the authorization (19). The Investigator may continue to use and disclose any PHI collected pursuant to a valid authorization before it was revoked, for study integrity and reporting purposes.

1. 45 CFR 164.508 (a)(1)
2. 45 CFR 164.508 (c)
3. 45 CRF 164.508 (b)(3)(i)
4. 45 CFR 164.508(b)(4)(i)
5. 45 CFR 164.512(i)(2)(ii)
6. 45 CFR 164.502(b)
7. 45 CFR 164.514(d)(3)(iii)(D)
8. 45 CFR 164.528(b)(2)
9. 45 CFR 164.514(e)(1)
10. 45 CFR 164.502(b)
11. 45 CFR 164.512(i)(1)(iii)
12. 45 CFR 164.502(b)
13. 45 CFR 164.502(d)
14. 45 CFR 164.514(a)
15. 45 CFR 164.514(c)
16. 45 CFR 164.512(i)(1)(ii)
17. 45 CFR 164.502(b)
18. 45 CFR 164.524(a)(2)(iii)
19. 45 CFR 164.508(b)(5)

8.2 Certificate of Confidentiality

A. It is the policy of TAMIU's Institutional Review Board (IRB) – to assure that the privacy and confidentiality protections are adequate for all research participants, which may include securing a Certificate of Confidentiality.

B. The Secretary of DHHS may authorize persons engaged in biomedical, behavioral, clinical, or other research (including research on mental health, including research on the use and effect of alcohol and other psychoactive drugs) to protect the privacy of individuals who are the subject of such research by withholding from all persons not connected with the conduct of such research the names or other identifying characteristics of such individuals. Persons so authorized to protect the privacy of such individuals may not be compelled in any Federal, State, or Local civil, criminal, administrative, legislative, or other proceedings to identify such individuals (1).

C. When a Certificate of Confidentiality has been obtained for a research study, a statement describing the protection must be added to the consent form to comply with IRB Policy 4.1 (2).

1. 42 USC 241 (d)
2. IRB Policy 4.1

9. IRB Compliance

9.1 IRB Compliance Responsibilities

A. It is the policy of TAMIU's Institutional Review Board (IRB) – to determine whether research under the jurisdiction of the IRB is being conducted in accordance with Federal regulations, state and local law, IRB policies and procedures, and TAMIU's FWA (1), and to take whatever actions are deemed necessary by the IRB if any such research is not being conducted in accordance with such requirements (1, 2, 3, 4).

B. TAMIUS IRB will conduct an audit of every fifth **non-exempt** research that is reviewed. In addition it will conduct an audit of researchers that have been found to be in noncompliance. This **IRB Compliance Review** will assess the following as applicable:

1. Protocol Records are complete:
    a. Copy of Approval Letter
    b. Copy of Application/Protocol with Modifications Required for Approval
    c. Copy of Modifications to the Protocol with Approval Letter
    d. Copy of Grant
2. Training Documentation
    a. Documentation of training of all investigators.
    b. Documentation of training of all research assistants interacting with participants/subjects, or non-coded/non-anonymous data.
3. Copy of signed consent forms (if applicable)
4. Secure Storage – all consent forms, identifiable data, keys to break coded data is stored securely either in a locked cabinet, or encrypted files for digital data kept on computers.
5. All adverse events/unanticipated events, complaints were documented and reported to the IRB.

C. Once per year the Records of the IRB will be inspected by the Dean of the Office of Graduate Studies and Research and the most senior member of the IRB (other than the IRB Chair) for compliance with this policy.

1. TAMIU's Federalwide Assurance
2. 45 CFR Part 46
3. 21 CFR Part 50
4. 21 CFR Part 56

9.2 Administrative Hold, Suspension, or Termination of IRB Approval

A. It is the policy of TAMIU's Institutional Review Board (IRB) – that all currently approved research is subject to modification or change in approval status, as deemed necessary by the TAMIU IRB. The IRB may ask the Investigator to place research on administrative hold to gather information or the IRB may suspend or terminate research due to cause for research not being conducted in accordance with the IRB's requirements or the Federal regulations or if it has been associated with unanticipated

problems/events involving risk to subjects or others. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and will be reported promptly to the investigator, appropriate institutional officials, OHRP and other applicable agencies (1, 2, 3).

Examples of a suspension for cause might include:

1. Inappropriate involvement of human subjects in research;
2. Violation of the rights or welfare of subjects or others;
3. Serious Non-Compliance: An action or omission taken by an Investigator that any other reasonable Investigator would have foreseen as compromising the rights and welfare of a participant. The following events will in most cases be considered Serious or continuing non-compliance with Federal regulations or IRB policies; or
4. New information regarding increased risk to human subjects or others.

1. 45 CFR 46.113
2. 21 CFR 56.113
3. IRB Policy 9.3

9.3 Reporting to the Appropriate Institutional Officials and Department or Agency Head(s)

A. It is the policy of TAMIU's Institutional Review Board (IRB) – to report the items described below according to the Federal regulations and TAMIU IRB policy.

The following items shall be reported to the entire IRB, appropriate Institutional Officials, the Office for Human Research Protections (1, 2), the Food and Drug Administration (3, 4), (if applicable) and the head of any Department or Agency that provides support for the study:

1. Any unanticipated problem/event involving risk to subjects or others (UPIRTSO); in accordance with IRB Policy 3.10 (5) and
2. Any serious or continuing non-compliance with Federal regulations, IRB policy or the requirements or determinations of the IRB; and
3. Any suspension or termination of IRB approval.

1. 45 CFR 46.103(b)(5)
2. 45 CFR 46.113
3. 21 CFR 56.108(b)
4. 21 CFR 56.113
5. IRB Policy 3.10

See IRB Policy 3.10 Reporting Unanticipated Problems Involving Risk to Subjects or Others

For further information.

Appendix

A.1 TAMIU IRB Forms
A.2 TAMIU's Federalwide Assurance
A.3 Belmont Report
A.4 Texas A&M University System (TAMUS) Policy 15.99.01: Use of Human Participants in Research
A.5 45 CFR 46
A.6 Exempt and Expedited Review Categories
A.7 OHRP Guidance on Continuing Review
A.8 OHRP Guidance on Reviewing and Reporting Unanticipated Problems Involving Risks to Subjects or Others and Adverse Events
A.9 OHRP Guidance for Reporting Incidents to OHRP
A.8 NIH – IRB and the Privacy Rule
A.10 OCR – Privacy Rule and Human Research
A.11 OHRP – IRB and the Privacy Rule
A.12 HIPAA – part of pertaining to research – 45 CFR 164
A.13 OHRP Guidance on Written IRB Procedures
A.14 OHRP Guidance on Compliance