UT Arlington IRB

Policies

and

Standard Operating Procedures

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I. Institutional Authority

A. Vice President for Research

The Vice President for Research (VPR) reports to the President of the University of Texas at Arlington (UT Arlington). The Office of the VPR has the authority to develop and administer all policies governing UT Arlington's research enterprise. UT Arlington operates a centralized structure for the administration of research, which includes the institutional review board (IRB) under the oversight of the VPR. As such, the leadership of the IRB report directly to the Office of the VPR.

B. Institutional Review Board

Human subjects research conducted at the University or under its auspices must be reviewed and approved by the UT Arlington IRB prior to the start of the research. The UT Arlington IRB reviews projects in a wide range of research disciplines in the social, behavioral, educational, and biomedical or clinical fields.

1. Scope

The UT Arlington IRB reviews protocols for research involving human subjects when conducted by or under the direction of any employee, student, or an agent of UT Arlington in connection with his or her institutional responsibilities or using any institutional property or facility. Also, the IRB (or Regulatory Services, as designee) reviews and acknowledges IRB reliance & reciprocity arrangements for research protocols of non-UT Arlington investigators when UT Arlington faculty, staff, or students are involved. Details of the scope of IRB review for each protocol is provided in Section VIII.A.

2. Authority

The authority conveyed to the UT Arlington IRB includes the following:

- **a.** Review/approval of new/continuing research protocols involving human participants and associated informed consent documents (ICD) prior to initiation/continuation of research;
- **b.** Monitoring of approved projects including regularly scheduled continuing review at least every twelve (12) months for certain non-exempt or greater than minimal risk studies;
- **c.** Verification of compliance with approved research protocols and informed consent procedures;
- **d.** Review of all planned changes to approved protocols prior to implementation;
- **e.** Review of all serious adverse events (SAEs) and unanticipated problems involving risks to subjects or others (UPs) occurring in approved projects, or in other projects related in context to the approved projects;
- **f.** Restriction of approved research activities to protect participants when necessary; and
- **g.** Suspension/termination of previously approved protocols for substantive new information that may affect the safety and welfare of human subjects, the integrity of the study, or noncompliance with established policies and procedures.

II. Principles & Compliance with Federal Regulations and University Policies

All research at UT Arlington that involves human subjects is guided by the ethical principles set forth in the report of the National Commission for the Protection of Human Participants of Biomedical and Behavioral Research entitled "Ethical Principles and Guidelines for the Protection of Human Subject of Research (Belmont Report)". This document is listed as the guiding statement of ethical principles as part of UT Arlington's Federalwide Assurance for the Protection of Human Subjects with the federal government.

All human subjects research conducted and reviewed by the UT Arlington IRB must comply with applicable federal and state laws/regulations and UT Arlington policies and procedures governing the conduct of research, including but not limited to the following:

- **a.** UT Arlington has filed a Federalwide Assurance (FWA) with the Department of Health and Human Services (DHHS) Office for Human Research Protections (OHRP) affirming that the University is in compliance with 45 CFR 46. This assurance applies to all research involving human subjects that is conducted, supported or otherwise subject to regulation by any federal department or agency as defined and regulated by the "Common Rule" – (DHHS regulations incorporate the Revised Common Rule as Subpart A of 45 CFR 46);
- **b.** The Department of Education Family Education Rights and Privacy Act (FERPA) for studies involving educational and/or student records;
- **c.** Food and Drug Administration (FDA) regulations; the UT Arlington IRB complies with the requirements set forth in 21 CFR 50, 21 CFR 56, 21 CFR 312, 21 CFR 600, and 21 CFR 812 for studies involving investigational drugs, biologics, devices, or diagnostic tests;
- **d.** Department of Defense (DoD) regulations and directives, including those at 32 CFR 219, 10 United States Code 980, and DoDI 3216.02, for studies funded or supported by DoD, and/or studies in which the subject population will intentionally include personnel (military and/or civilian) from a component of DoD;
- **e.** Texas State Law, including Section 261.101 of the Texas Family Code for mandatory reporting of child and elder abuse or neglect; and,
- **f.** UT Arlington institutional policies and procedures governing research, including UT Arlington's policy 5-705, Statement of Principles and Policies Regarding Human Subjects in Research, and this SOP document.

The purpose of the UT Arlington IRB is to assure that the rights and welfare of human subjects are adequately protected in research. The UT Arlington IRB advises investigators in the design of research projects in order to minimize potential harm to human participants; reviews all planned research involving human subjects prior to initiation of the research; approves research that meets established criteria for protection of human subjects; and monitors approved research protocols to ascertain whether human subjects are indeed protected.

The UT Arlington IRB also informs and assists UT Arlington faculty, staff, and students of ethical and procedural issues related to the use of human participants in research in order to facilitate compliance with relevant federal regulations and to provide a framework suitable for continued support by federal funding agencies, private foundations, and industry.

Primary responsibility for assuring that the rights and welfare of research participants are protected continues to rest with the Principal Investigator (PI) conducting the research. Others engaged in the research share this responsibility. Faculty who assign or supervise research conducted by students or staff have an obligation to consider carefully whether those individuals are qualified to safeguard adequately the rights and welfare of participants in the research.

III. Definitions

a. Administrative Modification - Changes proposed to the IRB for an approved study that are minor and non-substantive in nature and for which the IRB has delegated authority to IRB staff to conduct Administrative Review and approval, regardless of the study's initial level of review or funding source.

b. Adverse event - Any unfavorable or harmful occurrence to a human subject which occurs during the time that the subject is enrolled as a participant in the research, whether or not the occurrence is considered related to the subject's participation in the research. This includes any abnormal medical sign (for example, an abnormal physical exam or laboratory finding), symptom, disease, or death, as well as adverse psychological events such as suicidal behavior, homicidal behavior, or increase in depression or anxiety symptoms. Additionally, changes in life situations such as the arrest or runaway of a study participant, eviction or loss of home, or dropping out of school are also harmful occurrences that should be reported as adverse events whether or not they are related to participation in the research.

c. Advocate – An individual who has the background or experience to act in (and agrees to act in) the best interest of a potentially vulnerable subject for the duration of the subject's participation in a research study.

d. Anonymous Data - Data that never contains identifying values that can link the information to any participant. Once anonymous data has been collected, there is no way for the researcher (or anyone else) to identify any of the contributing participants. If any values or combination of values can be used to identify any specific participant, regardless of the kind of information provided, it is not considered anonymous; the data would be considered identifiable.

e. Benign Behavioral Intervention – A research intervention that is brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing.

f. Biospecimen - A quantity of tissue, blood, urine, or other human-derived material. A biospecimen can comprise subcellular structures, cells, tissue (e.g., bone, muscle, connective tissue, and skin), organs (e.g., liver, bladder, heart, and kidney), blood, gametes (sperm and ova), embryos, fetal tissue, and waste (urine, feces, sweat, hair and nail clippings, shed epithelial cells, and placenta). Some are collected originally for clinical lab tests, some are removed during surgeries, and some are obtained specifically for research.

g. Broad Consent – A type of consent process that is intended to serve as a substitute for traditional informed consent in certain circumstances. Broad consent allows subjects to agree to a wide range of future secondary research studies using their identifiable information or biospecimens. With broad consent, researchers would not be required to obtain additional consent for each future use, so long as the activities are within the scope of the original broad consent.

h. Clinical Investigation (*as defined by FDA*) - Any experiment that involves an FDA regulated "test article" and one or more human subjects, and that either must meet the requirements for prior submission to the Food and Drug Administration under section 505(i) or 520(g) of the act, or need not meet the requirements for prior submission to the Food and Drug Administration under these sections of the act, but the results of which are intended to be later submitted to, or held for inspection by, the Food

and Drug Administration as part of an application for a research or marketing permit. The term does not include experiments that must meet the provisions of part 58, regarding nonclinical laboratory studies. The FDA considers the terms research, clinical research, clinical study, study, and clinical investigation to be synonymous.

i. CLIA-Certified Laboratory - A laboratory that provides testing services for human specimens for the purposes of health assessment or diagnosis, prevention, or treatment of disease and is certified by the Center for Medicare Services (CMS) to meet federal regulatory quality standards for medical or clinical laboratory testing.

j. Coded Data – A dataset containing information about a living individual that has had the direct identifiers of the individual removed (e.g., name, SSN#, student #, etc.) and replaced with a code (e.g., 101, 102, 103, etc.); the research team typically keeps a separate file containing the list of subject code numbers and other identifiable information as a "Master List" so that the coded dataset can be re-linked to the subjects' identities if needed using the subject code numbers. Coded data is a type of identifiable subject data.

k. Conflict of Interest – Research Conflict of Interest (RCOI) is defined as a significant financial interest that could directly and significantly affect the design, conduct, or reporting of research. Researchers must disclose potential conflicts of interest that may impact research objectivity or integrity. Likewise, an IRB member may not vote on a project, and is not counted towards a quorum, when s/he serves as a co-investigator or other member of the research team or when s/he or an immediate family member has a conflict of interest with a project being reviewed.

l. Continuing Noncompliance – A pattern of noncompliance (serious or non-serious) that results in multiple findings of noncompliance over time for similar protocol violations (either on the same protocol, or for the same investigator across multiple protocols) despite prior communications from the IRB attempting to address and correct the violation(s); continuing noncompliance could also result from repeated failures of the investigator to respond to or resolve previous allegations or findings of noncompliance.

m. De-identified Data – a dataset containing only information about living individual(s) that has all direct identifiers removed from the data in a manner that any member of the research team is not able to identify the individual(s) from whom the information was collected. Links between the data and the individual about whom the data was recorded may still exist, but are not readily accessible, and will not be made available to the researcher(s) at UTA. Note that studies utilizing a coding system with a "Master List" linking subject codes to identifiable information are not considered de-identified; instead, these datasets are considered "Coded Data."

n. Device *(as defined by FDA)*- an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:

i) recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them;

ii) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals;

iii) or intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its primary intended purposes through chemical action within or

on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes.

o. Drug *(as defined by FDA)*- Substances that are:

i) recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and

ii) intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and

iii) (other than food) intended to affect the structure or any function of the body; and

iv) intended for use as a component of a medicine, but are not a device or a component, part or accessory of a device.

p. Exempt Review – A level of IRB review in which study submissions are reviewed by IRB staff or one member of the IRB and granted a determination of exemption; applies to federally funded or FDA-regulated studies that are no more than minimal risk to participants and involve only procedures listed in one or more of the categories allowable for exemption at 45 CFR 46.101(b) or 21 CFR 56.104.

q. Expedited Review – A level of IRB review in which study submissions are reviewed and granted approval by at least one member of the IRB; applies to federally funded or FDA-regulated studies that are no more than minimal risk to participants and involve only procedures listed in one or more of the categories allowable for Expedited review per 45 CFR 46.110 and 21 CFR 56.110.

r. FDA – The Food and Drug Administration is a federal agency of the United States Department of Health and Human Services. The FDA is responsible for protecting and promoting health through the regulation and supervision of clinical trials, including new drugs and investigational new medical devices.

s. Full Board Review – A level of IRB review in which study submissions are reviewed and voted upon by IRB Members at a convened IRB meeting; required for federally funded or FDA-regulated studies that are not eligible for exempt or expedited review procedures, or federally funded or FDA-regulated studies where the procedures involved would pose greater than minimal risks to the participants.

t. Good Clinical Practices (GCP) – A set of international ethical and scientific quality standards for the design, conduct, performance, monitoring, auditing, recording, analyses and reporting of clinical trials.

u. Greater than Minimal Risk – Research activities that do not meet the definition of Minimal Risk.

v. Greater than Minimal Risk Review Category (GMR Review) – An internal "flex" review pathway for UTA IRB study submissions that are not federally funded or supported nor FDA regulated and pose greater than minimal risks to study subjects; to qualify for GMR Review, the study must comply with the principles of the Belmont Report and UTA IRB Operating Procedures, but not necessarily all aspects of 45 CFR 46. GMR research may be reviewed by the IRB via consultation with IRB staff, by one or more IRB member(s), or by the full committee at an IRB meeting.

w. HIPAA - The Health Information Portability and Accountability Act (HIPAA) enacted by Congress and signed into law in 1996. The HIPAA Privacy Rule created national standards to protect individuals' medical records and other personal health information from unauthorized disclosure.

x. HIPAA Covered Entity – Organizations which are required to follow the HIPAA Privacy Rule due to the kinds of medical information they collect and use during normal business operations. Covered entities are defined in the HIPAA rules as (1) health plans, (2) health care clearinghouses, and (3) health care

providers who electronically transmit any health information in connection with transactions for which HHS has adopted standards. UT Arlington is not a HIPAA Covered Entity.

y. Human Subject – A living individual about whom an investigator (whether professional or student) conducting research obtains a) data through intervention or interaction with the individual, or b) identifiable private information, even if no intervention or interaction with the researcher occurs.

z. Identifiable Biospecimen - A biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen (such as through the use of codes which link to identifying information).

aa. Identifiable Data – A dataset containing any information that would allow someone (including members of the research team) to be able to directly or indirectly identify the person from whom the information was collected; a dataset in which the identity of the subject can be or may be readily ascertained by someone or is associated with the information.

bb. Institution – Any public or private entity, organization, business, or agency (including federal, state, or other agencies).

cc. Institutional Official (IO)- An officer of an institution who is legally authorized to speak for and legally commit the institution within legal agreements, including the adherence to the requirements of the federal regulations regarding the involvement of human subjects in biomedical and behavioral research.

dd. Interaction – A method of collecting research data about a human subject that includes communication and/or interpersonal contact between the investigator and the subject.

ee. Intervention - A method of collecting research data about a human subject for research purposes that could include both physical procedures by which data are gathered (for example, venipuncture), and/or manipulations of the subject or the subject's environment for research purposes.

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

gg. Major Modifications – Changes proposed to an IRB-approved research project that would or could increase the likelihood and/or severity of the risks posed to the study subjects.

hh. Minimal Risk – A term meaning that the probability and magnitude of harm or discomfort anticipated to the subject in the research are not greater in and of themselves than those ordinarily encountered in the subject's daily life or during the performance of routine physical or psychological examinations or tests; federally funded studies that involve greater than minimal risks to the participants are reviewed at the full board level.

ii. Minimal Risk Review Category (MR Review) – An internal "flex" review pathway for UTA IRB study submissions that are not federally funded or supported nor FDA regulated and pose no more than minimal risks to study subjects; to qualify for minimal risk review, the study must comply with the principles of the Belmont Report and UTA IRB Operating Procedures, but not necessarily all aspects of

45 CFR 46. IRB Staff is designated with responsibility and authority to review and approve MR research, with consultation from the IRB when deemed necessary.

jj. Minor Modifications – Changes proposed to an IRB-approved research project that pose no additional risks to participants beyond those previously identified at the time of the original protocol approval. A subset of minor modifications are eligible for Administrative Review by IRB staff.

kk. Monitoring Entity - The group or person(s) responsible for overseeing the safety of all subjects enrolled in a study in accordance with the approved protocol; this may be a Data Safety Monitoring Board (DSMB), a Data Monitoring Committee (DMC), a coordinating or statistical center, an experienced colleague not affiliated with the study, or a study sponsor.

ll. Non-Sensitive Data - Data that is not likely to cause harm to subjects in the event of a data breach; a dataset containing information about living individuals that may contain individually identifiable information, but which is not likely to place the subjects at risk of criminal or civil liability or be damaging to their financial standing, employability, educational advancement, or reputation if the information was disclosed outside of the research context.

mm. Noncompliance – A finding of failure on the part of the PI or any member of the study team to follow: i. federal regulations, state laws, or institutional policies relevant to human subjects research; or ii. the requirements and determinations issued by the reviewing IRB as stated in the approved IRB protocol.

nn. OHRP – The Office for Human Research Protections (OHRP) provides leadership in the protection of the rights, welfare, and wellbeing of subjects involved in research conducted or supported by the U.S. Department of Health and Human Services (HHS). OHRP helps ensure this by providing clarification and guidance, developing educational programs and materials, maintaining regulatory oversight, and providing advice on ethical and regulatory issues in biomedical and social-behavioral research.

oo. Protected Health Information (PHI) – Information transmitted or maintained in any form (i.e., by electronic means, on paper, or through oral communication) that: (1) was collected or maintained by a HIPAA Covered Entity or Business Associate and relates to the past, present, or future physical or mental health or condition of an individual, the provision of health care to an individual, or his or her past, present, or future payment for health care; and (2) identifies (or may reasonably identify) the individual. PHI is protected by HIPAA laws.

pp. Protected Individual Information (PII) - Any personally identifiable information (other than PHI) that may cause substantive harm to subjects if there was a breach of confidentiality, such as social security numbers; financial information such as credit card numbers or bank account numbers; school grades; employment performance records; or information about illegal behaviors or criminal activity. PII is not protected by HIPAA laws, but may have other legal considerations depending upon the type of data.

qq. Principal Investigator (PI) – The person who directs a research project or program and is ultimately responsible for the design, conduct, and reporting of the research. The PI is responsible for the protection of human subjects and the ethical conduct of research in compliance with federal regulations and University policies and procedures.

rr. Private Identifiable Information - Includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, as well as information which has been provided by an individual for specific purposes and which the individual

can reasonably expect will not be made public (i.e., medical records or student records). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

ss. Protocol Violation – A divergence from the approved IRB protocol by the PI and/or research team without the prior IRB approval of a study modification request. Upon reported allegations or discovery of a potential protocol violation, the IRB and/or IRB staff will follow IRB procedures for investigating potential noncompliance included in this SOP, and will issue a finding of noncompliance if evidence indicates a violation has occurred.

tt. Quorum – The required amount of members to be present at a convened IRB meeting in order for a vote to be effective per the regulations; a majority of voting members of an IRB (i.e., 50% of the IRB members on the IRB roster plus one), including at least one member whose primary expertise is in a nonscientific area.

uu. Reliance – An option for IRB approval of collaborative research projects where a single institution's IRB can serve as the designated "IRB of Record" for all (or some) of the study sites engaged in the research project. Reliance must be sufficiently documented between the IRBs of both the Reviewing and Relying institutions to be effective; this documentation may be through a standing institutional reciprocity agreement or an individual IRB Authorization Agreement as appropriate for each specific study and collaborating institution.

vv. Repository – A central location where data or human biological materials are organized, labeled, and stored with the specific intent of future research use.

ww. Research - A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research even if they are a component of another non-research activity (e.g., instruction, community service, program evaluation, quality improvement, demonstration).

xx. Risk – The probability of harm or injury (physical, psychological, social, or economic) occurring as a result of participation in a research study. Both the probability and magnitude of risks may vary from minimal to significant.

yy. Secondary Research – Re-use of identifiable information or biospecimens for research purposes that were or will be collected for some other primary / initial purpose or activity (whether research or non-research).

zz. Sensitive Data - Data that could potentially cause harm to subjects in the event of a data breach; a dataset containing information about living individuals that could reasonably place the subjects at risk of criminal or civil liability or be damaging to their financial standing, employability, educational advancement, or reputation if the information was disclosed outside of the research context.

aaa. Serious Adverse Event (SAE) – Any adverse experience in a research participant that results in any of the following outcomes: death; a life-threatening adverse experience; inpatient hospitalization or prolongation of existing hospitalization; a persistent or significant disability/incapacity; a congenital anomaly/birth defect; required intervention to prevent permanent impairment or damage; suicide attempts; or other serious medical events.

bbb. Serious Noncompliance - Noncompliance with federal regulations or institutional policies and procedures that, in the judgment of the reviewing IRB, affects the rights and welfare of subjects; may cause a significant risk to enrolled subjects or others; or affects the integrity of the study.

ccc. Unanticipated Problems (UPs) - Any incident, experience, or outcome that happens during a study and meets all of the following criteria:

i. Is 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;

ii. Is related or possibly related to participation in the research (meaning there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and

iii. 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.

ddd. Unexpected Adverse Event (UAE) – Any adverse experience or suspected adverse reaction that is not listed in the approved IRB protocol, consent form, or other item included in the IRB application, such as the investigator brochure or package insert; or is not listed in the study materials at the specificity or severity that has been observed; or is otherwise not consistent with the risk information described in the protocol or informed consent document.

IV. Roles and Responsibilities

A. Institutional Official (IO) – Vice President for Research (VPR)

The VPR is responsible for the UTA research enterprise. The Office of the VPR develops and administers all institutional policies governing UTA's research and provides management of UTA's research programs. The VPR is responsible for ensuring adequate resources for the IRB operation. The VPR is routinely informed of IRB business and has the authority to review decisions of the IRB. In instances of disagreement, the IO works with the IRB to resolve specific issues. The VPR cannot approve a study which the IRB has disapproved; however, the VPR can disapprove of a study that the IRB has approved.

The VPR is informed of incidents of serious and/or continuing noncompliance, as well as study suspensions and terminations by the IRB. As signatory to the FWA, the VPR is responsible for ensuring that human subjects research is conducted ethically and in compliance with regulatory standards.

B. Institutional Review Board (IRB)

The UT Arlington IRB is responsible for ensuring that all research that it reviews has a protocol (or written plan) to conduct the research ethically and in accordance with all applicable regulatory requirements and/or applicable internal policies and procedures. Additionally, the IRB has the responsibility to ensure that the study procedures are adequately explained within the protocol and supporting documents in order to make all necessary regulatory determinations for the protection of human subjects; to ensure that participants are provided with adequate information to facilitate an informed decision about study participation during the Informed Consent process; and to provide ongoing oversight of all research that it approves to ensure that studies continue to meet the ethical principles of the Belmont Report and all applicable regulations and policies. The IRB also has the responsibility to provide written policies, guidance, and education/training to its members, IRB staff, and researchers to enhance the ethical and compliant conduct of research at UT Arlington.

C. IRB Chair & Vice Chair

The IRB Chair reports directly to the IO. Responsibilities of the IRB Chair include: (i) determining the level of risk and most appropriate review type for studies when requested by IRB staff; (ii) serving as primary reviewer of protocols when appropriate or delegating this responsibility to another IRB member; (iii) conducting the business of full board meetings following basic parliamentary rules; (iv) reviewing on behalf of the IRB, revisions to protocols/consent documents required as a condition of approval; (v) reviewing reports of serious adverse events and unanticipated problems in coordination with Regulatory Services and other members of the IRB; (vi) reviewing reports of noncompliance in coordination with Regulatory Services; (vii) participating in routine and for-cause audits to ensure that studies are conducted in accordance with the IRB-approved protocol; (viii) assessing and recommending appropriate training for the IRB, investigators, and support Staff; (ix) serving as a resource for investigators, IRB members, and IRB staff regarding issues related to University and federal policies.

The IRB Vice Chair assumes the above listed responsibilities of the IRB Chair when the IRB Chair is unavailable or has a conflict of interest for specific studies. In addition, the IRB Chair and Vice Chair may

work together to address the above listed responsibilities, especially in times of increased workload or when IRB activities would benefit from the combined expertise from both roles.

D. IRB Members

Responsibilities of members include (i) attending IRB meetings; (ii) reviewing protocols to be discussed at IRB meetings, including new submissions, modifications/amendments, continuing reviews, adverse events, unanticipated problems, noncompliance cases, and audit findings; (iii) being prepared to discuss issues related to human participants protections at IRB meetings; (iv) serving as primary reviewer at IRB meetings or on expedited protocols when requested by the IRB Chair or IRB staff; (v) determining the level of risk and most appropriate review type for studies when requested by IRB staff; (vi) being informed about the specific requirements regulating the participation of human subjects in research; and (vii) maintaining the confidentiality of IRB meeting discussions.

E. Regulatory Services

The Director of Regulatory Services reports directly to the Assistant VPR. Regulatory Services is responsible for the management and operation of the UTA IRB, including the development and scope of these written IRB procedures. The Director of Regulatory Services and IRB Staff prepare and maintain these written procedures, including writing, revising, and approving them. These procedures will be updated as needed based upon changes to federal regulations, regulatory guidance, and University policies and procedures. These procedures apply to all UTA students, faculty, and staff as applicable based upon each individual's role within the University. Failure to follow these procedures may considered noncompliance with University IRB procedures and will be handled according to section XVII.

F. Principal Investigator / Co-Principal Investigator

The Principal Investigator (PI) and Co-Principal Investigator (Co-PI) direct a research project or program and are responsible for the design, conduct, and reporting of research. Since the electronic system only allows one person to be listed as PI on a particular protocol, the PI is always the main point of contact between the IRB and the research team. Only individuals with a current faculty, staff, or student affiliation with the University of Texas at Arlington can serve as the PI of a UTA IRB protocol.

Regardless of whether the PI is UT Arlington faculty, staff, or student, the PI is always responsible for the following:

i. the protection of human subjects and the ethical conduct of research in compliance with federal regulations and University policies and procedures;
ii. obtaining IRB approval prior to initiation of any research involving human subjects;
iii. delegation of all responsibilities of the study to research staff who are listed as IRB protocol personnel and for ensuring that responsibilities are delegated to individuals who are qualified and appropriately trained to conduct those responsibilities;
iv. oversight of the research study and the protocol/research personnel staff to ensure that the study is conducted in accordance with the IRB-approved protocol, UT Arlington Policies and procedures and all regulatory requirements;

v. obtaining IRB approval via a modification request prior to the implementation of any changes from the approved version of the protocol, and for submitting continuing reviews in a timely manner when required;
vi. obtaining informed consent and data from human subjects in a manner consistent with federal regulations and in accordance with an IRB-approved protocol;
vii. submitting prompt reports of any unanticipated problems involving risks to subjects or others, or non-compliance with federal regulations or determinations of the IRB; and,
viii. maintaining the confidentiality of human subject data as specified in the IRB protocol, and for maintaining records and documentation in accordance with federal regulations and University policies.

Students may act as the PI of an IRB protocol; however, the student's instructor or mentor on the project must be listed as the Faculty Advisor/Supervising Investigator on the IRB protocol. Oftentimes, the student's thesis or dissertation advisor is listed as faculty advisor. If the advisor changes over time through the course of the student's academic career, the IRB protocol must be updated accordingly via the submission of a modification request in the electronic system. Faculty Advisors share responsibility with a student PI and maintain certain authority over the student-led research; please see the defined role of Faculty Advisor/Supervising Investigator for details.

G. Faculty Advisor / Supervising Investigator

This role is required when the Principal Investigator (PI) is a student. There may be other special situations when a faculty advisor/supervising investigator (SI) is appointed for a specific study, such as when a non-UTA Collaborator is listed as PI on a protocol; these situations are implemented on a case by case basis.

The faculty advisor/supervising investigator (SI) is responsible for oversight of the ethical conduct of research and data collection, and for ensuring that the research is conducted in compliance with federal regulations and University policies and procedures, in accordance with an IRB-approved protocol. The SI is responsible for ensuring appropriate qualifications of the student PI, and for vetting the protocol's purpose, design, methodology, and procedures. The SI is also responsible for record retention in compliance with federal regulations and University policies (for example, if the student leaves the University, the SI must take over recordkeeping duties to meet retention policies). The SI is responsible for ensuring that reporting requirements are met, including continuing reviews, serious adverse events, unanticipated problems, or non-compliance with federal regulations or determinations of the IRB.

Faculty Advisors are informed of their responsibilities via a dedicated page on the UTA IRB website.

H. Protocol Personnel / Research Staff

Research/study team members that will interact or intervene with the human subjects during the course of the research, or will have access to identifiable human subject data, must be specifically listed by name on the IRB protocol as Protocol Personnel. Examples of activities that would require a person to be listed as IRB Protocol Personnel include administering the consent process with subjects; delivering a research intervention to subjects; manipulating a subject's environment for research purposes; collecting research

data from subjects; answering questions about the research study for potential subjects; and analyzing identifiable subject data. Individuals who engage in any of these activities must be listed as IRB protocol personnel regardless of their affiliation with UT Arlington.

Protocol Personnel are responsible for the ethical conduct of research and for adhering to the procedures in an IRB-approved protocol that were delegated to them by the PI. Protocol Personnel are responsible for complying with federal regulations and University policies and procedures pertaining to human subjects research. Protocol Personnel are responsible for reporting any adverse events or unanticipated problems to the Principal Investigator. **Additionally, if noncompliance with the IRB protocol, federal regulations, or UT Arlington policies and procedures is suspected, any member of the study team (or any other person with this knowledge) should report this immediately to the IRB by way of Regulatory Services at RegulatoryServices@uta.edu or 817-272-3723. Concerns can also be reported anonymously online via the Regulatory Services web page.**

V. IRB Membership

Through the appointment, management, and training of IRB members, the UTA IRB will ensure that the IRB committee has the appropriate expertise and diversity to ensure that its composition meets the requirements of 45 CFR 46.107 (and 21 CFR 56.107). The IRB will maintain a roster of at least five (5) members with varying types of expertise, experience, and diversity to promote complete and adequate review of human subjects research at UT Arlington. At least one member should be from outside UT Arlington (i.e., not otherwise affiliated with UT Arlington and who is not part of the immediate family of a person who is affiliated with UT Arlington) and represent community interests and values. Membership will also include at least one member with scientific expertise and at least one member whose primary concerns are in nonscientific areas. Whenever the UTA IRB reviews federally funded research including prisoners as subjects, it will also ensure that it includes at least one prisoner advocate to meet the requirements of 45 CFR 46 Subpart C.

A. Appointment of IRB Chair

The VPR recommends to the President individuals willing to serve as IRB Chair. The appointment is finalized by a written appointment letter signed by the Vice President of Research. The IRB Chair should be a respected, active member of the University community who is well-informed in regulations relevant to the use of human participants in research. Whenever the IRB Chair is not available to conduct IRB business, he/she may designate a Vice Chair or other board member to assume his/her responsibilities during the period of his/her absence.

B. Appointment of IRB Members and Alternates

The IRB Chair and/or Regulatory Services recommends to the VPR the appointment of all IRB members and their alternates. All appointments are confirmed with a written approval letter. A current curriculum vitae (CV) will be collected for each IRB member at the time of appointment.

IRB Members may discontinue service on the IRB at any time for any reason during their term period by notifying Regulatory Services. Additionally, Regulatory Services or the VPR may also discontinue a member's IRB service at any time for any reason, including but not limited to circumstances such as failure to complete required IRB member trainings in a timely manner; inability to consistently attend scheduled IRB meetings when needed for quorum; breach of confidentiality regarding internal IRB discussions; unwillingness to serve on investigation or post-approval monitoring panels when requested; displaying patterns of disruptive or inappropriate behavior during the conduct of IRB business; findings of ethical misconduct or as a result of other University disciplinary action; or simply dismissal due to changes in needed IRB expertise based upon shifts in UTA's research activities.

C. Voting Capacity of Alternate Members at Convened Meetings

Alternates serve at-large and only vote when replacing a regular member. If both the alternate and the regular member attend the same convened meeting, only one vote will be counted. In such cases, the meeting minutes reflect the primary member as the voting member.

D. Non-Voting (Ex Officio) Members

The VPR may, at his/her discretion, recruit and appoint non-voting (ex officio) members from among the academic or administrative Staff of UT Arlington, whose presence at the meetings of the IRB would aid the IRB in conducting its duties. These members may take part in all meetings of the IRB, participate in the discussions, and make recommendations to influence decisions, but they may not vote on the decisions. Non-voting members are not included in determining or establishing a quorum at the meetings. IRB meeting minutes reflect the presence of non-voting members.

E. Consultants / Ad-hoc Reviewers

At its discretion, the UT Arlington IRB may invite scientists or non-scientists from within or outside UT Arlington, who have special expertise, to function as consultants and ad hoc reviewers of a protocol application. These individuals have access to all documents submitted to the IRB relevant to the specific project under review, may participate at the deliberations and make recommendations on the project, but may not vote.

At the time of preliminary review of a new project application or modification, the IRB Chair or Regulatory Services as designee may determine that the study requires further review by a consultant with expertise outside of the current IRB membership. This determination may be made based on the scientific design of the study, the ethical issues of the study, the potential risks or benefits of the study, specific privacy and confidentiality concerns, or considerations relative to a particular study population.

Upon identifying the need for a consultant review, the IRB Chair or Regulatory Services will identify a consultant based on the particular issues to be addressed. For issues requiring only simple clarification, a written set of questions may be developed for submission to the consultant. The consultant's written response to these questions will be provided to the full IRB for review at the time of the convened meeting. For issues requiring more than simple clarification, the consultant may also be invited to attend the full board meeting during the review of that particular study. Documentation of the discussion with the consultant will be included in the meeting minutes.

No person with a conflict of interest as defined in Section XV of this SOP will serve as a consultant for the purposes described in this section.

F. Compensation of IRB Members

IRB members do not generally receive monetary compensation above their University salary for participation on the board. The IRB Chair and IRB Vice Chair receive financial compensation and/or release time authorized by the Office of the VPR to ensure a sustained level of high performance.

G. Member Liability

IRB members are covered by UT Arlington general liability coverage when acting within the course and scope of their IRB duties.

H. IRB Conflicts of Interest

IRB members may not participate in the initial review, continuing review, modification review, or any other review of any project in which the IRB member has a conflict of interest, except to provide information requested by the board. When the investigator-member has a conflicting interest, he or she may be present at IRB meetings only to provide information requested by the board, like any investigator. He or she must leave the meeting room during the subsequent discussion and voting phases of the review and may not vote (e.g., abstain, table, approve, disapprove) on the study; in these instances, the absent member with a conflict is considered recused. Members that are absent during the vote do not count toward a quorum. Minutes reflect whether or not these requirements have been met.

VI. IRB Operations and Coordination with Other University Components

A. Regulatory Services Structure and Mission

The Director of Regulatory Services is responsible for the management and operation of the IRB. The office provides resources, professional guidance, and administrative resources for the review of all research proposals by the IRB. This office governs these Operating Procedures and ensures that the reviews conducted by the IRB comply with federal regulations and institutional policies.

Regulatory Services supports two full time positions that are exclusively devoted to administrative support of the IRB and customer service for researchers with human subjects research studies. These two positions include the Regulatory Services Manager and Research Support Specialist II titles. Throughout this document, these individuals are collectively referred to as "IRB Staff."

The mission of Regulatory Services is to facilitate innovation by supporting University research and researchers in the conduct of ethical, scientifically sound, and compliant research studies. We achieve this mission by providing excellent customer service to UTA students, faculty, and staff; through educating the UTA community on regulatory requirements pertaining to research and research ethics; by ensuring that UTA research submissions are conducted ethically and in accordance with applicable regulations and UTA policies and procedures; by finding new ways to reduce burden for investigators; and by maintaining efficient operations within our office. **Please provide your feedback on how we can better achieve our mission by sending your ideas to RegulatoryServices@uta.edu** .

B. Responsibilities of IRB Staff

IRB Staff is part of Regulatory Services and provides administrative support to the IRB. The IRB Staff is an integral part of the IRB, but serves in a non-voting, ex-officio capacity.

The IRB Staff conduct the following responsibilities:

1. Provide administrative support to the IRB and investigators in all aspects of the IRB process;
2. Assist investigators throughout the protocol submission, review and approval processes, and provides information regarding protocol status;
3. Organizes, coordinates and attends IRB meetings and records detailed minutes of IRB meetings;
4. Maintains all IRB records (e.g., agendas, minutes, policies, regulations, reference materials and individual protocol files) in a secure environment;
5. Maintains the electronic system for tracking IRB protocols (e.g., new protocol submissions, protocol/informed consent modifications, annual continuation applications, safety reports, unanticipated problems involving risks to subjects/adverse event documentation, etc.);
6. Coordinates with IRB Chair for follow-through on all action items resulting from IRB meetings (e.g., modifications to protocol documentation, Informed Consent changes, etc.);
7. Works with IRB Chair/Vice Chair to evaluate investigator responses to documentation changes to determine appropriateness;
8. Is designated responsibility and authority by the IRB to conduct review of federally funded exempt research and make exempt determinations in accordance with 45 CFR 46.101, including documentation of the specific exempt category or categories which apply;

9. Is designated responsibility and authority to review and approve non-federally funded, non-FDA regulated Minimal Risk (MR) research, with consultation from the IRB when deemed necessary;
10. Keeps abreast of changes to federal rules/regulations and updates IRB Chair & IRB Members regarding changes;
11. Is designated responsibility and authority by the IRB and IRB Chair to conduct review and initial evaluation of issues of non-compliance and make initial determinations of serious or non-serious, resolution plans for non-serious issues, and escalation plans for serious issues; and,
12. Organizes and coordinates a comprehensive campus outreach program to communicate regulatory requirements and university policies/procedures to UT Arlington students, faculty, and staff, and provides guidance to researchers on proper protocol preparations.

C. Appropriation of Required Institutional Resources

The University and IO provides adequate facilities, equipment, and staffing to support the operation of the UT Arlington IRB and Regulatory Services in the performance of the functions described in this document.

D. Other Administrative Units and Processes Managed by Regulatory Services

The UT Arlington IRB coordinates the review with other research administrative offices and/or institutional committees when appropriate as described below. None of these offices or committees are a formal part of UT Arlington IRB structure, but there is communication between the committees regarding status of review and/or conditions of approval if there are human participants involved.

1. **Institutional Animal Care and Use Committee (IACUC)** - The IACUC is responsible for ensuring that research involving animal participants complies with the Animal Welfare Act and Animal Welfare Regulations, the Public Health Service Policy, and Office of Laboratory Animal Welfare (OLAW) guidelines. Investigators are required to submit a protocol to the IACUC for all research involving live vertebrate animals. The protocol must be reviewed and approved by the IACUC prior to the initiation of the research.

   IACUC deliberations are normally not shared with the IRB unless there are specific issues involving human participants. In instances where both animal and human participant research issues are involved, investigators should: i) notify Regulatory Services and the IRB and IACUC chairs; and ii) submit separate protocols to the IRB and IACUC, respectively. In certain instances, the IRB may deem it appropriate to receive notification of the related IACUC approval before approving the IRB protocol.

2. **Institutional Biosafety Committee (IBC)** - The IBC is responsible for ensuring that recombinant DNA activities comply with the National Institutes of Health (NIH) Guidelines for Research Involving Recombinant DNA Molecules. Investigators are required to submit an exemption form and/or an application form to the IBC for all recombinant DNA experiments. The investigator must receive approval from the IBC and IRB prior to the initiation of the research. When both IBC and IRB review are required, the IRB will ensure that IBC approval is granted prior to releasing of its approval. IBC deliberations are generally not shared with the IRB unless there are specific issues

related to human participants. In instances where both biosafety and human participant research issues are involved, investigators should: i) notify Regulatory Services and the IRB and IBC chairs; and ii) submit separate protocols to the IRB and IBC, respectively. In certain instances, the IRB may deem it appropriate to receive notification of the related IBC approval before approving the IRB protocol.

3. **Institutional Review Entity (IRE)** - The IRE is responsible for ensuring that all Dual-Use Research of Concern (DURC) complies with the USG Policy for Institutional DURC Oversight. Investigators are required to submit an exemption form and/or an application form to the IRE for all dual-use research of concern experiments. The investigator must receive approval from the IRC and IRB prior to the initiation of the research. When both IRE and IRB review are required, the IRB will ensure that IRE approval is granted prior to releasing of its approval. IRE deliberations are generally not shared with the IRB unless there are specific issues related to human participants. In instances where both biosafety and human participant research issues are involved, investigators should: i) notify Regulatory Services and the IRB and IRE chairs; and ii) submit separate protocols to the IRB and IRE, respectively. In certain instances, the IRB may deem it appropriate to receive notification of the related IRE approval before approving the IRB protocol.

4. **Research Conflicts of Interest Committee (RCOIC)** - Every Faculty member engaged in Greater than Minimal Risk (GMR) human subjects research must submit an annual COI Disclosure Form. For every new GMR research study involving human subjects submitted, the IRB staff will contact the Faculty members listed on the study to confirm whether the last COI Disclosure Form submitted is still current or whether any new conflicts arise with the new study. For any positive response that meets or exceeds the $5,000 threshold, the COI staff will refer the COI Disclosure Form for review by the COI Committee. The IRB will also be informed so that they will not approve the study until the COI Committee completes its review and has made the appropriate determination.

   The COI Committee will review all conflicts greater than the $5,000 threshold to determine whether the conflict should be eliminated, can be appropriately mitigated. Once a final determination has been made, the COI Committee will report its conclusion to the PI and to the IRB.

   For FDA-regulated research, the COI Committee and the IRB will ensure compliance with 21 CFR 54.

E. Review of Research Activities by Other University Offices or Committees

The UT Arlington IRB and IRB Staff coordinates with other research administrative offices external to Regulatory Services when appropriate as described below.

1. **Grants and Contract Services (OGCS)** – Regulatory Services maintains close communication with Grants and Contracts to help that office ensure that IRB approval is granted prior to the initiation of grants and contracts. Regulatory Services also receives copies of grant proposals from Grants &

Contracts Services in order to perform congruency checks between grant submissions and submitted IRB protocols for these funded projects. For industry-supported studies, Regulatory Services helps Grants and Contracts ensure consistency between informed consent language and terms of contracts.

2. **University Compliance and Legal Affairs** – Regulatory Services interacts with the legal office on an ad hoc basis when the IRB requires legal counsel or for serious noncompliance cases that require reporting to federal agencies and/or sponsors.

3. **Environmental Health and Safety (EH&S)** – Regulatory Services works closely with EH&S to ensure that EH&S personnel are notified independently of the human subjects approval process regarding pending or approved IRB submissions requiring EH&S oversight. For example, for studies involving collection of blood or blood-borne pathogens, IRB staff notifies the Biological Safety Specialist within EH&S that a protocol with biological agents has been submitted for IRB review. For research studies involving radiation, IRB staff notifies the Radiation Safety Officer within EH&S that a protocol with radiation has been submitted for review. In addition, for studies involving laser technology, IRB staff notifies the Laser Safety Officer that a protocol involving lasers has been submitted. IRB staff may also inquire with EH&S staff whether appropriate considerations are in place within specific IRB protocols for the safe operation and use of the EH&S-governed equipment. Once EH&S has been informed that a study requires EH&S consideration, Regulatory Services will continue with the processing of the IRB submission while EH&S is responsible for following up independently with the investigator for any EH&S-related concerns.

VII. Procedures for Processing of New IRB Applications

A. Electronic Submission System

UT Arlington IRB's electronic submission system is designed for online submission of human subject research protocols for IRB review. This system is accessible to all UT Arlington faculty, staff, and students. Non-UT Arlington research personnel may request a guest Net ID under certain circumstances; contact Regulatory Services for information about this process. The recommended browser for use with the electronic system is Mozilla Firefox.

All IRB applications must be submitted in the electronic submission system for formal review, including new studies, study modifications, continuing reviews, requests for reliance and external acknowledgements, and study closure reports. Investigators can use the system to complete, submit, modify, renew, and track their applications from anywhere with a secure internet connection. Regulatory Services staff and IRB members will use the electronic system to conduct study reviews and to provide feedback to researchers on pending protocol requests. **IRB submissions cannot be accepted over email**.

UT Arlington students, faculty, and staff can use their usual Net ID and password to enter the electronic submission system. UT Arlington researchers should check their UT Arlington email often if they are listed as Principal Investigator, Faculty Advisor, or research personnel, as the system will also communicate updates through UT Arlington email.

B. Submission of New Human Subjects Research Applications

UT Arlington requires that all "research with human subjects" must be submitted to the IRB for review and approval prior to the initiation of any research procedures, including study recruitment. All new IRB applications must be submitted electronically through the electronic submission system to the IRB Staff for IRB review. IRB Staff conduct preliminary reviews of all IRB protocol submissions for completeness, determination of the appropriate study classifications and / or regulatory framework, and type of review. **Submissions lacking the required details or documentation necessary for a complete protocol review will be returned to the Principal Investigator in the electronic submission system for revisions.**

C. Determination of Appropriate Study Classifications and Type of Review

After a new protocol is submitted in the electronic submission system, IRB staff conduct a preliminary review of the entire application and make initial determinations as to whether the project constitutes human subject research and, if so, the appropriate type of review based upon the source of study funding (if any) and whether any other regulatory framework (such as FDA or DoD regulations) applies.

Note that some of the classifications below implement flexible internal review pathways which may deviate from 45 CFR 46.

Possible study classifications and IRB review pathways at UT Arlington are as follows:

1. Determination of "Not Human Subjects Research"

IRB staff will determine that submissions that do not meet the definitions of "research" and "human subjects" in accordance with 45 CFR 46 and are also not clinical investigations of a test article as

defined in 21 CFR 50 will be determined "not human subjects research" (NHSR). Studies that are determined to be NHSR do not require the submission of a protocol to the IRB for review, as they are outside of the IRB's regulatory purview. NHSR submissions in the electronic submission system will be returned to the Principal Investigator with instructions for deletion. However, there are times when a sponsor, conference organizer, or academic journal will request a letter from the IRB stating that IRB review is not required for a specific project. For any project determined to be NHSR, IRB Staff will provide such a letter to the PI upon request.

2. Classification and Initial Review of Non-Federally Funded, Non-FDA Regulated Research Protocols

With support from UT Arlington's Institutional Official and the UT Arlington IRB, Regulatory Services has implemented a flexible review procedure for qualifying studies that are not federally funded nor subject to FDA regulations. In this new procedure, UTA will maintain the same high ethical standards for research, but the review process limitations/requirements for these studies will be simplified to allow for additional flexibility and efficiency.

Some procedures for the review and approval of studies eligible for these "flex" internal review pathways will vary compared to the procedures implemented for federally-funded and/or FDA-regulated research, and in some cases, these review procedures may deviate from the federal regulations. Therefore, **research which invokes any federal regulatory framework is ineligible for these internal flexible review procedures**, and must be reviewed under the appropriate regulatory framework(s) referenced elsewhere in this Operating Procedure. Likewise, **if a study receives initial approval under this flexible review procedure and later receives federal funding or is procedurally modified to invoke a federal regulatory framework, the protocol must receive additional review at that time under the appropriate federal regulations and is no longer eligible for these internal flexible review classifications**.

2a. Initial Classification of Eligible Research Based Upon Level of Risk

Upon initial pre-review by IRB Staff, research protocols will be classified as either 1) Minimal Risk (MR), or 2) Greater than Minimal Risk (GMR). As defined in Section III above, "Minimal Risk" means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. Research that does not meet the definition of Minimal Risk (MR) will be classified as Greater than Minimal Risk (GMR). The classification of MR or GMR will be determined by IRB Staff with consultation from the IRB as necessary.

Studies qualifying for the MR or GMR "Flex" Internal Review Pathways must still comply with the principles of the Belmont Report and relevant UTA IRB Operating Procedures. Additionally, studies approved under these internal review categories still require that **modification requests must be submitted and approved in the electronic submission system** before any changes from the approved version of the protocol are implemented.

2b. Initial Review of Minimal Risk (MR) Research

IRB Staff is designated with responsibility and authority to review and approve new MR research applications, with consultation from the IRB when deemed necessary. MR research may include procedures or populations requiring additional assessment and expertise of an IRB Member or outside consultant. IRB Staff is granted authority to determine when MR research will require additional review or consultation. Review of research by the IRB or a consultant will not automatically change its designation from MR to GMR, unless the reviewer(s) provides rationale and the reasoning is documented.

2c. Initial Review of Greater than Minimal Risk (GMR) Research

New GMR research applications may be reviewed by the IRB via consultation, by one or more IRB member(s), or by the full committee at a board meeting. The method of review will be determined by IRB Staff in consultation with the IRB Chair or Vice-Chair when necessary.

3. Classification and Review of Federally Funded and FDA Regulated Research Protocols

New research that *is* federally funded or FDA regulated must comply with the principles of the Belmont Report, the existing IRB Operating Procedures, *plus* the full requirements of the Revised Common Rule 45 CFR 46 and / or FDA regulations at 21 CFR 50 and 21 CFR 56, as applicable. **Even if not mentioned specifically in this section, research which invokes any regulatory framework must be reviewed in accordance with those pertinent regulations.** If a federally funded study receives initial approval under the Revised Common Rule and the funding ends but the project continues, the study may be reclassified to MR or GMR under the "flex" internal review pathway.

3a. Exempt Review

Federal regulations recognize certain types of research involving human participants as being "exempt" from the full regulatory requirements of IRB oversight; however, UT Arlington requires that an IRB protocol application must be submitted in the electronic submission system for all "research with human subjects" requiring IRB review, including exempt-level projects.

Upon review of initial applications, the IRB or IRB staff will determine whether the proposed research meets the qualifications for exempt review. Certain classifications of exempt research require that the IRB must conduct a limited IRB review in order to make necessary determinations for exemption; in these cases, an IRB member will conduct the limited IRB review as required by regulation to determine whether the study can be deemed exempt. Studies determined to be exempt will be issued a formal Notice of Exemption Determination to be sent to the PI by IRB Staff.

Exemptions are limited to research involving one or more of the following categories per 45 CFR 46.104; note that for FDA regulated studies, the only allowable exemption on this list per FDA regulations at 21 CFR 56.104 is Exemption #6 for taste and food quality evaluation and consumer acceptance studies.

1. Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact

students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

2. Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:
   (i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
   (ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
   (iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).
3. (i) Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:
   (A) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
   (B) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
   (C) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).
   (ii) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.
   (iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception

through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research. Research involving the collection or study of existing data, documents, records if these sources are publicly available or if the information is recorded by the investigator in such a manner that participants cannot be identified, directly or through identifiers linked to the participants.

4. Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:
   (i) The identifiable private information or identifiable biospecimens are publicly available;
   (ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;
   (iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of “health care operations” or “research” as those terms are defined at 45 CFR 164.501 or for “public health activities and purposes” as described under 45 CFR 164.512(b); or
   (iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for non-research activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.
5. Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

(i) Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

6. Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.
7. Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by §46.111(a)(8).
8. Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:
   (i) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with §46.116(a)(1) through (4), (a)(6), and (d);
   (ii) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with §46.117;
   (iii) An IRB conducts a limited IRB review and makes the determination required by §46.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; and (iv) The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

While some institutions do not require the submission of modification requests for exempt projects, the UTA IRB requires that **any change to any study requires the submission and approval of a modification request in the electronic submission system** for determination whether the change affects the study's exempt status **before the change is implemented**.

The IRB, at its discretion, also retains the right to require continuing review when warranted by the nature of the research and/or inclusion of vulnerable subject populations; however, unless specifically required by the IRB in its Notice of Exemption Determination for an individual research project, continuing reviews do not need to be submitted to the IRB for studies that are determined to be exempt.

Protocols that are reviewed and determined to be exempt are reported to all IRB members on a monthly basis.

i. Exempt + Limited IRB Review

Studies that are eligible for exemption under the Revised Common Rule categories 2, 3, 7, and 8 may require that an IRB member conduct a "limited IRB review" in order to determine whether the criteria for exemption are fully met. In these cases where limited IRB review applies, the limited IRB review process will be conducted by the Chair or an experienced IRB member using expedited procedures in accordance with the specific regulatory IRB approval criteria referenced in the exemption category(ies) as follows:

(i) For exemptions 2(iii) & 3(i)(C), the limited IRB review serves to determine that adequate provisions are in place to protect the privacy of subjects and maintain confidentiality of the data as described in 46.111(a)(7).

(ii) For exemption 7, the limited IRB review is required to determine that the requirements for broad consent are met; that broad consent is appropriately documented or documentation of broad consent is appropriately waived; and that there are adequate provisions in place to protect the privacy of subjects and maintain confidentiality of the data, if there will be a change made for research purposes in the way the identifiable private information or identifiable biospecimens are stored or maintained, as described in 46.111(a)(8).

(iii) For exemption 8, the regulation requires an IRB to determine through limited review that there are adequate provisions in place to protect the privacy of subjects and maintain confidentiality of the data, and that the research to be conducted is within the scope of the obtained broad consent as described in 46.111(a)(7).

The determination of exemption by limited review procedures will be noted in the study approval letter provided to the Principal Investigator.

3b. Expedited Review

The expedited review process may be used by the IRB to review applications that present no more than minimal risk to human subjects and involve only procedures listed in one or more of the expedited categories specified in either 45 CFR 46.110 (OHRP) or 21 CFR 56.110 (FDA). Studies that are eligible for Expedited review are reviewed by one or more experienced IRB Member Reviewers (often the IRB Chair or IRB Vice-Chair) who evaluate whether the criteria for IRB approval referenced in 45 CFR 46.111 or 21 CFR 56.111 are met. If the designated IRB Member Reviewer determines that the selected categories of research qualify for Expedited review, that the study procedures involve no greater than minimal risk to subjects, and the criteria for IRB approval at 45 CFR 46.111 or 21 CFR 56.111 are sufficiently satisfied, he/she may approve the study without referring the protocol to a convened IRB meeting.

Researchers may request expedited review of a project when submitting an application by so noting in the IRB Form. However, the IRB Chair has the ultimate responsibility for determining whether it is appropriate to review the application through the expedited process or whether the

study requires full board review. The IRB Chair may proceed and conduct the IRB review by the expedited review process, or may delegate the review to one or more experienced IRB member(s). A protocol, however, may not be disapproved utilizing the expedited review process; in this case, the protocol must be deferred to a convened IRB meeting for review prior to disapproving the research.

The expedited review process may be used for research projects involving no more than minimal risk, and only those procedures listed in one or more of the following categories:

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met: (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.); (b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows: (a) from healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8-week period and collection may not occur more frequently than 2 times per week; or (b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.
3. Prospective collection of biological specimens for research purposes by noninvasive means. Examples: (a) hair and nail clippings in a non-disfiguring manner; (b) deciduous teeth at the time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gum base or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.
4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves; moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes.
6. Collection of data from voice, video, digital, or image recordings made for research purposes.
7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

Expedited categories 8 and 9 pertain to continuing reviews for full board studies which can be eligible for expedited review in specific situations, so these categories will be discussed in Section IX. A.

The expedited review procedure is not used where identification of the participants and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections are implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

Even when the above criteria are met, the IRB Chair or another member of the IRB retains the right to require full board review when warranted by the nature of the research.

Note that studies approved at the Expedited level of review prior to **January 21, 2019** are subject to continuing review at least annually per the federal regulations; this information was communicated to the investigator in the initial study approval letter. However, under the Revised Common Rule, studies approved at the Expedited level of review after **January 21, 2019** are no longer required to submit continuing reviews unless the IRB specifically determines otherwise. When the IRB determines that a continuing review is required for an Expedited project under the Revised Common Rule, the IRB must document why it has determined that such continuing review is necessary. This determination will also be noted in the study approval letter with the expiration date of study approval.

Protocols that are reviewed and approved through the expedited process are reported to all IRB members on a monthly basis.

3c. Full Board Review

All federally funded or FDA regulated studies that are considered to be greater than minimal risk or which do not satisfy the exempt or expedited review categories, and any other study for which the IRB Chair makes a determination that the study would benefit from additional expertise than that provided by the expedited review procedure, will be reviewed by the full board.

i. **Scheduling of Convened Meetings** - The convened IRB normally meets once per month; scheduled meetings are posted on the Regulatory Services IRB Website. Individual meetings may be cancelled by Regulatory Services or the IRB Chair due to a) insufficient applications requiring full board

review; b) University holidays; c) inability to secure a quorum for attendance; or d) other reasons as may arise that make a scheduled meeting unnecessary or otherwise inappropriate. Following a cancelled meeting, the IRB Chair will work with the IRB Staff to schedule an alternate meeting date as soon as possible.

Emergency meetings of the convened IRB may be possible on a case by case basis, usually in situations of extreme and unforeseen immediacy (i.e., a serious adverse event that may be related to the research; a study sponsor requests immediate IRB action; etc.). However, there is no guarantee that the IRB will be able to secure a quorum without sufficient notice. The IRB Chair may also decline requests for emergency meetings without sufficient justification that the request is a result of extreme and unforeseen immediacy, in which case the submission will be added to the agenda for the next regularly scheduled convened IRB meeting.

ii. **Notification of Meetings and Distributions of Materials** - Agenda and application materials will be distributed to IRB members with sufficient time in advance of the meeting date to allow time for review, generally one week in advance. The agenda indicates the date, time, and place of the meeting, as well as the list of protocol submissions up for review. For new projects, modification requests and continuing reviews by the full board, IRB members have access to the submitted study materials in the electronic submission system, including the application form, Informed Consent and/or Assent Document(s), recruitment materials, data collection materials, device manuals, drug dosage and safety sheets, and relevant correspondence, as applicable.

iii. **Assignment of Primary Reviewers** - The IRB may elect to utilize a Primary Reviewer for a submission prior to review by the full board at a convened meeting. The IRB Chair or a member of the IRB serves as the Primary Reviewer for a full board meeting. In selecting the Primary Reviewer for a specific study submission, consideration is given to the reviewer's knowledge of the subject area embodied in the proposal.

The Primary Reviewer reviews the application, Informed Consent Document(s), and all supplemental materials (including, if applicable, the grant application, protocol, and/or investigator's brochure). In addition, for continuing review applications, the Primary Reviewer reviews the complete project file, which includes all modifications and reports of adverse events or unanticipated problems involving risks to participants. The Primary Reviewer will have access to other supporting documents to facilitate the review as appropriate, including physician's consultations, EH&S documentation, required FDA submissions and correspondence, and relevant correspondence between the IRB Staff and the investigator(s) regarding the research study in the electronic IRB system.

The Primary Reviewer may contact the investigator in advance of or during the board meeting for additional information or clarification. The Primary Reviewer leads the discussion of the new project, modification, or continuing review application, and is also requested to submit completed Primary Reviewer materials to IRB staff prior to the convened meeting. The Primary Reviewer may not have a conflict of interest regarding the project under review and is expected to notify IRB staff and the IRB Chair of any potential conflicts.

iv. **Convened Meeting Procedures** - IRB meetings are called to order when a quorum of members is in attendance. Initial and continuing reviews of research must be conducted by the IRB at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. The meeting is ended by adjournment or suspended whenever a quorum is no longer present for deliberations. Alternates can substitute for regular IRB members when the regular voting member for that area is absent. When this occurs, the alternate member counts toward the quorum.

IRB meetings are typically convened with all members physically present. However, due to extenuating circumstances where one or more members are not able to attend the meeting in person, their participation may be included via teleconference or online video conference as long as the member has received all required materials in advance of the meeting. Likewise, when an extra convened board meeting is scheduled to review any type of IRB business and time, weather, or other extenuating circumstances do not allow for a convened board meeting, the entire meeting may be held by teleconference when all other requirements of these policies and procedures are upheld.

At the discretion of the IRB Chair, IRB Staff and/or Primary Reviewer, investigator(s) may be invited to attend the IRB meeting to answer questions, obtain clarification of specific points, or to participate in the preliminary discussion of the project. Invited investigator(s) are required to leave the meeting for subsequent IRB discussions and voting on the protocol.

Voting is by a show of hands, or in the case of teleconference participation, by verbal vote. The official meeting minutes document the number of votes for, against, or abstaining for each protocol submission. A simple majority vote of the members present at the meeting is required for approval.

Investigators are notified in writing of the decisions of the IRB and are provided with any required conditions or suggested modifications for approval.

v. **Meeting Minutes** - Minutes are generated following each IRB meeting and must contain the following elements: (1) The names of members in attendance at each meeting, and whether a quorum was present; (2) A record of the vote on actions taken for each protocol submission, including the number of votes in favor, against and abstaining; (3) The basis for requiring conditions or modifications to the research, or for disapproving the research; (4) The length of time of the current approval (if less than 1 year); (5) A brief summary of the discussion of any controverted issues and their resolution; (6) Specific IRB findings relevant to the inclusion of certain vulnerable populations, or for waivers of consent; (7) Whether the protocol was found to be minimal risk or greater than minimal risk to the study subjects.

In addition to the above items, meeting minutes may sometimes include information regarding expedited approvals, approved modifications, study closures, adverse events, and any other business appropriate for board meetings.

vi. **Notification of IRB Activities** - Members of the IRB receive minutes of full board meetings and reports of IRB business. Reports include written notification of all new projects approved (full board, expedited, Minimal Risk, and Greater than Minimal Risk), projects determined to be exempt, modification requests, and continuing reviews (full board and expedited). The IRB minutes are also distributed to the VPR on a quarterly basis to inform the IO of the actions of the IRB.

D. Approval of Protocol Submissions

The IRB (or Regulatory Services as designee, when applicable) will conduct a thorough review of all IRB submissions to ensure the protection of human subjects, the ethical conduct of research, compliance to all applicable regulatory considerations, and the scope and criteria for approval listed in Section VIII. IRB Staff will also ensure that researchers have completed all required trainings as indicated in Section XX prior to the approval of protocol submissions.

The review of an application by the IRB could include the following outcomes:

1. Approval as Submitted

If the protocol is approved as submitted by a majority vote by the convened IRB, or if the IRB reviewer or IRB staff approves a protocol without revisions for a qualifying review category, the investigator is notified that the application is approved and does not require further revisions. The IRB Staff will provide the approval letter and stamped consent documents to the investigator via the electronic submission system.

2. Approval with Conditions

For studies reviewed under the Expedited, Minimal Risk, or Greater than Minimal Risk review categories, the IRB Reviewer(s) or IRB Staff may issue a specific list of required changes needed to secure final approval. In this case, the study will be returned to the Principal Investigator in the electronic submission system with the list of conditions for approval. Upon resubmission of the requested revisions in the electronic system, the conditions for approval will be verified by the IRB Reviewer(s) and/or IRB Staff prior to the issuance of the official study approval.

When the convened IRB reviews and approves a research study (or proposed changes to a previously approved research study), the IRB may require as a condition of approval that the investigator (a) make specified changes to the research protocol or informed consent document(s); (b) confirm specific assumptions or understandings on the part of the IRB regarding how the research will be conducted; or (c) submit additional documents, such that, based on the assumption that the conditions are satisfied, the IRB is able to make all of the determinations required for approval under the HHS regulations at 45 CFR 46.111 and, if applicable, subparts B, C, or D of 45 CFR part 46.

With respect to research reviewed and approved with conditions by the IRB at a convened meeting, note that because the IRB is able to make all these determinations, the IRB may designate the IRB Chair (and/or other individual(s) with appropriate expertise or qualifications) to review responsive materials

from the investigator and determine that the conditions have been satisfied, and further review by the IRB at a subsequent convened meeting would not be necessary.

When the IRB approves research with conditions, verification procedures must be included as part of the IRB approval process, under which the IRB Chair (and/or other individual(s) designated by the IRB) will review the resubmitted materials from the investigator required by the IRB, and determine whether the conditions of approval have been satisfied (45 CFR 46.102(h)). The IRB's verification that the investigator has satisfied all conditions of approval stipulated by the IRB helps to ensure that the investigator does not initiate any research that is different from what was approved by the IRB at the convened meeting.

After the conditions have been satisfied and the official approval is granted, IRB Staff will provide the approval letter and stamped consent documents to the investigator via the electronic submission system.

3. Requires Significant Modifications Prior To Approval

The IRB may return a study for significant revisions in situations where a vote of "Approve As Submitted" or "Approve with Conditions" is not possible due to lack of information; the IRB is unable to determine whether criteria for approval are met under 45 CFR 46.111; and/or the IRB is not able to specify changes that would allow the IRB to make the required determinations for approval. The IRB will then request changes to the study to secure approval and will defer these proposed changes for further review at a future date after the required revisions are submitted by the investigator. After the initial review by the convened IRB, the list of required modifications will be sent to the investigator by IRB staff detailing the IRB's request for application revisions, clarification, or additional information.

If a study is reviewed at a convened IRB meeting and returned to the investigator pending major modifications, further review by the IRB at a subsequent convened meeting is necessary prior to approval.

4. Disapproval

Note that study submissions can only be officially disapproved at a convened full board IRB meeting.

Any time the IRB cannot make one or more of the determinations required for approval at 45 CFR 46.111 and, if applicable, subparts B, C, or D of 45 CFR part 46, the IRB cannot approve the research project. This applies to both initial and continuing review of research, and review of proposed changes to previously approved research. Investigators are advised to consult with the IRB Staff prior to resubmission of previously disapproved applications.

When the IRB is unable to approve research because it cannot make the determinations required for approval, the IRB can either disapprove the project, or defer the project for further review at a future date. When deferring the project, the IRB, under its authority to require modifications in order for an investigator to secure approval, may require that the investigator (a) make changes to the protocol or informed consent documents, or (b) submit clarifications or additional documents for consideration

prior to the next review. If the IRB defers a research project, the research may not proceed until the IRB reviews the revised research project and approves it at a subsequent convened meeting.

When the IRB reviews a research project under an expedited review procedure and is unable to approve the project because the IRB reviewer cannot make the determinations required for approval, the IRB reviewer can either refer the project to the IRB for further review and action at a convened meeting, or defer approval of the research project and require that the investigator (a) make changes to the protocol or informed consent documents, or (b) submit clarifications or additional documents prior to further review by the IRB reviewer. Research may not be disapproved under an expedited review procedure (45 CFR 46.110(a)).

If the IRB decides to disapprove an application for research involving human participants, the investigator(s) shall be notified in writing of the decision of the IRB along with a detailed statement summarizing the IRB concerns that led to the decision. The investigator(s) must be afforded an opportunity to respond to the decision in person and/or in writing. An appeal must follow the procedures outlined in Section IX, 10, "Appeal of IRB Decisions."

Research that has been approved by the UT Arlington IRB may require further review and approval by officials of the institution. However, those officials may not approve the research if it has not been approved by the UT Arlington IRB (45 CFR 46.112).

E. Length of Initial Approval Period

Some approved studies require the submission of a "continuing review" as a way of reporting progress to the IRB; more information about the continuing review process is available under Section IX. A.

Investigators should note that the initial study approval letter will contain specific information about whether or not the approved protocol is required to submit continuing reviews, and, if so, the length of the initial approval period and study expiration date. As a courtesy, IRB Staff will make every effort to notify Principal Investigators in advance of the expiration date when their projects are due for continuing review; however, the PI is ultimately responsible for keeping track of continuing review deadlines and ensuring that materials are submitted in a timely manner to maintain approval of research and avoid study expiration.

VIII. Scope of IRB Review and Criteria for IRB Approval

The IRB (or IRB Staff as designee, when applicable) will conduct a thorough review of all submissions for human subjects research to ensure the protection of human subjects, the ethical conduct of research, and compliance to all regulatory considerations listed in Section I.B.2 above. For FDA-regulated research, the IRB or IRB Chair will determine if a physician consultant review is required. The IRB applies the following considerations to the review of all new and continuing protocol applications, as well as modifications/amendments to protocols.

The IRB Staff will begin with a pre-review of each submission for inclusion of all required documents and information and for consideration of regulatory requirements. The regulatory considerations are shared with the Primary Reviewer and the convened IRB (or are made available in the electronic submission system).

A. Scope of IRB Review

In addition to the submitted protocol application documents (Form 1, Informed Consent Document, etc.), the IRB may, at its discretion, request supplemental materials from the Principal Investigator as needed if these materials are deemed necessary to evaluate whether a proposed project meets the criteria for approval listed in Section VIII. B.

The charge of the IRB is to provide an ethical review of research studies for the protection of human subjects. Although the IRB is not designed to serve as a scientific review committee, it must have sufficient expertise so it can conduct the level of scientific review necessary to evaluate the risks and benefits of the research. The IRB must also be sufficiently composed to be able to make a determination as to whether it is ethical to expose subjects to greater than minimal risks when the research is not appropriately designed to meet its objectives (i.e., address the hypothesis). The IRB will also apply the Criteria for IRB Approval as outlined in 45 CFR 46.111 and 21 CFR 56.111, which are included among the below mentioned considerations. The IRB will be appropriately composed to meet this charge.

Scientific Review - The following provides a framework for the amount of attention the IRB should dedicate to scientific review. When the research involves greater than minimal risks, the IRB must determine that the research is appropriate to conduct with human subjects considering the risk to benefit ratio and the ethical issues regarding the study's design.

1. The UT Arlington IRB will rely on the scientific peer review process when the research is supported by a federal agency. This reliance applies to all protocols that have received a formal peer review from a federal funding agency. In this instance, the UT Arlington IRB will not be required to consider the research design and scientific merit of federally-funded protocols; however, the IRB may still note potential problems with the research design if it would impact the safety, rights, or welfare of the study subjects.

2. For unfunded research protocols, the UT Arlington IRB (or IRB staff as designee when performing MR or GMR Reviews) is responsible for assessing the research design and scientific merit in order to determine the risk vs. benefit analysis. In this assessment, the IRB or designee will determine

the validity of the research and the nature and degree of risk as well as the nature and level of the anticipated benefits in the research design.

3. When conducting scientific review for evaluating the probability of risk and the potential benefits associated with the research, the IRB may consider ways to minimize risks by reviewing information in the protocol regarding the experimental design and the scientific rationale underlying the proposed research, which include the results of previous studies. For protocols that are greater than minimal risk, the IRB may request additional information to support its review of research design and scientific merit. This may include justification for inclusion of human subjects, literature review, additional explanations of direct or indirect benefit, and additional explanation of research design.

The review of research design is not required by federal regulation for exempt research. However, recommendations may be made by the IRB (or designee) to improve research design in the context of a risk versus benefit analysis. The IRB has no obligation to disapprove the research on this basis.

B. Criteria for IRB Approval of Research

The below criteria for IRB approval must be satisfied appropriately not only during the initial review of a research study, but also during the review of modifications and continuing reviews. Note that for studies that are not federally funded or supported nor FDA regulated, IRB Staff is designated with the responsibility and authority to review and approve unfunded research, with consultation from the IRB when deemed necessary. The following criteria for IRB approval will be used as a guideline by IRB Staff in these cases.

1. Identification of Risks

The IRB must identify the risks associated with participating in the research study and differentiate them from the risks that the subjects would encounter if they were not in the study. The risks may include physical, psychological, emotional, economical/financial risks, and those related to a loss of privacy or a breach of confidentiality. Additional risks may be introduced if the investigators do not have sufficient training or qualifications to conduct the proposed research procedures; therefore, the IRB must evaluate the qualifications of the investigator(s) and study staff to conduct the proposed research, as well as evaluate the adequacy of the site and facilities to ensure the safety of subjects. The IRB's identification of risks is based on review of the protocol, supporting information submitted to the IRB for review, the IRB members' experience and knowledge, and from external sources such as a review of the literature. The IRB must be able to determine whether the potential risks are minimal risk or greater than minimal risks so that the appropriate level of review can be applied to the research.

2. Minimization of Risks

The study design and study procedures will be evaluated to determine whether risks have been minimized to the fullest extent possible that will still permit the ethical conduct of the study and that study objectives can be met. Whenever possible, procedures should be utilized that will otherwise be

performed on subjects if they were not enrolled in the study (e.g., in cases of biomedical research, using diagnostics or treatments that would already be conducted in the course of standard medical practice).

The IRB may request that risks be minimized using any of the following means:

- Removing the risk by removing the procedure, intervention, or interaction that will cause the risks;
- Substituting an alternative procedure, intervention, or interaction that reduces risks while achieving a substantially similar outcome;
- Adding precautions, procedures, interventions, or interactions that will manage or remove the risks;
- Adding safeguards such as additional monitoring or testing that will identify the risks earlier and allow intervention or removal of the risks before they are exacerbated.

3. Benefits and the Risk/Benefit Ratio

The IRB will identify the probable benefits to be derived from the research and must determine whether the risks are reasonable in relation to the anticipated benefits. The IRB should not consider the possible long-term effects of potential knowledge that may be gained from the study when considering whether to approve the study (e.g., the possible effects of the research on public policy).

4. Equitable Selection of Subjects

The IRB must ensure that protocols have appropriate plans for the equitable (fair) selection of subjects by reviewing the purpose of the study, the setting in which the research will be conducted and inclusion and exclusion criteria for selection of subjects. The IRB should also consider the settings and/or communities from which subjects will be recruited and review the recruitment plan, recruitment materials, and even the informed consent document(s) from this perspective (See Section IX). When reviewing these considerations, the IRB should be aware of issues related to the enrollment of vulnerable populations such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons. Decisions on whether vulnerable subjects should be included should be made with consideration of the justice principle of the Belmont Report.

5. Informed Consent

The IRB must ensure that protocols have plans to obtain legally-effective informed consent from potential participants or the subjects' Legally Authorized Representative (LAR), unless informed consent is specifically waived by the IRB; and that informed consent documents provide the elements of informed consent required by federal regulations, including an accurate and fair description of the risks and/or discomforts associated with study participation, as well as any anticipated benefits.

Since informed consent is such an integral activity for the ethical conduct of research and there are many considerations for the effectively obtaining consent from subjects, a separate section is devoted to the topic in Section IX.

6. Documentation of Informed Consent

The IRB must ensure that the informed consent process is documented appropriately by a signed, written consent form to ensure legally-effective consent, unless this requirement is specifically waived by the IRB. The waiver of documentation of informed consent is not permitted for FDA-regulated studies, with the exception of Emergency Research.

7. Monitoring of Collected Data

Where appropriate, The IRB must determine that adequate provisions are in place for monitoring the collected data to ensure the safety and well-being of subjects. For all studies that are greater than minimal risk, the IRB shall review the protocol for details on how the study data will be monitored to ensure safety of subjects. The IRB will determine whether the study data can be sufficiently monitored by the investigator and research team, or whether there should be an additional review of safety data by a separate person, committee (e.g., data monitoring committee/data safety monitoring board), and/or the sponsor. Some considerations for when a monitoring committee will be required include moderate to high risk biomedical research (especially studies that may include death as a risk); inclusion of vulnerable subjects or high-risk patient populations; and double-blind study designs.

When considering a separate monitoring committee, the IRB may determine that the monitoring board should be entirely independent from the research team(s) and/or the sponsor so to remove all potential conflicts of interest. Additional considerations for when a monitoring committee will be necessary include requirements by the FDA or NIH or the sponsor for research regulated or supported by them.

The IRB shall also determine whether additional monitoring may be required by UT Arlington when the PI is also the PI of a multicenter study. In such situations, the IRB may determine that the monitoring plan should provide details of how safety data will be collected in a timely manner from all performance sites and how the plan will ensure the safety and well-being of subjects at all sites.

8. Privacy and Confidentiality

The IRB must determine the adequacy of the provisions to protect subject privacy and maintain data confidentiality. If the research study involves greater than minimal risk as a result of a potential breach of confidentiality, a data protection plan will be required for review by the IRB. Details regarding data protection plans and data security considerations can be reviewed in Protecting Human Subject Data section (Section XI).

9. Special Considerations for Projects Including Vulnerable Study Populations

The IRB considers certain groups of human participants to be particularly vulnerable in a research setting or susceptible to coercion or undue influence. The IRB considers additional protections for research activities involving pregnant women, human fetuses and neonates (see Section X.B), prisoners (see Section X.C), children (See Section X.A), and cognitively impaired persons. In reviewing these research projects, the IRB ascertains that the inclusion of the vulnerable population is adequately justified and that safeguards are implemented to minimize risks unique to each population.

For approval of research projects involving vulnerable populations, the IRB considers if one of the following conditions is met:

1. the research does not involve more than minimal risk to the subject;
2. the research is likely to benefit the subject directly, even if the risks are considered to be more than minimal; or
3. the research involves greater than minimal risk with no prospect of direct benefit to individual participants, but is likely to yield generalizable knowledge about the subject's disorder or condition.

The IRB will also consider any additional regulatory criteria for approval which must be met for specific vulnerable populations as part of its protocol review process.

IX. Procedures for Review of Other Types of IRB Submissions

IRB review of a human subjects research project does not stop after the initial protocol approval is granted. Other types of protocol submissions which may be required throughout the life of an approved protocol include continuing reviews, modification requests / amendments, adverse event reports and reports of unanticipated problems, and study closure requests.

A. Continuing Reviews

Some approved studies require the submission of a "continuing review" as a way of reporting progress to the IRB. This provides the IRB with an opportunity to reevaluate the project in terms of the study's progress over time; the status of subject enrollment and participant attrition; whether any adverse events, findings of noncompliance, or unanticipated problems have occurred; whether any new information has been identified that could impact participants or change their likelihood to participate in the research; whether the approved study monitoring procedures have been implemented and are effective; and whether the study continues to meet the criteria for approval discussed in Section VIII.

As a courtesy, IRB Staff will make every effort to notify Investigators in advance of the expiration date when their projects are due for continuing review; however, the PI is ultimately responsible for keeping track of continuing review deadlines and ensuring that materials are submitted in a timely manner to maintain approval of research and avoid expiration. **Failure to adhere to the IRB-mandated continuing review process may result in the suspension or termination of study approval.**

1. Initial Determination of Whether Continuing Review is Required

Although the IRB may request continuing reviews for any study for any reason regardless of study classification or review type, whether or not a study requires continuing review is typically determined by its classification, review type, and level of risk as follows:

1a. Minimal Risk (MR) Approved Projects

Studies approved under the Minimal Risk (MR) "Flex" Internal Review Pathway do not require continuing reviews after initial approval **unless** this has been specifically stated as required in the initial Minimal Risk approval letter. The IRB or designee has the option to request continuing reviews or other IRB-approved method for ensuring continued safety of the research subjects for any reason, even on approved Minimal Risk research.

1b. Greater than Minimal Risk (GMR) Approved Projects

Studies approved under the Greater than Minimal Risk (GMR) "Flex" Internal Review Pathway require an **annual continuing review or other IRB-approved method** for ensuring continued safety of the research subjects. This may involve the submission of the typical continuing review form for IRB consideration at a convened IRB meeting; however, for non-federally funded, non-FDA regulated research, the IRB may consider and/or require alternative methods of continuing review based on the nature of the research and the risk level. Examples of alternative methods of continuing review include (but are not limited to): protocol audits, laboratory visits, observation of the consent process, audit of consent forms, or a meeting with the PI.

1c. Projects Determined to be Exempt

Unless specifically required by the IRB in its Notice of Exemption Determination for an individual research project, continuing reviews do not need to be submitted to the IRB for studies that are determined to be exempt. However, the IRB, at its discretion, retains the right to require continuing review when warranted by the nature of the research and/or inclusion of vulnerable subject populations.

1d. Expedited Approved Projects

Studies approved at the Expedited level of review prior to 7/19/2018 are subject to continuing review at least annually per the federal regulations; this information was communicated to the investigator in the initial approval letter. However, under the Revised Common Rule, studies approved at the Expedited level of review are no longer required to submit continuing reviews unless the IRB specifically determines otherwise. When the IRB determines that a continuing review is required for an Expedited project under the Revised Common Rule, the IRB must document the specific reason why it has determined that such continuing review is necessary. Information about whether a continuing review is required will be included in the approval letter for Expedited studies approved under the Revised Common Rule.

1e. Full Board Approved Projects

All full board research involving human participants is subject to continuing review based on the level of risk as assessed by the board. This review takes place **no less than annually** as required by federal regulation, and may require more frequent review or reports as determined by the IRB. For projects receiving full board review, the length of approval is calculated from the date of the original convened IRB meeting date where the Board voted to approve the study (with or without conditions).

2. Determining Intervals for Continuing (or Additional) Review by the IRB

The interval for re-review by the IRB should be based on the risks of the research and any concerns that may affect the safety and welfare of subjects. For example, if a study involves a new intervention for which there is little experience and data regarding risks, the IRB may be inclined to provide a shorter interval for re-review/continuing review. Studies approved under the federal regulations at the full board level (and at the expedited level prior to the effective date for the Revised Common Rule) require continuing review **no less than annually.** See Sections VII.M and VII.N for details.

3. Submission and Review Process for Continuing Reviews

Continuing Reviews are submitted to the Office of Research Administration, Regulatory Services through the electronic submission system.

Federally-funded or FDA regulated research approved previously by expedited review is considered eligible for expedited review at the time of its regular continuing review, if, during the course of the study, the risks of the study have not increased. Projects that were initially reviewed by the full board continue to receive full board review unless the convened IRB, IRB Chair, or designee determines that

the study meets the specific criteria for expedited review categories 8 or 9. The IRB Staff and/or IRB will consult with collaborating sites and/or other institutional agencies that no material changes have occurred since the previous IRB review. The IRB Staff will compare all continuing review materials and compare them to the previous IRB review (including modifications) to ensure that no changes have been made without IRB review and approval. For FDA-regulated research, when adverse events or problems are reported the IRB or IRB Chair will determine if a physician consultant review is required.

When continuing review is conducted either by the full board or by expedited review, the criteria for IRB approval (45 CFR 46.111 and 21 CFR 56.111) will be considered. For continuing reviews reviewed by the full board, an IRB member will be assigned as a primary reviewer. The primary reviewer will have access to all materials submitted for continuing review. All other members will receive a protocol summary, including the progress summary report, and the informed consent. The continuing review will consider the whether the study should be approved for less than one year because of some risks or challenges that may compromise the protection of human subjects. Full Board continuing reviews will be added to the full board agenda and reviewed at the convened meeting per the operating procedures explained in Section VII.C.3c.

Studies approved under the "Flex" Internal Review Pathways requiring continuing review may utilize the traditional continuing review process or another IRB-approved method for ensuring continued safety of the research subjects. This may involve the submission of the typical continuing review form for IRB consideration by IRB Staff, the IRB Chair, or at a convened IRB meeting; however, for non-federally funded, non-FDA regulated research, the IRB may consider and/or require alternative methods of continuing review based on the nature of the research and the risk level. Examples of alternative methods of continuing review include (but are not limited to): protocol audits, laboratory visits, observation of the consent process, audit of consent forms, or a meeting with the PI.

Studies reviewed under the Revised Common Rule or the "Flex" Internal Review Pathway that reach the data analysis phase may be moved to an annual check-in process in which the PI will notify the IRB once data analysis is complete. FDA regulated studies, and those reviewed prior to the implementation of the Revised Common Rule, that reach the data analysis phase must submit a continuing review. For all studies, when data analysis is complete the protocol can be closed.

4. Lapses in Approval for Studies Requiring Continuing Review

Federally funded or supported projects and FDA regulated studies must submit continuing reviews as required by applicable federal regulations and the determinations of the IRB. The HHS regulations at 45 CFR part 46 make no provision for any grace period extending the conduct of research beyond the expiration date of IRB approval. A lapse in IRB approval of research occurs whenever an investigator has failed to provide continuing review information to the IRB or the IRB has not conducted continuing review and re-approved the research – with or without conditions – by the expiration date of IRB approval.

Likewise, for studies approved under the Greater than Minimal Risk (GMR) "Flex" Internal Review Pathway, or for any other study where the IRB has previously determined that continuing review is required, failure on the part of the investigator to provide continuing review information to the IRB

prior to the study expiration date or other formally issued deadline is considered a potentially serious protocol violation which is subject to IRB deliberation and could result in the suspension or termination of study approval.

In both circumstances, the IRB or IRB Staff sends a notice to the Principal Investigator that IRB approval has expired, and all research activities involving human subjects must stop. Enrollment of new subjects cannot occur after the expiration of IRB approval. Continuing participation of already enrolled subjects in a research project during the period when IRB approval has lapsed may be appropriate, for example, when the research interventions hold out the prospect of direct benefit to the subjects or when withholding those interventions poses increased risk to the subjects (see section J below for additional guidance). The determination regarding whether it is in the best interests of already enrolled subjects to continue to participate in the research after IRB approval has expired may be made initially by the investigator, possibly in consultation with the subjects' treating physicians (if the investigator is not the subjects' treating physician), but the investigator as soon as possible should submit a request for confirmation that the IRB agrees with this determination.

The determination by the IRB may be made by the IRB Chair, by another IRB member or group of IRB members designated by the IRB Chair, or at a convened meeting of the IRB. Furthermore, this determination may be made for all enrolled subjects as a group or for each individual subject. If the investigator or IRB determines that it is not in the best interests of already enrolled subjects to continue to participate, investigators must stop all human subjects research activities, including intervening or interacting with subjects and obtaining or analyzing identifiable private information about human subjects (45 CFR 46.109(a) and (e)).

For studies where IRB approval has lapsed, the research activities may only resume upon written authorization and approval from the IRB. At the IRB's discretion, this may require the submission of a continuing review with written justifications for the lapse, as well as corrective actions to prevent future lapses in IRB approval; or the submission and approval of a brand-new IRB protocol application outlining the remaining research activities to be performed.

5. Determining the Effective Date of Initial IRB Approval and the Dates for Continuing Review

If a study is approved (with no conditions), the final approval is effective the day the study is approved.

For full board studies, the approval date is considered to be the date of the convened IRB meeting at which approval was granted, with or without conditions. If a study is approved pending specific minor conditions, the approval letter and stamped informed consent document will not be released to the Principal Investigator until all of the Board's requested conditions have been met and verified. Therefore, the expiration date of the initial approval period, which is the date of the first continuing review must occur, may be as late as one calendar year after the date of the convened meeting that initially granted IRB approval with conditions.

6. Determining the Date for the Second and all Subsequent Continuing Reviews

For all subsequent continuing reviews of a study, the IRB will perform a continuing review and may re-approve (with or without conditions) the protocol within 30 days before the IRB approval period

expires. In this instance, the IRB will retain the anniversary of the expiration date of the initial IRB approval as the expiration date of each subsequent one-year approval period. This is done in order to keep the expiration date of the IRB approval period constant from year to year.

If a study requests that a continuing review should be reviewed and approved outside of the required 30-day window before the expiration date, this will change the study expiration date going forward to the anniversary date on which this new continuing review was approved.

B. Modification Requests / Amendments

All studies approved (or determined exempt) by the UT Arlington IRB require that **modification requests must be submitted and approved in the electronic submission system** before any changes from the approved version of the protocol (and associated protocol documents) are implemented. This applies to studies determined to be exempt; studies approved through the MR or GMR "flex" internal review pathways; and studies approved at the Expedited or Full Board level per the federal regulations. Modifications may only be implemented without prior IRB review and approval when necessary to eliminate apparent an immediate hazard to the subject(s), and in this case, the IRB must be informed of this change as soon as possible after the fact. **Failure to obtain IRB approval for changes prior to implementation is considered both a protocol violation and noncompliance subject to IRB review and deliberation**.

Possible modifications include, but are not limited to, procedural changes to a protocol; addition or removal of study sites or recruitment methods; adding or removing protocol personnel; requesting additional participants beyond the approved number; reporting changes in funding; and changes in approved study documents, including Informed Consent Document(s) and recruitment materials.

When an investigator wishes to modify a protocol, he or she must submit these modifications in the electronic submission system along with all supporting documentation and the rationale for the requested changes.

1. Pre-Review of Modifications

IRB Staff conduct a pre-review of all modification requests for completeness, to ensure that all documents impacted by the proposed changes have been sufficiently modified, and to determine whether the proposed changes will impact the previously chosen approval category or review type. **Submissions lacking the required details or documentation necessary for these determinations will be returned to the Principal Investigator in the electronic submission system for revisions.**

Every modification reviewed will include consideration of whether the changes in the research will affect the informed consent document(s). A determination will also be made whether currently enrolled subjects will need to have consent re-obtained with the newly revised consent form. The IRB may also determine that a notification describing the changes would be sufficient in informing subjects. If an informed consent document is updated as part of the modifications being requested, the new version will be stamped reflecting the updated approval date and/or version number.

Once IRB Staff have verified that the modification request has all the needed details and documents to be able to make further determinations, IRB Staff (with input from the IRB Chair or others as

necessary) will then determine whether the proposed modification would be considered a “major” or “minor” modification. Specific minor/major determinations are made on a case-by-case basis.

2. Review of Major Modifications

Major modifications are proposed changes to a study which will or could increase the probability or magnitude of the potential risks to study subjects. Major modifications may also involve a decrease in benefit or that otherwise result in alteration of the risk/benefit assessment of the research.

In the case of federally funded or otherwise federally regulated studies, major modifications would not follow an administrative review process and would require either expedited or full board review. If the modification meets the criteria for expedited review and the study is currently an approved Expedited-level project, the major modification would be reviewed under the expedited review process. However, if the study is currently an Expedited-level project, and the major modification involves procedures outside the expedited categories listed in Section VII.C.3b and/or increases the risk level to more than minimal risk, the major modification must be reviewed at a convened meeting of the IRB, and the study would be reclassified to the Full Board level of IRB review. If the study is currently an approved Full Board-level project, the major modification must be reviewed at a convened meeting of the IRB. For FDA-regulated studies, the IRB or IRB Chair will determine if a physician consultant review is required.

Major modifications to studies approved through the MR or GMR “flex” internal review pathways may be reviewed by IRB Staff or one or more members of the IRB. IRB Staff is designated with responsibility and authority to review and approve major modifications to MR research, with consultation from the IRB and/or external consultants when deemed necessary. For situations where proposed changes may impact the risk level to participants and result in a reclassification from MR to GMR, or for major modifications to approved GMR studies, modification requests may be reviewed by the IRB via consultation, by one or more IRB member(s), or by the full committee at a board meeting. The method of review will be determined by IRB Staff in consultation with the IRB Chair or Vice-Chair when necessary.

Studies requiring reclassification to a new level of review due to a major modification will be appropriately reclassified within the electronic submission system, and a notice will be sent to the Principal Investigator via email to notify them of this change. The notice will also explain any additional obligations that may result from reclassification to the new review category, such as the submission of annual continuing reviews.

3. Review of Minor Modifications

Minor modifications are those which do not increase the probability or magnitude of risk to subjects. A minor change is one in which makes no substantial change in:

- The study risk/benefit ratio;
- The presumed willingness of current subjects to remain in the study;
- The scientific validity of the study;
- The number of subjects enrolled (less than a 20% change for Full Board / GMR projects);

- The qualifications of the research team to perform the proposed procedures (Note: the addition or deletion of investigators usually is minor; however, a change in PI may not qualify as a minor change);
- The facilities available to support safe conduct of the research.

In the case of federally funded or otherwise federally regulated studies, if the minor modification meets the criteria for expedited review and the study is currently an Expedited-level project, the minor modification would be reviewed under expedited review or administrative review* procedures. If the minor modification meets the criteria for expedited review and the study is currently a Full Board-level project, the minor modification will be reviewed under expedited review or administrative review* procedures. If an informed consent document is updated as part of the modifications being requested, the new version will be stamped reflecting the updated approval date.

Minor modifications to studies approved through the MR or GMR "flex" internal review pathways may be reviewed by IRB Staff or one or more members of the IRB. The method of review will be determined by IRB Staff in consultation with the IRB Chair or Vice-Chair when necessary.

*A subset of minor modifications may qualify for Administrative Review – see Section IX.B.4 below.

4. Administrative Review of Certain Minor Modifications

Some minor modifications can be classified as Administrative in nature. The IRB has delegated authority to the Regulatory Services IRB Staff to conduct Administrative Review and approval of certain minor modifications for all approved human subjects research studies, including federally-funded non-exempt IRB protocols.

The minor modifications that may undergo Administrative Review by the IRB Staff have all of the following characteristics:

- All requested changes to the study have been adequately justified;
- The requested changes do not impact the study's risk/benefit assessment;
- The requested changes do not change the review category of the research that is already assigned;
- Any personnel added have completed required training and conflict of interest disclosures.

The types of minor, non-substantive modifications that qualify for Administrative Review are limited to the following:

- Addition/deletion of protocol personnel;
- Change of Principal Investigator or Co-PI, if the qualifications and experience are substantially similar to the previous PI/Co-PI;
- Update to study title;
- Update in study funding (grant congruency and potential impact on review pathway will be verified by IRB Staff);
- Updated contact phone number, address, email address, and other contact information of research personnel in the protocol or study documents;

- Addition of documents translated into non-English versions, when accompanied by a description of the service or personnel responsible for the translation, and their qualifications;
- Deleting items from a research tool, questionnaire, survey, or interview without changing the risk level of the project;
- Adding items to a research tool, questionnaire, survey, or interview that are substantially similar in nature to previously approved materials and do not change the risk level of the project;
- Minor editorial revision(s) to the Informed Consent document, recruitment materials, and other study documents that do not alter the intent or meaning of the previously approved version(s);
- Addition of recruitment materials (flyers, advertisements, communication pieces) when the content is substantially similar to previously approved materials;
- Deletion of a research site/location, or addition of a new site/location when site approval is confirmed/documented, and procedures taking place at the new site are substantially similar to those previously approved.

Approval of these administratively-reviewed minor modifications will be completed by the IRB Staff and documented via an approval letter referencing the review process utilized under this section. An approval letter and stamped consent document (if applicable) will be uploaded in the electronic submission system.

C. Adverse Event Reports and Unanticipated Problems

Post-approval monitoring of research includes reviewing reports of any risks or harms to subjects or others peripherally involved in the research (e.g., family members who may be indirectly harmed by the research). The reports of harms or risks can come to the IRB from different sources including investigators, study personnel, research subjects, sponsors, and data and safety monitoring boards/data monitoring committees.

1. IRB Review of Adverse Events (AEs)

An adverse event (AE) is defined as, "Any unfavorable or harmful occurrence to a human subject which occurs during the time that the subject is enrolled as a participant in the research, whether or not the occurrence is considered related to the subject's participation in the research." This definition includes any abnormal medical sign (for example, an abnormal physical exam or laboratory finding), injury, symptom, disease, or death, as well as adverse psychological events such as suicidal behavior, homicidal behavior, or increase in depression or anxiety symptoms.

AEs are not required to be reported promptly to the IRB unless they are considered serious in nature, or if they also meet the definition of an unanticipated problem (UP, defined below). For studies requiring continuing reviews, AEs that are not serious nor UPs must be summarized in the continuing review submission. For studies that do not require continuing reviews, AEs should be reported via an email describing the circumstances of the AE to RegulatoryServices@uta.edu.

2. IRB Review of Serious Adverse Events (SAEs)

A serious adverse event (SAE) is defined as, "Any adverse experience in a research participant that results in any of the following outcomes: death; a life-threatening adverse experience; inpatient hospitalization or prolongation of existing hospitalization; a persistent or significant disability/incapacity; a congenital anomaly/birth defect; required intervention to prevent permanent impairment or damage; suicide attempts; or other serious medical events." Per FDA guidance, examples of SAEs include allergic brochospasm (a serious problem with breathing) requiring treatment in an emergency room, serious blood dyscrasias (blood disorders) or seizures/convulsions that do not result in hospitalization, as well as the development of drug dependence or drug abuse.

SAEs should be promptly reported to the IRB if they are related or possibly related to participation in the research, or if they also meet the definition of UP. Investigators or Sponsor-Investigators for FDA regulated studies must also comply with the additional reporting requirements for adverse drug reactions that are both serious and unexpected (see 21 CFR 312.32) and for unanticipated adverse device effects (UADE) that are serious, life-threatening, cause death and are unexpected (see 21 CFR 812.150). Reports of SAEs should be sent to IRB Staff via an email describing the circumstances of the SAE to RegulatoryServices@uta.edu.

3. IRB Review of Unanticipated Problems (UPs) Involving Risks to Subjects or Others

An Unexpected Problem (UP) is defined as, "Any incident, experience, or outcome that happens during a study and meets all of the following criteria:

i. Is 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, investigator brochure and informed consent document; and (b) the characteristics of the subject population being studied;
ii. Is related or possibly related to participation in the research (meaning there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures or test articles involved in the research); and
iii. 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.

Unanticipated Problems (UPs) must be reported to the IRB within five working days of the research team's discovery of the event or incident.

3a. Content Reports of UPs

The investigator will submit UPs to the IRB via an email to RegulatoryServices@uta.edu within the five working day reporting period which must contain all of the following information:

i. Identifying information for the research protocol, including the study title, investigator name, and the IRB protocol number;
ii. A detailed description of the UP, incident, experience, or outcome;
iii. An explanation of the basis for determining that the finding, incident, experience, or outcome represents an UP; and,

iv. A description of any changes to the protocol or other corrective actions that have been taken or are proposed in response to the UP.

3b. IRB Review of UP Reports

The IRB Chair, or designee, reviews all UPs and determines which ones require review by the convened full board versus expedited review. UPs that constitute serious adverse events or harms that raise potential concerns regarding the safety and well-being of subjects and/or the integrity of the study and will be reviewed by the convened full board meeting. Actions that the IRB may require include, but are not limited to: informing enrolled participants of the UP; modifying the Informed Consent Document; or modifying other aspects of the protocol or its procedures.

3c. Reporting of UP Reports to Institutional Officials and Regulatory Agencies

All UPs that result in a change in the protocol and/or the consent documents (either by the IRB, the investigator, or the sponsor) shall be reported to appropriate institutional officials, Relying institutions when the UTA IRB is the IRB of Record, the supporting agency head (or designee), and OHRP and / or other appropriate regulatory agencies within one month of the IRB's receipt of the report (as applicable). If the IRB suspends or terminates a study due to reported adverse experiences, the University notifies federal regulatory agencies in accordance with UT Arlington policy. Sponsor-Investigators of FDA regulated device studies must report the IRB's evaluation of a UADE under 812.46(b) to the FDA within 10 working days after first receiving notice of the effect. Sponsor-Investigators of FDA regulated drug studies must submit an IND Safety Report to the FDA no later than 15 calendar days after determining that information qualifies for reporting under 21 CFR 312.32.

D. Requests for Study Closure

The investigator should notify the IRB that he/she has completed an approved IRB study through the electronic submission system via the submission of a Closure Report. Alternatively, researchers may send an email to RegulatoryServices@uta.edu to notify IRB Staff of a study's closure, and IRB Staff may be able to close out specific studies on behalf of the Principal Investigator. Once a closure is officially documented in the electronic submission system and a notice has been sent to the Principal Investigator via email, this starts the clock for the required 3-year research record retention period following study closure.

X. Study Recruitment and Informed Consent

A. Recruitment of Human Subjects / Participants in Research

The IRB will review proposed methods of recruitment and recruitment materials to ensure that the process will be conducted in a manner that that is ethical. It is essential that subjects are recruited and enrolled in research in a manner that does not introduce coercion or undue influence and provides subjects with consistent and accurate information to facilitate an informed decision about study participation. Since the informed consent process is considered to start with the recruitment process and materials, the IRB also considers recruitment materials during its review of informed consent.

Recruitment materials may include flyers, recruitment letters, recruitment emails, advertisements, television or radio ads, study websites, and posting on social media, among other strategies. The IRB review of recruitment materials will ensure that the benefits to participation are not overstated nor presented in a manner that may pose undue influence over a subject's decision-making process. For these reasons, the information provided in recruitment materials should be limited to information that will generate interest from the subject, determine their eligibility, and provide contact information for the research team. As relevant, the recruitment material may include following:

- An explanation of the purpose of the study;
- Eligibility information (e.g., brief summary of the main inclusion/exclusion criteria);
- A summary or brief list of the procedures and benefits;
- Time, travel, or other commitments required from subjects for participation;
- Whether or not compensation will be offered for participation;
- The name of the researcher and/or research institution or facility;
- Contact information for the research team.

If the recruitment material presents the amount of compensation offered for participation, the amount should not stand out more than the rest of the content in the recruitment material by increasing the font size, bold font, or brighter color. **Undue emphasis on study compensation is not appropriate for IRB-approved recruitment materials.**

If UTA researchers intend to access or receive private, individually identifiable information about potential research participants from an external site for the purposes of study recruitment, the UTA researchers must first obtain written permission from an authorized person at the Non-UTA recruitment site for the purpose of gaining access to private identifiable information in order to initiate recruitment contact. This written permission must be submitted to the UTA IRB as part of the IRB protocol application materials. Note that this permission letter is not needed when the UTA research team will only forward IRB-approved recruitment materials to the external site for distribution without the UTA researchers accessing or receiving any private, individually identifiable information about the potential subjects themselves.

Only recruitment material that is presented directly to subjects needs review by the IRB. Materials or media coverage about the research that is intended for scientists, educators, health professionals or other individuals not targeted as subjects for the study do not need to be reviewed by the IRB.

Under the Revised Common Rule (45 CFR 46.116(g)), the IRB may approve a research procedure in which information or biospecimens is obtained for the purpose of screening, recruiting, or determining the eligibility of potential subjects without their informed consent if either of the following conditions are met:

- The investigator will obtain information through oral or written communication with the subject.
- The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable specimens.

B. Informed Consent

As an ethical standard for all research, UT Arlington requires that all IRB submissions involving the prospective collection of data from human subjects must include an informed consent process regardless of study classification or review type. This basic obligation arises from the principle of respect for persons, one of the 3 ethical principles governing human subject research described in the Belmont Report, the guiding document for the operations of the UT Arlington IRB.

For federally funded studies, FDA regulated studies, or studies which invoke any other federal regulatory framework, legally-effective informed consent must be obtained from every subject enrolled in human subject research, unless the requirement for obtaining informed consent has specifically been waived by the IRB per the criteria at 45 CFR 46.117(c) or per the FDA Guidance Document "IRB Waiver or Alteration of Informed Consent for Clinical Investigations Involving No More Than Minimal Risk to Human Subjects," July 2017.

1. General Requirements for Informed Consent

Except under alternative procedures approved by the IRB, no investigator may involve 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 (LAR). 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 and/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.

1a. Required Elements of Informed Consent

The following elements will be provided to each subject as part of the informed consent process, as applicable:

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

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

iv. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

v. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained. Statement(s) should be included to explain who has access to review the research records for inspectional purposes (e.g., UT Arlington IRB, OHRP (for federally-supported or conducted research), and / or FDA (for FDA-regulated research)). A brief explanation of how the collected paper and / or electronic data will be kept secure should also be included, although listing the exact building and room number where this information will be stored is discouraged to prevent potential theft of the research records. Additionally, if the subject data collected may be shared with external sponsors or may be posted in a location for public or restricted access by persons external to the research team, this must also be disclosed in this section of the informed consent.

   For NIH-supported grants or contracts, language should be included to explain the protections provided by and limitations to the protections granted by the Certificate of Confidentiality, which are automatically provided for all NIH grants (as of October 1, 2017). For non-NIH-supported grants, an explanation of the protections provided by a Certificate of Confidentiality should be included whenever one has been obtained for the study.

vi. 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;

vii. 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;

viii. 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; and,

ix. For studies subject to the Revised Common Rule, one of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:

   (i) A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or

(ii) A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

x. For studies involving clinical trials, there must be added statements explaining that the clinical trial has been registered on the ClinicalTrials.gov website. The IRB shall ensure that the following statements are included in such consent forms: "A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time."). These statements are usually placed towards the beginning of the consent document after the Purpose section.

1b. Optional Elements of Informed Consent

When appropriate, one or more of the following elements of information shall also be provided to each subject:

i. 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;
ii. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
iii. Any additional costs to the subject that may result from participation in the research;
iv. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
v. 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
vi. The approximate number of subjects involved in the study.

For studies subject to the Revised Common Rule, one or more of the following elements of information, when appropriate, shall also be provided to each subject:

i. A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit;
ii. A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and
iii. For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

2. Broad Consent

When broad consent is utilized for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens (collected for research studies other than

the proposed research or nonresearch purposes), the following elements must be provided to each subject or the subject's LAR:

i. A description of any reasonably foreseeable risks or discomforts to the subject;
ii. A description of any benefits to the subject or to others which may reasonably be expected from the research;
iii. A statement describing the extent, if any, to which confidentiality of records identifying the subject must be maintained;
iv. 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;
v. For research involving biospecimens, a statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit;
vi. For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen);
vii. A general description of the types of research that may be conducted with the identifiable private information or identifiable biospecimens. This description must include sufficient information such that a reasonable person would expect that the broad consent would permit the types of research conducted;
viii. A description of the identifiable private information or identifiable biospecimens that might be used in research, whether sharing of identifiable private information or identifiable biospecimens might occur, and the types of institutions or researchers that might conduct research with the identifiable private information or identifiable biospecimens;
A description of the period of time that the identifiable private information or identifiable biospecimens may be stored and maintained (which period of time could be indefinite), and a description of the period of time that the identifiable private information or identifiable biospecimens may be used for research purposes (which period of time could be indefinite);
ix. Unless the subject or legally authorized representative will be provided details about specific research studies, a statement that they will not be informed of the details of any specific research studies that might be conducted using the subject's identifiable private information or identifiable biospecimens, including the purposes of the research, and that they might have chosen not to consent to some of those specific research studies;
x. Unless it is known that clinically relevant research results, including individual research results, will be disclosed to the subject in all circumstances, a statement that such results may not be disclosed to the subject; and
xi. An explanation of whom to contact for answers to questions about the subject's rights and about storage and use of the subject's identifiable private information or identifiable biospecimens, and whom to contact in the event of a research-related harm.

Investigators must include information in the protocol regarding the circumstances under which broad consent will be obtained, the proposed process for tracking of responses, and the proposed consent form(s) (or oral script if a waiver of documentation of consent is sought) and any other consent materials (e.g., information sheet, audiovisual materials, etc.). The investigator must implement a process for tracking subjects' responses (accept or decline) to avoid utilizing data for future research purposes from subjects that declined broad consent.

When investigators propose research involving the use of identifiable private information and/or identifiable biospecimens research for which broad consent was obtained, the investigators must provide a reference to the protocol number which provided approval for storage and maintenance of the private information/biospecimens (if the protocol was approved at UTA) or, (if approved outside of UTA) include documentation of the IRB approval for the storage or maintenance of the information or specimens and include a copy of the approved consent form and/or other materials. The IRB will evaluate the use of identifiable information or biospecimens and verify that it falls within the scope of the broad consent originally obtained.

3. Documentation of Informed Consent

Except under alternative procedures approved by the IRB (detailed in part 3 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. The consent form may be either of the following:

i. A written consent document that embodies the elements of informed consent required by 46.116. 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; or

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

4. Waivers of Informed Consent or Some Elements of Informed Consent

Per 45 CFR 46.117(c), 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 above, or waive the requirement to obtain informed consent, provided the IRB finds and documents that:

1. The research involves no more than minimal risk to the participants;
2. The waiver or alteration will not adversely affect the rights and welfare of the participants;
3. The research could not practicably be carried out without the waiver or alteration; **and**

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

If a research study requests a waiver or partial waiver of the informed consent process but the IRB determines that the four criteria above cannot be satisfied, then the waiver request cannot be approved by the IRB.

5. Waivers of Documentation of Informed Consent

The IRB may waive the requirement for the investigator to obtain signed consent forms for some or all participants, if it finds either:

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

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

6. Required Consent Statement for Studies to be Registered on ClinicalTrials.gov

Under 21 CFR 50.25(c), the following statement must be reproduced word-for-word in informed consent documents for applicable clinical trials which will be registered on ClinicalTrials.gov:

"A description of this clinical trial will be available on http://www.ClinicalTrials.gov , as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time."

7. Informed Consent Considerations for DoD-Supported or Conducted Research

The following are additional considerations that apply in addition to the above items for DoD-supported or conducted research per Department of Defense (DoD) regulations and directives, including those at 32 CFR 219, 10 United States Code 980, and DoDI 3216.02:

i. The IRB must determine, relative to coverage of research-related injury, that the disclosure includes provisions for research-related injury that follow the requirements of the Department of Defense component.

ii. The Assistant Secretary of Defense for Research and Engineering may waive the requirements for consent when all of the following are met:
   - The research is necessarily to advance the development of a medical product for the Military Services.
   - The research may directly benefit the individual experimental subject.
   - The research is conducted in compliance with all other applicable laws and regulations.

iii. If the research subject does not meet the definition of "experimental subject," the IRBs are allowed to waive the consent process.

iv. If the research subject meets the definition of "experimental subject", the IRBs must prohibit a waiver of the consent process unless a waiver is obtained from the Assistant Secretary of Defense for Research and Engineering;

v. If consent is to be obtained from the experimental subjects' legal representative, the research must intend to benefit the individual subject;

vi. The determination that research is intended to be beneficial to the individual experimental subject must be made by an IRB, and

vii. An exception from consent in emergency medicine research is prohibited unless a waiver is obtained from the Secretary of Defense.

8. Compensation to Research Subjects

Any compensation proposed to subjects as a result of participation in a study will be evaluated by the IRB to determine whether the compensation could potentially create undue influence that may affect the subject's willingness to accept risks that the subject may not otherwise accept if the compensation was not offered. Study compensation should be appropriately based on the amount of time, effort, and inconvenience posed to the research subjects. Providing excessive compensation for the amount of time, inconvenience, and effort involved in a study may create further problems such as creating unintentional bias in the study sample; some individuals may be influenced to lie or to withhold information in order to participate in the study when they don't meet the eligibility criteria; or parents may coerce or pressure their children into study participation. All of these issues may impact the data integrity and validity of the study, as well as the safety and well-being of the study participants.

8a. Financial Compensation and Items of Monetary Value to Research Subjects

Compensation of subjects using monetary (cash, gift cards, etc.) and/or non-monetary (gifts, goods or services, other items of monetary value) methods may also create a reporting requirement with the Internal Revenue Service. Per UT Arlington Accounting Services procedures, research participant compensation must be documented for tax purposes using a W-9 form unless an exception is specifically granted by the Accounting department. For that reason, sensitive information, such as social security numbers, may need to be obtained to process payment and for reporting purposes, as outlined below. UT Arlington faculty and staff have the legal obligation to maintain confidentiality of human subjects as well as to fulfill the University's responsibility for financial accountability.

UT Arlington is obligated to report to the IRS all non-university employees (U.S. citizens or resident aliens) who receive income greater than $600 in an annual year. If UT Arlington pays $600 or more to a U.S. tax resident during the calendar year, then UT Arlington is required to report the payments to the IRS and issue the recipient a Form 1099. As a result, when the IRB reviews studies that compensate subjects, the IRB shall ensure that language is included in the informed consent form to inform subjects of the IRS requirement.

Requests for exceptions to the W-9 collection requirement are granted by Accounting Services on a case by case, per-protocol basis. Exception requests are submitted through SharePoint. Contact Accounting Services at acctservices@uta.edu with questions about the exception request process.

8b. Course Credit or Extra Credit Used as Compensation to Research Subjects

In the social and behavioral sciences course credit or extra credit is commonly offered to students as compensation for research participation. When course credit or extra credit is given to students who participate in research, students are to be given other, non-research alternative options for earning the same amount of course credit or extra credit. These alternative options must be comparable to the research in terms of time, effort and educational benefit to ensure that students are not being coerced or unduly influenced into becoming research subjects. Example alternative assignments may include short papers; special projects; book reports; brief quizzes on additional readings; attending research seminars; or completing a similar project. Alternatives offered to student subjects require prior IRB approval.

9. Informed Consent Information Regarding Compensation to Subjects

9a. Consent Information for Financial Compensation and Items of Monetary Value

Within the informed consent document, studies providing monetary or non-monetary payments to subjects must specify the amount and type of compensation to be offered; how and when during the course of the study compensation will be provided or transmitted to the subjects; whether partial payments will be offered for partial completion of study procedures; and how confidentiality will be maintained in the process of providing payment or compensation to subjects (for example, use of coding in payment log books/receipts). If the research team intends to hold a raffle, the informed consent must explain the expected time period that the raffle will be drawn, and how participants will be contacted if they win the drawing.

For studies involving monetary compensation for subjects, the following statement is also required for inclusion in the informed consent document per UTA Accounting Services:

"The Internal Revenue Service (IRS) considers all payments made to research subjects to be taxable income. Your personal information, including your name, address, and social security number, may be acquired from you and provided to UT Arlington's accounting office for the purpose of payment. If your total payments for the year exceed $600.00, UT Arlington will report this information to the IRS as income and you will receive a Form 1099 at the end of the year. If you receive less than $600.00 total for payments in a year, you are personally responsible for reporting the payments to the IRS."

9b. Consent Information for Course Credit or Extra Credit Used as Compensation

Studies offering course credit or extra credit as participant compensation must include in the informed consent document the exact amount and type of credit to be offered; whether partial credit will be offered for partial completion of study procedures; and the list of non-research alternative assignments available for earning the same amount of course credit or extra credit.

XI. IRB Review of Research Including Vulnerable Populations

Whenever the IRB identifies that a research study may enroll vulnerable subjects (such as children, prisoners, pregnant women, neonates, the elderly, subjects who lack decision-making capacity or are mentally-ill or otherwise cognitively disadvantaged, students, employees, economically disadvantaged, etc.), the IRB will consider additional protections to ensure that the research is conducted ethically.

Note that for studies approved under the Minimal Risk (MR) or Greater than Minimal Risk (GMR) "Flex" Internal Review Pathways, the IRB or IRB Staff as designee will still consider the ethics and appropriateness for including vulnerable study populations as part of the research using the below federal regulatory criteria and considerations as guidelines. This may or may not involve the additional assessment and expertise of an IRB Member or outside consultant to review the proposed protocol procedures in the context of the vulnerable population. However, not all of the regulatory findings may be documented in the same way as with federally funded or FDA regulated research, and in some cases, these review procedures may deviate from the federal regulations.

A. Review of Research Involving Children

Children, like other potential vulnerable populations, require additional protections when they are research subjects. At the same time, children should not be denied the opportunity to enroll in research, nor the prospective benefits of participating in research. There are federal regulations in 45 CFR 46 Subpart D that provide additional protections for children when they are research subjects.

Federal guidelines require that children be included in certain research activities unless there is a justification for excluding them, while federal regulations also require that additional precautions be taken when children are research subjects, depending on the degree of risk involved in the research. NIH policy, which guides the conduct of much human research due to funding relationships, has similar requirements.

The regulations also set forth requirements for obtaining parental permission and, where appropriate, assent by the children themselves. The IRB will review research that involves children in consideration of Subpart D of the applicable HHS and FDA regulations, Texas state law, and institutional policy. When appropriate, requirements for involvement of minors in research postulated by the Texas Department of Family and Protective Services (DFPS), and/or Department of Education, are also considered.

Information provided by the investigator regarding level of risk, prospect of direct benefit (when applicable), assent and parental permission, and inclusion of wards/foster children is evaluated by the IRB, which may concur with the investigator's determinations, make alternative determinations, or impose additional requirements.

1. Determination of Appropriate Risk/Benefit Category

When the IRB (or qualified reviewer for research that is eligible for expedited review) reviews research involving children, it will be determined which of the risk/benefit categories described in 45 CFR 46 (Subpart D) and 21 CFR 50 (Subpart D) the research fits into; whether assent will be required; the manner in which assent will be obtained, if required; the requirements for parental permission or

approval of waiver thereof; and the appropriateness of the inclusion of wards/foster children if their involvement is proposed for research that involves greater than minimal risk with no prospect of direct benefit. The IRB will consider information provided by the research team in the IRB protocol submission. The IRB's (or reviewer's, for research that is eligible for expedited review) determinations will be entered into the minutes for the meeting at which the research was reviewed, if full Board review is indicated, or in the IRB record, in the case of expedited reviews. Any concern with the information provided by the researchers should be included in the documentation of Subpart D findings.

Per federal regulations, the IRB may approve research involving children only if it meets the criteria in one of the four following categories:

1a. Research not involving greater than minimal risk. 45 CFR 46.404; 21 CFR 50.51.

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

The IRB, or designated expedited reviewer, will provide the basis for the determination of minimal risk.

If consent cannot be waived in accordance with 45 CFR 46.116(d), the IRB, or designated expedited reviewer, will almost always require that the permission of only one parent is necessary for research in this category, and will determine whether assent is required for some or all minors. However, the IRB has the discretion to require that the permission of both parents must be obtained.

1b. Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects. 45 CFR 46.405; 21 CFR 50.52.

For research to be approved under this category, the convened IRB must find that:

i. The risk is justified by the anticipated benefits to the subjects; and
ii. The relation of the anticipated benefit to the risk must be at least as favorable to the subjects as that presented by available alternative approaches.

The IRB, at a convened meeting, will provide the basis for the determinations of greater than minimal risk and prospect of direct benefit.

The IRB may determine that the permission of one or both parents is required for research in this category, and will determine whether assent for some or all minors is required.

1c. 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. 45 CFR 46.406; 21 CFR 50.53.

For research to be approved under this category, the Board must find that it meets the requirements of 45 CFR 46.406 and 21 CFR 50.53, as follows:

i. The risk represents a minor increase over minimal risk;
ii. 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;
iii. The intervention or procedure is likely to yield generalizable knowledge about the subject's disorder or condition which is of vital importance for the understanding or amelioration of the subject's disorder or condition;
iv. Adequate provisions are made for soliciting and documenting assent of the children; and
v. Adequate provisions are made for soliciting the permission of both parents of each child 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. (45 CFR 46.407 and 408).

The IRB, at a convened meeting, will provide the basis for the determinations of greater than minimal risk and no prospect of direct benefit.

The permission of both parents is required for research in this category, unless one parent cannot reasonably provide permission, as allowed per Subpart D. The assent of the minors involved is required unless the Board determines that some or all are not capable of providing assent.

1d. Research not fitting into the aforementioned categories which presents a reasonable opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children. 45 CFR 46.407; 21 CFR 50.54.

The IRB, at a convened meeting, will provide the basis for its determinations regarding risk level and potential for direct benefit.

If the research is supported by HHS jurisdiction, and falls in this category, it cannot be performed without review by the Secretary of the HHS as outlined in 45 CFR 46.407.

Research under FDA jurisdiction that falls in this category cannot be performed without review by the Commissioner of Food and Drugs as outlined in 21 CFR 50.54.

If the research is HHS-supported or under FDA jurisdiction, the IRB staff will prepare a request for panel review promptly after the IRB review, and will provide such to the Director of the IRB. The Director, or designee, will prepare a report for submission to OHRP to request a panel review as described in 45 CFR 46.407 or 21 CFR 50.54, as applicable.

Research in this category that is not federally funded and does not involve FDA-regulated products will be reviewed by a special panel convened by the UT Arlington IRB office to make the determinations that would be otherwise be made by HHS or FDA when evaluating research in this category.

The permission of both parents is required for research in this category, unless one parent cannot reasonably provide permission, as allowed per Subpart D. The assent of the minors involved is required unless the Board determines that some or all are not capable of providing assent.

2. Assent Determination

After the Board makes the risk/benefit determination, they must consider the issue of child assent, as described in 45 CFR 46.408(a) (Subpart D). The Board must decide whether assent is necessary, and also whether and how it will be documented if it is necessary.

Among the formats the Board may consider are the following:

i. Waiver of assent;
ii. Determination that the children lack the ability to provide assent;
iii. Verbal assent, without documentation;
iv. Verbal assent, with documentation by the investigator and/or the legally authorized representative(s);
v. Written assent form, with subject signature; or
vi. Subject signature block on consent form (for older children only).

The federal regulations do not require that assent be sought from children starting at a specific age, but that their assent should be sought when, in the judgment of the IRB, the children are capable of providing their assent. IRBs are to take into account the ages, maturity, and psychological state of the children involved (see 45 CFR 46.408(a)).

When the research offers the child the possibility of a direct benefit that is important to the health or well-being of the child and is available only in the context of the research, the IRB may determine that the assent of the child is not necessary (45 CFR 46.408(a)).

3. Inclusion of Wards in Research

Special protections must be considered whenever children who are wards of the state or any other institution, agency, or entity are considered for inclusion in research that is greater than minimal risk with no prospect of direct benefit. Of primary concern are consent issues, i.e., who has authority to enroll a child who is a ward in research. Responsibility for ensuring that appropriate individuals provide permission rests with the PI, and must be in compliance with applicable statutes and the process described in the protocol that was approved by the IRB.

Federal regulations do not require special provisions for wards enrolled in research that is either minimal risk or greater than minimal risk with the prospect of direct benefit. However, the IRB may impose additional requirements if the research and/or status of the child(ren) warrant additional safeguards. Texas state laws and the Texas DFPS policies will be considered during review of research that involves wards.

Wards may only be included in research that is greater than minimal risk and does not offer the prospect of direct benefit (45 CFR 46.406) when such research is either related to their status as wards, or conducted in a facility at which most of the children are not wards.

If it is proposed that wards will be enrolled in research that is greater than minimal risk and does not offer the prospect of direct benefit, an advocate or advocates who will serve to ensure the best interests of each child are being upheld must be appointed, in addition to obtaining permission from any other individual acting on behalf of the child, e.g., as guardian or in loco parentis. One individual may serve as an advocate for more than one child.

B. Review of Research Involving Pregnant Women, Human Fetuses, or Neonates

Like other potentially vulnerable populations, pregnant women/fetuses/neonates require additional protections when they are research subjects. At the same time, they should not be denied the opportunity to enroll or the prospective benefits of participating in research. There are federal regulations in 45 CFR 46 Subpart B that provide additional protections for pregnant women/fetuses/neonates when they are research subjects.

Distinction should be made between studies that are designed to study pregnant women or the characteristics of the pregnant woman and/or fetuses/neonates (i.e., the inclusion criteria is geared to enroll pregnant women, fetuses, and/or neonates in the research), and studies for which pregnant women may enroll incidentally or by chance. With regards to the latter, Subpart B requirements need not be met unless the study would or could pose potential risks to pregnant women, neonates, or fetuses. In this case, appropriate safeguards should be considered for women of child-bearing potential.

The IRB will ensure that the requirements of Subpart B are appropriately satisfied prior to granting approval of any study designed to study pregnant women, fetuses, or neonates. In addition to the considerations made by the IRB in the scope of its review (in accordance with Section VIII.A), the IRB will also consider the following:

1. Whether there is adequate expertise on the IRB to evaluate the risks and benefits related to the inclusion of pregnant women, fetuses and neonates. When additional expertise is needed, the IRB will consider adding an appropriate consultant(s);
2. The determinations required by Subpart B must be documented appropriately in the IRB records (in the IRB minutes for reviews conducted by the convened IRB or in the documentation for review for expedited reviews);
3. Whether any involvement of pregnant women or fetuses meets all requirements as stated in 45 CFR 46.204;
4. Whether any involvement of neonates meets all requirements as stated in 45 CFR 46.205;
5. Whether any research involving, after delivery, the placenta, the dead, macerated fetal material, or organs excised from a dead fetus will be conducted in accordance with 45 CFR 46.206, as well as applicable federal, state, or local laws and regulations;
6. Proposals that are supported by HHS and for which the inclusion of pregnant women, neonates, or fetuses is not approvable per Subpart B will be referred to the HHS Secretary for review. For other such proposals, the IRB will establish a separate panel composed of individuals with appropriate expertise to determine whether the research meets ethical and regulatory standards and whether the research should be approved. If the research is supported by another federal agency or sponsor, their requirements must be considered during this process;

7. Informed consent is obtained per provisions of Subpart B for pregnant women who have reached the age of majority or are legally emancipated;
8. Informed consent is obtained per provisions of Subpart B and D for pregnant minors (where research is related to prenatal care, consent of the pregnant minor may be acceptable);
9. Consent documents contain information regarding risks of breastfeeding, when risks to the pregnant woman or neonate is determined to be greater than minimal;
10. Consideration is given to excluding women of child-bearing potential when the woman's reproductive status is not relevant to the research and risks to the pregnant woman or fetus is determined to be greater than minimal.

C. Review of Research Involving Prisoners

Prisoners, like other potentially vulnerable populations, require additional protections when they are research subjects. Although prisoners should not be denied the opportunity to enroll in research that provides potential benefits, the submission for IRB review and approval should include a justification for the inclusion of prisoners as subjects in the study, particularly if the research will be conducted solely on prisoners. There are federal regulations in 45 CFR 46 Subpart C that provide additional protections for prisoners when they are research subjects.

A prisoner is defined by the federal regulations as any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures, which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing. Individuals who are currently on parole are usually not considered prisoners because they are not detained, even though they are subject to the limitations and requirements specific to their parole.

No federally-supported or -conducted research involving prisoners is eligible for exemption. Therefore, all research protocols that involve prisoners must receive at least expedited review.

However, care must be given to applying the expedited review criteria because the definition of minimal risk under Subpart C is different than the definition of minimal risk for research not involving prisoners. For prisoner research, minimal risk is compared to "healthy persons" rather than what is experienced in "daily lives, or in the routine medical…examination of healthy persons", thereby raising the threshold of what may be permitted under expedited review. The following definition of minimal risk will be applied to research involving prisoners:

"*The probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.*"

For prisoner studies requiring review by the convened IRB, a prisoner representative will be involved in the review of the study.

In addition to other considerations in these IRB Operating Procedures, the IRB will only approve federally-supported or -conducted research involving prisoners if it finds that the study meets all the requirements of 45 CFR 46.300 (Subpart C).

The IRB may proceed and approve the study if it determines that the research under review represents one of the following minimal risk categories in category 1 or 2 below. If the IRB determines that the research falls under category 3 or 4 below and the research is federally supported or conducted, the research must be submitted to OHRP for review by a panel before the research can be conducted.

1. Study of the possible causes, effects, or processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to subjects; or
2. 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;
3. Research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults) provided that the study may proceed only after the Secretary has consulted with appropriate experts including experts in penology, medicine, and ethics, and published notice, in the Federal Register, of its intent to approve such research; or
4. 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 (i.e., HHS) has consulted with appropriate experts including experts in penology medicine and ethics, and published notice in the Federal Register, of its intent to approve such research.

D. Review of Research Involving Other Potentially Vulnerable Populations

Although the federal regulations only provide explicit additional protections for certain populations including children, pregnant women & neonates, and prisoners, there are many other different types of study populations which could be considered vulnerable for various reasons. These potentially vulnerable populations may include, but are not limited to, the following:

- Individuals with mental disabilities or cognitive impairments, especially those that could prevent the subject's understanding of the research
- Individuals with age-related conditions such as Alzheimer's disease, dementia, or advanced physical frailty or cognitive decline
- Institutionalized persons, such as persons living in a mental health facility or nursing home
- Individuals with physical disabilities
- Economically disadvantaged persons
- Educationally disadvantaged persons
- Homeless individuals
- Individuals who are terminally ill or very sick, especially if the diagnosis happened recently
- Individuals with stigmatized medical conditions such as HIV or AIDS
- Individuals who are under the influence of medications, illegal drugs, or alcohol

- Illegal immigrants
- Individuals with refugee status
- Individuals who do not speak the native language of the research study, or who are otherwise unable to communicate effectively with the researchers
- Individuals who are not members of the local dominant culture, race, or ethnicity
- Individuals who belong to groups that have historically been stigmatized in research
- Individuals who are socially vulnerable due to a local caste system or other social power differential
- Gay, lesbian, bisexual, or transgender individuals
- Victims of abuse or trauma
- Workers and employees
- Students

While each of these potentially vulnerable populations is distinct, some individuals may have more than one of these potential vulnerabilities at one time. It is also possible (and, in fact, probable) for a person to be transitionally vulnerable as his or her life circumstances change throughout the person's lifespan.

When the IRB reviews a protocol with a potentially vulnerable population, the IRB should consider why the specific study population has been chosen and whether any potential risks to the study population might be exaggerated due to the population's specific vulnerabilities. The IRB should consider whether there are any aspects of the study which may pose undue influence for encouraging study participation for the vulnerable population; for example, subjects who are economically disadvantaged may be unduly influenced to participate in a risky study in order to receive financial compensation. Some subjects may feel pressured to participate in research to maintain a relationship, such as when supervisors recruit employees for research participation or when researchers recruit family members. Still other subjects may feel coerced to participate in research due to the real or perceived threat of physical or mental harm from an authority figure. The IRB must be mindful of these issues when considering study recruitment and the consent process.

The IRB must also consider whether the Informed Consent process is sufficiently understandable for the study population and whether any additional strategies are needed to better facilitate subject understanding. This may include the translation of the Informed Consent into the subjects' native language; a short form in their native language; simplifying the language of the consent to a reduced reading level; or adding pictures to the consent to illustrate research procedures. In some instances, such as when adult subjects are unable to make legally effective decisions about their own research participation, the IRB may require researchers to obtain consent from the Legally Authorized Representative (LAR) as well as assent from the adult subject.

The IRB may request the services of a consultant as needed to review protocols that include any type of potentially vulnerable population as subjects in order to make the required determinations regarding whether the criteria for approval are satisfied (see Section VIII).

XII. IRB Review of Research at Schools or Other Educational Institutions

The UT Arlington IRB often reviews human subjects research projects that involve UTA students as a subject population, as well as projects that enroll students from local school districts, charter schools, and child-care centers. It is important that all UTA researchers must understand the legal requirements for conducting research with students, as well as the processes for obtaining the proper approvals from local schools and districts with whom they partner. Maintaining great relationships with our local partners in academic research fosters trust within the local community and ensures that UTA will inspire future generations of researchers for years to come.

A. Legal Requirements for Research at Schools or Educational Institutions

Any research that is supported by the Department of Education or conducted in public schools must adhere to the Family Educational Rights and Privacy Act (FERPA; 34 CFR Part 99) and Protection of Pupil Rights Amendment (PPRA; 34 CFR Part 98).

1. Family Educational Rights and Privacy Act (FERPA)

FERPA is designed to protect the privacy of a student's education records at all public elementary and secondary schools and virtually all public and private postsecondary institutions. At UT Arlington, FERPA rights apply to students. A student is a person who has been admitted and is registered, regardless of the person's age.

Per HOP Policy 13-1100, the University will not disclose education records or personally identifiable information from an education record without prior consent of the student to a third party, except as authorized by FERPA and its policies. **This includes the use of protected educational records (and personally identifiable information from protected educational records) for research purposes**.

All disclosures or uses of FERPA-protected educational records must be conducted in accordance with FERPA laws. The following are exceptions to the consent requirement for access to educational records which are allowable under FERPA:

1. Directory Information as listed below;
2. University Officials with a Legitimate Educational Interest (as part of their job duties to provide educational services to students), and affiliated services or institutions with Legitimate Educational Interests (such as employees at Blackboard, which is used to administer online courses for students); **NOTE that this does NOT give the University Official permission to use students' educational records for research purposes without prior student consent when the Official's regular job function in relation to the students does not involve research**.
3. Other Institutions. The University may release a student's education records to officials of other educational institutions in which that Student seeks or intends to enroll or is enrolled;
4. Audit or Evaluation of Federal or State education programs;
5. Financial Aid, to the extent necessary for such purposes as determining eligibility, amount, conditions, and enforcement of terms or conditions of such financial aid;
6. State and Local Officials Pursuant to Statutes Concerning Juvenile Justice;
7. Accrediting Organizations;

8. Designated Parents of a Tax Dependent;
9. Judicial Order or Subpoena;
10. Health and Safety;
11. Disciplinary Hearing Results;
12. Defense of Litigation or Complaints against the University;
13. Status as a Registered Sex Offender; and
14. Organizations conducting studies for, or on behalf of, the University for the purpose of developing, validating, or administering predictive tests, administering student aid programs, and improving instruction, provided that the study is conducted in a manner which will not permit the personal identification of Students and/or their parents by individuals other than representatives of the organization; and the information will be destroyed when no longer needed for the purposes of the study was conducted. This exception usually requires the execution of a legal agreement which outlines how the study will meet FERPA requirements.

For all activities that are not covered by the above categories, FERPA requires that **students must give active consent for the disclosure of individually identifiable educational records or the individually identifiable contents of those educational records**, which includes the use of this information for research purposes.

Note that even if a UTA instructor has access to FERPA-protected educational records as part of his/her regular job duties, the **instructor still cannot use these individually identifiable FERPA-protected educational records for research purposes without the explicit consent of the students**.

Some information about a student has been designated by the University as "Directory Information" which may be published or publicly disclosed without the student's consent (unless the student has previously notified the University that s/he wishes to opt out of such disclosures). Per the UTA Office of Records, the following information is considered "Directory Information" which may be used for research without prior student consent (unless the student has specifically opted out via the official University process):

1. Name
2. Local and permanent postal addresses
3. Email address
4. Telephone number
5. Place of birth
6. Field of study
7. Dates of attendance
8. Enrollment status
9. Student classification (i.e., freshman, graduate student)
10. Degrees awarded
11. Certificates and awards (including scholarships) received
12. Photographs
13. Participation in officially recognized activities and sports
14. Weight and height of members of athletic teams

15. Most recent previous educational agency or institution attended.

Educational records may be released without consent under FERPA if all personally identifiable information has been removed prior to release including:

- The student's name and other direct personal identifiers, such as the student's social security number or student ID number;
- Indirect identifiers, such as the name of the student's parent(s) or other family members; the student's or family's address, and personal characteristics or other information that would make the student's identity easily traceable; date and place of birth and mother's maiden name;
- Biometric records, including one or more measurable biological or behavioral characteristics that can be used for automated recognition of an individual, including fingerprints, retina and iris patterns, voiceprints, DNA sequence, facial characteristics, and handwriting;
- Other information that, alone or in combination, is linked or linkable to a specific student that would allow a reasonable person in the school community, who does not have personal knowledge of the relevant circumstances, to identify the student with reasonable certainty.

2. Pupil Rights Amendment (PPRA)

PPRA is designed to protect the rights of parents and students in programs that receive funding from the Department. These regulations apply to any research that is funded by the DOE, with the exception of the following funded programs:

- High School Equivalency Program and College Assistance Migrant Program (Section 418A of the Higher Education Act of 1965 as amended by the Education Amendments of 1980 (Pub. L. 96–374) 20 U.S.C. 1070d–2)
- Programs administered by the Commissioner of the Rehabilitative Services Administration (The Rehabilitation Act of 1973 as amended by Pub. L. 95–602 (29 U.S.C. 700, et seq.)
- College Housing (Title IV of the Housing Act of 1950 as amended (12 U.S.C. 1749, et seq.)

PPRA states that no student shall be required, as part of any research project, to submit without prior consent to surveys, psychiatric examination, testing, or treatment, or psychological examination, testing, or treatment, in which the primary purpose is to reveal information concerning one or more of the following:

- Political affiliations.
- Mental and psychological problems potentially embarrassing to the student or his or her family.
- Sex behavior and attitudes.
- Illegal, anti-social, self-incriminating and demeaning behavior.
- Critical appraisals of other individuals with whom the student has close family relationships.
- Legally recognized privileged and analogous relationships, such as those of lawyers, physicians, and ministers.
- Religious practices, affiliations, or beliefs of the student or student's parent.
- Income, other than that required by law to determine eligibility for participation in a program or for receiving financial assistance under a program.

Prior consent means:

- Prior consent of the student, if the student is an adult or emancipated minor; or
- Prior written consent of the parent or guardian, if the student is an un-emancipated minor. Schools and contractors obtain prior written parental consent before minor students are required to participate in any ED-funded survey, analysis, or evaluation.

For research not funded by the US Department of Education, the IRB must verify compliance with DOE regulations that schools are required to develop and adopt policies in conjunction with parents regarding the following:

- The right of a parent of a student to inspect, upon the request of the parent, a survey created by a third party before the survey is administered or distributed by a school to a student.
- Any applicable procedures for granting a request by a parent for reasonable access to such survey within a reasonable period of time after the request is received.
- Arrangements to protect student privacy that are provided by the agency in the event of the administration or distribution of a survey to a student containing one or more of the following items (including the right of a parent of a student to inspect, upon the request of the parent, any survey containing one or more of such items):
    - Political affiliations or beliefs of the student or the student's parent.
    - Mental or psychological problems of the student or the student's family.
    - Sex behavior or attitudes.
    - Illegal, anti-social, self-incriminating, or demeaning behavior.
    - Critical appraisals of other individuals with whom respondents have close family relationships - Legally recognized privileged and analogous relationships, such as those of lawyers, physicians, and ministers.
    - Religious practices, affiliations, or beliefs of the student or the student's parent.
    - Income (other than that required by law to determine eligibility for participation in a program or for receiving financial assistance under such program).
- The right of a parent of a student to inspect, upon the request of the parent, any instructional material used as part of the educational curriculum for the student.
- Any applicable procedures for granting a request by a parent for reasonable access to instructional material received.
- The administration of physical examinations or screenings that the school or agency may administer to a student.
- The collection, disclosure, or use of personal information collected from students for the purpose of marketing or for selling that information (or otherwise providing that information to others for that purpose), including arrangements to protect student privacy that are provided by the agency in the event of such collection, disclosure, or use.
- The right of a parent of a student to inspect, upon the request of the parent, any instrument used in the collection of personal information before the instrument is administered or distributed to a student.

- Any applicable procedures for granting a request by a parent for reasonable access to such instrument within a reasonable period of time after the request is received.

B. Local Approvals for Research at Schools or Educational Institutions

In addition to federal requirements for school-based research, all studies must comply with local and site-specific approval requirements when conducting research at educational institutions outside UT Arlington**. The enrollment of human subjects at participating schools or school districts is not permitted until the official approval letter from the school(s) or district(s) has been received and confirmed by the UTA Institutional Review Board (or designee).** This approval will be uploaded in the electronic submission as part of the protocol application.

C. Ethical Considerations for Research Involving Students as Subjects

The use of students as research subjects is integral to many research protocols, especially those involving the investigation of teaching methods, curricula, and factors of student success. However, students may feel pressured to participate in research conducted within their department or by academic superiors. It is therefore important to consider the mission of the University as an educational institution for students in addition to the legal and ethical complexities of enrolling students in research when designing research protocols with students as a subject population.

UTA prohibits the recruitment of its students or use of student data by external parties for the purpose of human subjects research, unless the project will contribute to research or academic value for the University. To qualify, the project must involve a University employee or student to be engaged in the research project as a true collaborator. If UTA personnel are not engaged in the research but there is potential for other types of benefit (i.e., sharing of useful data to UTA, a program/service, educational materials), an exception to this policy may be considered. Requests for a policy exception should be made to the Office of Regulatory Services with an explanation of the potential benefit to UTA or its students. The Office of Regulatory Services will evaluate the request to ensure it meets the intent of this policy and will facilitate submission of the request to the Office of the Vice President for Research for evaluation and a final determination.

An underlying ethical principle of the regulations governing use of human subjects in research is that the subject's participation must be voluntary and based upon full and accurate information. The inherent imbalance of power in the student-teacher relationship raises the issue of whether student participation is done on a voluntary basis. Students may volunteer to participate in research believing that doing so will place them in a favorable situation with faculty (e.g., better grades, good recommendations, employment possibilities), or that failure to participate will negatively affect their relationship with the investigator or faculty (e.g. lower grades, less favorable recommendations, being "uncooperative" and "not part of the scientific community").

Care should be taken to eliminate or reduce the risk that undue influence of faculty or coercion affects student participation in research. The following guidelines are offered to assist departments and faculty who engage in research projects in which students will be asked to be research subjects:

- To provide legally effective consent, students must be of the age of majority in the state of Texas (18 years old). Research involving minors requires a signed parental (or legal guardian) consent, as well as the signed assent of the student. However, some types of research may qualify for a waiver of consent for parental permission when minors are involved.
- Generally, due to FERPA regulations, researchers may not access classroom performance evaluations, student grades, and information in a (current) student's educational records for research purposes without prior written permission from the student, regardless of the access an investigator may have in his/her academic role.
- When extra credit is given to students who participate in research, students are to be given other non-research options for earning the same amount of extra credit, for example; short papers, special projects, book reports, and brief quizzes on additional readings, attending research seminars, or completing a similar project. These projects must be comparable in terms of time, effort and educational benefit to participation as a research subject to ensure that students are not being coerced into becoming subjects. Alternatives offered to student subjects need prior IRB approval.
- Likewise, when students are required to complete an assignment for course credit, they must not be forced to allow the researcher to use this required class assignment for research purposes. Students must always be given the option to complete all required coursework without having to allow the use of these assignments for research analysis. Students cannot be penalized in any way for refusing to participate in research.
- Whenever possible, researchers should avoid data collection during regularly scheduled class meetings. When study participation consumes a significant portion of a class section, loss of instructional time for both participants and non-participants may be considered a loss of benefits – students are paying to receive an education, after all. When research participation is expected during the same session at which participation is invited, students may also be unduly influenced to take part due to peer pressure, perceived stigmatization from non-participation, or a sense of having otherwise wasted time by attending that day's class.
- Like other research volunteers, students who become research participants must be allowed to withdraw from the study at any time. The informed consent statement should make clear the consequences of withdrawing from a research project prior to completion. In general, it is favorable to give credit if the subject withdraws, unless the student withdraws immediately or there is evidence of bad faith on the part of the student.
- Departmental subject pools must provide alternative non-research options for students to earn the required course credits for their classes. All pre-screening questionnaires used in departmental subject pools must be approved by the IRB, in addition to the individual studies listed within the subject pool for credit.

XIII. IRB Review of International Research

Research projects that take place outside the United States require compliance with UT Arlington policies and the relevant laws of the host country. International research must also comply with 45 CFR 46 or equivalent standards, such as the 1993 Council of International Organization of Medical Sciences (CIOMS) International Ethical Guidelines for Biomedical Research Involving Human Subjects and the International Conference on Harmonization (ICH) standards.

The IRB must consider the following in addition to the review requirements described in Section VI, "IRB Review of Research" and in other relevant sections of this document.

A. Addressing the Needs, Issues, and/or Benefits of the Local Community

The research protocol should generally be designed to address an issue characteristic of the local setting, or conditions that affect the local setting, particularly in developing countries. The rationale for choosing the specific international setting for the study should be made clear in the IRB protocol.

B. Local Context

For all international research studies, researchers should provide details of the local context within the protocol to provide a basis for the IRB review. The IRB may also obtain local knowledge from literature, documentation, or available written information, or by inclusion of a consultant knowledgeable of the local setting. IRB Staff will review the OHRP International Compilation of Research Standards for additional assistance in determining the appropriate rules and regulations for each local setting.

Investigators should recognize that international ethical review committees which are affiliated with an institution may not be willing to review research conducted by investigators outside their institution. Access to local ethical review committees may be facilitated when researchers collaborate with researchers at the local institution.

For more details on the procedures applied for the collection of biological samples in other countries where the samples will be transported back to the U.S., see Section XIV.A.

C. Informed Consent

If the legal age of an adult differs in another country from state law (e.g., 18 years of age), the IRB should accept the local age of majority when considering who may provide their own consent.

When consent and recruitment documents have already been translated into a language other than English, the researcher should provide a copy of the document in English, a copy in the language to be used in the foreign location, and certification from an appropriate individual that the translated version of the document is complete and does not contain information that is not presented within the context of the approved English version of the document. While the UT Arlington IRB does not require researchers to use professional translation services for document translations, the researcher must still provide an explanation as to who provided the document translation and this person's qualifications to serve as a translator for the language.

D. Approval by the International Institution Where Research Will be Conducted

When the research will be conducted in an institution or organization such as a school, business, or hospital that is not otherwise involved in the research, a letter(s) of agreement should be submitted from the appropriate official(s) (e.g., government officials, school officials, community officials, chief executive officers, etc.) indicating that the research protocol, and any and all instruments to be used, have been reviewed and that the study is acceptable to be conducted in the institution or organization.

XIV. IRB Review of Biomedical Research

A. Research with Biological Specimens

If blood, tissues, or other biological samples will be collected for research purposes, a plan for collection, storage, and protection of confidentiality should be provided to the IRB. The IRB will review the plan and determine the physical risks associated with the collection of the sample and the risks associated with the results or any information that may be produced from tests on the samples. The IRB will then ensure that the protocol has an appropriate plan to minimize potential risks to subjects. Integral to the assessment of the plan to minimize risks will be to consider whether results will be returned to subjects and the plan to protect confidentiality of the data.

The first step in assessing risk of research with biological specimens is to determine how the samples will be obtained (i.e., directly from subjects or from residual samples that were collected for other purposes) and whether the samples will be individually identifiable.

The UT Arlington IRB applies the OHRP guidance document entitled, "Guidance on Research Using Coded Private Information or Specimens" (October 16, 2008). As a result, research that solely involves coded or deidentified samples (for which the research team cannot identify the subjects either directly or indirectly through coding systems) and that does not otherwise involve human subjects research may be determined as not human subjects research in accordance with 45 CFR 46.

If the research involves collection of biological samples in other countries and the samples will be transported back to the U.S., the plan should also include a section on how the samples will be sent back to the U.S. The plan should comply with both local and U.S. laws/policies. Unsterilized specimens of human and animal tissues (such as blood, body discharges, fluids, excretions or similar material) containing an infectious or etiologic agent require a permit in order to be imported (USPHS 42 CFR 71) to the U.S. Details on the regulatory requirements, process for obtaining a permit, and shipping and handling of such tissues can be found on the Centers for Disease Control and Prevention (CDC) website. If the material being imported has been rendered sterile (e.g., radiation or chemical treatment) and is known not to contain infectious agents for humans, a permit is not required for importation.

If a repository will be created or biological specimens will otherwise be collected, stored, and distributed for research purposes, the UTA IRB will apply the OHRP guidance document entitled "Issues to Consider in the Research Use of Stored Data or Tissues" (November 7, 1997). The IRB will review and approve a protocol specifying the conditions under which data and specimens may be accepted and shared, and will ensure that adequate provisions are in place to protect the privacy of subjects and maintain the confidentiality of data. The IRB will also review and approve a sample collection protocol and informed consent document for distribution to tissue collectors and their local IRBs. A Certificate of Confidentiality may be necessary to protect confidentiality of repository specimens and data (Note that if the research is supported by an NIH grant after October 1, 2017, a Certificate of Confidentiality is automatically provided).

Whenever biological samples will be received by UT Arlington or sent to others outside of UT Arlington a Materials Transfer Agreement must be signed by the institution; the agreements should be forwarded to Regulatory Services and to Dan Vincenzo, UTA's Research Agreements Manager, for review and authorized signature.

B. Research with Protected Health Information (PHI) / HIPAA Considerations

The federal Health Insurance Portability and Accountability Act (HIPAA) applies only to "covered entities," defined in the HIPAA rules as (1) health plans, (2) health care clearinghouses, and (3) health care providers who electronically transmit any health information in connection with transactions for which HHS has adopted standards. These organizations are required to follow the HIPAA Privacy Rule due to the kinds of medical information they collect and use during normal business operations. The HIPAA Privacy Rule requires a Privacy Board to evaluate patient privacy and grant waivers of research authorization.

UT Arlington is not a covered entity, and therefore HIPAA does not directly apply to the university. Because UTA is not a HIPAA covered entity, when research data is collected from human subjects on the UT Arlington campus, it is not considered PHI protected by HIPAA even if some of the information collected may relate to the subjects' physiology or health status. However, when UT Arlington researchers are collecting, receiving, or utilizing PHI from covered entities, UT Arlington researchers may be asked to sign a Business Associates Agreement (BAA) or Data Use Agreement (DUA) with the covered entity. The BAA and/or DUA will clarify that the UT Arlington researchers must comply with HIPAA and the covered entities' policies for the secure storage and use of the PHI as stated in the agreement. Dan Vincenzo, UTA's Research Agreements Manager, will facilitate the agreement and authorized signature process for all BAA and DUAs.

For submissions for IRB review that involve PHI, the UT Arlington IRB will require documentation of approval from the HIPAA Privacy Officer or HIPAA Privacy Board from the institution that is releasing PHI. The approval may involve a HIPAA authorization for release of PHI for the research study, an approved HIPAA waiver of authorization, or use of a limited data set (with appropriate safeguards in accordance with 45 CFR 164.514(e) and an executed DUA).

In limited circumstances, the UTA IRB may serve as the HIPAA Privacy Board and will approve either a HIPAA authorization or waiver of authorization.

The UT Arlington IRB will review the plan for protection of confidentiality and ensure that the plan adequately protects the PHI from potential breach of confidentiality. The review of the plan to protect confidentiality will be conducted within the IRB's review to minimize risks. The IRB will consider the procedures in the "Protecting Human Subject Data" section (Section XI) when reviewing plans to protect confidentiality.

Whenever a UT Arlington research study will involve the prospective collection of PHI (usually as a result of data collection taking place at a HIPAA covered entity), the IRB will also review the informed consent document to ensure that the use of PHI and efforts to minimize risks and protect confidentiality are appropriately described in the informed consent document, unless informed consent can be waived in accordance with 45 CFR 46.116(d). When appropriate, the IRB will also review the HIPAA authorization for

release of PHI from the institution that is releasing PHI for consistency with the informed consent document.

C. Research with Investigational Drugs

For studies involving the use of an investigational drug, or an FDA-approved drug used outside of its approved indication (i.e., off-label), the IRB will ensure that an Investigational New Drug (IND) application has been approved by FDA, unless the requirement for an IND is exempt from FDA regulations in accordance with 21 CFR 312(b).

The IRB staff will help the IRB ensure the appropriate regulatory status of any drug used in the research. During the IRB pre-review process, IRB staff will check that the regulatory status of the drug as used in the proposed research is clearly documented in the materials submitted for IRB review.

For FDA-approved drugs (that will be used for an off-label or new use), the package insert will be required. For an investigational drug, one of the following will be required:

1. An explanation and justification from the sponsor/investigator that an IND is not required (investigators are strongly encouraged to consult with FDA for an official determination).
2. An explanation and justification from the sponsor/investigator as to why the drug may be exempt from the IND requirements in accordance with 21 CFR 312.2(b). If the drug is indicated for oncology, the IRB may rely on the FDA Guidance titled, "IND Exemptions for Studies of Lawfully Marketed Drug or Biological Products for the Treatment of Cancer."
3. An approved IND#, appearing on the sponsor's protocol, the Investigator's Brochure, and/or the IND letter from FDA.
4. The sponsor's or investigator's (in an investigator-initiated study) letter to the FDA for submission of an IND application. Regarding this option, the IRB approval letter will state that study enrollment may not begin until 30 days have passed from the date of submission to the FDA, and there has been no notice from FDA of a hold placed on the drug.

If adequate documentation has not been obtained that an investigational drug has an IND# or that a determination has been made by FDA that an IND is not needed for the study, the IRB will determine in a convened meeting whether an IND is needed and document its determination in the minutes. The IRB or an investigator can find information regarding drug approvals and the drug approval process at https://www.fda.gov/Drugs/default.htm. Alternatively, one can submit questions regarding whether an IND is needed by contacting the FDA's Center for Drug Evaluation (CDER) (Human Drug Information, Division of Drug Information) by sending an email to druginfo@fda.hhs.gov or by calling (855) 543-3784 or (301) 796-3400.

The IRB will also review the investigator's plan on how the drug (whether investigational or FDA-approved) will be supplied, stored, dispensed and administered to subjects, and whether any special handling of the drug is required. The plan must ensure that the integrity and quality of the drug will not be compromised during the storage process. For example, if temperature controls are needed to maintain the stability of the drug, the plan must document how the drug will be stored accordingly. The plan should also describe how drug accountability will be maintained (who will be responsible for the

storage, distribution and record-keeping of the drug; e.g., research pharmacy or research team, and if the latter which member of the research team).

If there is a known antidote for the drug in case of overdose or over-administration resulting in toxicity, the investigator's plan for management and storage of the drug should also include that the antidote, its availability and potential use, will be clearly communicated to research staff members.

If there is specific information regarding birth control measures that should be taken by subjects with reproductive capacity, the IRB will ensure during its review of the informed consent document(s) that that information is included in the Risks section.

If the research involves gene transfer with a biologic or drug (i.e., transfer of DNA or RNA derived from recombinant RNA), IBC review and approval is required before the IRB can complete its review and grant its approval. If the study will also be reviewed by the Recombinant DNA Advisory Committee (RAC) at NIH, the IRB will receive its review and approval letters prior to completing its review of the research. For such studies, the investigator must comply with the reporting requirements of Appendix M to the Office of Biotechnology Assessment (OBA) in the NIH Office of Science Policy. As a result, the investigator must submit serious adverse events to the IBC.

D. Research with Investigational Devices

For studies involving the evaluation of the safety and effectiveness of a non-FDA approved device, or an FDA-approved device used outside of its approved indication (i.e., off-label), the IRB will ensure that an Investigational Device Exemption (IDE) application has been approved by FDA, unless the requirement for an IDE is exempt from FDA regulations in accordance with 21 CFR 812.2(c) or the use of the device in the study is determined to be a non-significant risk (NSR) device by the IRB of the FDA (and the abbreviated IDE requirements are satisfied in accordance with 21 CFR 812.2(b)).

The IRB staff will help the IRB ensure the appropriate regulatory status of any device whose safety and effectiveness is being evaluated in the research. During the IRB pre-review process, IRB staff will check that the regulatory status of the device as used in the proposed research is clearly documented in the materials submitted for IRB review. The IRB staff may also consult with the FDA database for approved devices on the FDA website at: https://www.fda.gov/MedicalDevices/default.htm. Alternatively, one can submit questions regarding whether an IDE is needed by contacting the FDA's Center for Devices and Radiological Health (CDRH) [Division of Industry and Consumer Education (DICE)] by sending an email to DICE@fda.hhs.gov or by calling 1-800-638-2041 or 301-796-7100.

For FDA-approved devices (that will be used for an off-label or new use), the device brochure or manual will be required. For an investigational device, one of the following will be required:

1. An explanation and justification from the sponsor/investigator that an IDE is not required (investigators are strongly encouraged to consult with FDA for an official determination).
2. An explanation and justification from the sponsor/investigator as to why the device may be exempt from the IDE requirements in accordance with 21 CFR 812.2(c).
3. An approved IDE#, appearing on the sponsor's protocol, the Device Brochure, and/or the IDE letter from FDA.

4. The sponsor's or investigator's (in an investigator-initiated study) letter to the FDA for submission of an IDE application. Regarding this option, the IRB approval letter will state that study enrollment may not begin until 30 days have passed from the date of submission to the FDA, and there has been no notice from FDA of a hold placed on the device.

If the regulatory status is not clear, the IRB Chair will determine whether the use of an investigational device in the study satisfies the exemption criteria in accordance with 21 CFR 812.2(c).

If the investigational device is determined to not meet the exemption criteria (and again the research involves the evaluation of the safety and effectiveness of the device), the convened IRB must review the study and determine whether the device is considered to be a NSR device in accordance with 21 CFR 812 and FDA's guidance, "Information Sheet Guidance for IRBs, Clinical Investigators, and Sponsors: Significant Risk and Nonsignificant Risk Medical Device Studies." If the convened IRB determines that the device is a significant risk (SR) device, then an IDE must be approved by the FDA before the study may begin recruitment or enrollment. If an IDE must be approved by the FDA, the PI will be informed in writing and instructed to inform the sponsor of the SR determination (if applicable).

The review of the device by the convened IRB and the determination of either a SR or NSR device will be documented in the minutes. These determinations will be made in addition to the overall risk determination of the protocol of minimal risk or greater than minimal risk. If the IRB determines the device to be a NSR device and the overall risk in the study to be minimal risk, the convened IRB may determine whether the continuing review may be done by expedited review. If such a determination is made, it will be documented in the meeting minutes.

The IRB will also review the investigator's plan on how the device (whether investigational or FDA-approved) will be supplied, stored, and utilized in the study, and whether any special handling of the device is required. The plan must ensure that the integrity, quality, and sterility of the device will not be compromised during the storage process. For example, if temperature controls are needed to maintain the stability of the device, the plan must document how the device will be stored accordingly. The plan should also describe how device accountability will be maintained (who will be responsible for the storage, distribution and record-keeping of the device). If the device is implanted, or otherwise requires sterilization, and does not come in a sterilized package, the autoclaving of the device (or other sterilization technique that will be used) should be described in the plan.

E. Research with Biologics

For studies involving an investigational biologic, or an FDA-approved biologic used outside of its approved indication (i.e., off-label), the IRB will ensure that an Investigational Biologic-Based IND (BB-IND) application has been approved by FDA, unless the requirement for an IND is exempt from FDA regulations, and will follow the IRB procedures in the Section XIII.D (Research with Investigational Drugs) above.

F. Compliance with Good Clinical Practice (GCP)

All FDA regulated research involving investigational drugs, devices, or biologics and studies meeting the NIH definition of a clinical trial must comply with the International Conference for Harmonization (ICH) E-

6 R2 Good Clinical Practice (GCP) Guidelines, to the extent that the GCP standards apply to the research study. Additionally, it is recommended that all biomedical research complies with these GCP standards to the extent that the standards apply to the research.

In accordance with this guidance, the IRB should obtain the following documents: Trial protocol(s) / amendment(s), written informed consent form(s) and consent form updates that the investigator proposes for use in the trial, subject recruitment procedures (e.g., advertisements), written information to be provided to subjects, Investigator's Brochure (IB), available safety information, information about payments and compensation available to subjects, the investigator's current curriculum vitae and/or other documentation evidencing qualifications, and any other documents that the IRB may require to fulfil its responsibilities.

UT Arlington has additional training requirements for GCP (See Education and Training, Section XIV).

G. Registration of NIH-Funded Clinical Trials and Applicable Clinical Trials (ACTs) on ClinicalTrials.gov

Federal regulations require that the person responsible for the conduct of certain types of clinical trials must register each clinical trial on the federal website ClinicalTrials.gov. UT Arlington requires that investigators who are responsible for eligible clinical trials must comply with this federal requirement. Regulatory Services and IRB Staff serve as the ClinicalTrials.gov account administrators for the University.

The following types of studies require registration on ClinicalTrials.gov:

- The NIH Policy on Dissemination of NIH-Funded Clinical Trial Information, effective for competing applications and contract proposals submitted on or after January 18, 2017, states that all NIH-funded awardees and investigators conducting clinical trials will register and report the results of their trial in Clinicaltrials.gov.
- Per 42 CFR 11.22, interventional studies that evaluate at least one drug, biological, or device product regulated by the United States Food and Drug Administration (U.S. FDA), and:
    - The study is not a Phase 1 study of a drug and/or biological product;
    - The study is not a device feasibility study; and
    - At least one of the three following items applies:
        - at least one study facility is located in the United States or a U.S. territory, OR
        - the study is conducted under a U.S. FDA Investigational New Drug application (IND) or Investigational Device Exemption (IDE), OR
        - the study involves a drug, biological, or device product that is manufactured in and exported from the U.S. (or a U.S. territory) for study in another country.

Investigators may also be notified of the requirement to register a clinical trial on ClinicalTrials.gov in several ways. The Terms & Conditions section of an NIH Notice of Grant Award may include this requirement; pertinent language may be included in certain NIH Funding Opportunity Announcements; and certain drug, biological, and device product applications or submissions made to FDA may require certification of compliance with the requirements for trial submission to ClinicalTrials.gov. Regardless of the method, **if an investigator is informed that his/her clinical trial requires registration on**

ClinicalTrials.gov, he/she is responsible for doing so within the required time period and for keeping the study records current within the ClinicalTrials.gov Protocol Registration and Results System (PRS) after the initial registration.

For additional assistance in determining whether a study must be registered on ClinicalTrials.gov, researchers are encouraged to read the additional guidance at Elaboration of Definitions of Responsible Party and Applicable Clinical Trial and Checklist and Elaboration for Evaluating Whether a Clinical Trial or Study is an Applicable Clinical Trial.

Per 42 CFR 11, Sponsors or Principal Investigators must register each Applicable Clinical Trial (ACT) on ClinicalTrials.gov **not later than 21 calendar days after enrolling the first human subject**.

Under 21 CFR 50.25(c), the following statement must be reproduced word-for-word in informed consent documents for applicable clinical trials which will be registered on ClinicalTrials.gov:

"A description of this clinical trial will be available on http://www.ClinicalTrials.gov , as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time."

H. Genetic Research

Genetic research studies may create additional potential risks to human subjects and their relatives. Additionally, genetic research may create stigmatization of subjects or the social group to which the subjects belong.

The IRB will consider, during the review of the protocol and informed consent document(s), the additional potential risks posed to subjects, such as medical, psychosocial, non-paternity, loss of privacy, and economic risks (e.g., effect on subjects' insurability or employability).

During the IRB's review of genetic research studies, the IRB will determine whether the genetic research involves germatic or somatic genes. For research that does not involve germatic genes, the potential for discovery of non-paternity can be ruled out.

The IRB will also review the researchers' plan for release of genetic results to the subjects and ensure that any reporting of results is consistent with CLIA policies, federal regulations, and guidance. For each study where results may be returned to subjects, the IRB will consider the validity of the tests performed; whether or not the results will be generated from FDA-approved diagnostic tests or from CLIA-certified laboratories; and the potential for false results when considering whether or not returning results to subjects is appropriate. Additionally, any study that will provide genetic testing results to subjects must have a plan to provide genetic counseling to the subjects.

The IRB will review the researcher's plan for sharing of genetic samples and information with other researchers, repositories, and with NIH (if supported by NIH), particularly if the information/samples involve genomic wide associations studies (GWAS). If the latter, the IRB will ensure that the protocol's plan for sharing samples/information complies with current NIH policy.

XV. Protecting Human Subject Data

As part of the IRB application, all study protocols must explain the precautions that will be taken to protect the confidentiality of the human subject data collected and to inform subjects of the parties who will or may have access to their identifiable subject data. This information must also be communicated to subjects in the Informed Consent Document.

Any data to be collected for the research that may pose risk or harm to subjects if a breach of confidentiality were to occur must have the data adequately protected from such a potential breach in order to secure IRB approval. The methods or processes for protecting the confidentiality of the data should be proportionate to the level of potential risk of the study and the level of sensitivity of the data. The higher the risk of a research study and the more sensitive the collected data, the more protections should be considered and implemented to prevent a breach of confidentiality. Data protection plans must be considerate of the security of the initial methods of data collection; the security of the data storage method(s); and all methods of destruction or complete de-identification of the data. Additionally, such confidentiality plans should include details for all modes of storage: paper, electronic, video/audio recordings, films, etc.

Whenever possible, direct identifiers should be removed from human subject datasets that could potentially cause harm to subjects upon a breach. These direct identifiers can then be replaced with unique subject identifiers such as subject ID numbers or pseudonyms, and the dataset can be analyzed in this coded form. The log or "Master List" that cross-references the subject's identity with the unique subject identifier should be stored in a separate location from the coded dataset and should be protected from unauthorized access. The PI should consider how many and which staff should have access to the Master List. Limiting the number of staff who has access to the Master List should be considered, particularly for more sensitive high-risk data.

Information regarding UT Arlington's classification of data can be found at https://www.uta.edu/security/data_classification/. Additional guidance and authorized mechanisms to protect data can be found at https://www.uta.edu/security/approved_storage/index.php as well as the menu on the left side of the Information Security Office website.

Research data collected under IRB protocols at UT Arlington is recognized as a form of protected intellectual property that is owned by the UT Arlington, and is subject to protection by University policies, Data Use Agreements, and applicable US laws.

A. Data Security for Paper Research Records

All paper documents must be managed and stored in the specified building and room number on the UTA campus unless the IRB grants approval for an alternate location. It is recommended that paper records containing research data should be stored in a locked cabinet. The level of security and restriction should increase depending on the sensitivity of the data being captured in the research records. In any case, access to individually identifiable human subjects data must be limited to research personnel on the given study (unless the IRB specifically approves otherwise; usually this will require the subjects' explicit consent).

B. Data Security of Electronic Research Data

For data that is collected, managed, analyzed, or stored via electronic means, all data from research projects supported by UTA (and therefore belonging to UTA) must be maintained on UTA servers. The UTA Office of Information Technology has many resources that researchers can use for secure data storage. Researchers should visit the list of Sanctioned University and Cloud Data Storage Locations available on the Information Security Office website for a list of available University-sanctioned electronic data security options. The University's Information Security Officer can assist with customized data storage plans for situations requiring complex or high-risk data security measures.

Three significant sources for a breach of data stored electronically are laptops, USB drives, and websites. It is imperative that any sensitive data stored or transmitted electronically that could produce risks to subjects upon a breach is handled with the appropriate protections. UT Arlington researchers should review the UT Arlington Data Security Policies and Guidelines for appropriate measures to protect against a breach of confidentiality (e.g., not storing identifiable data on laptops and flash drives, encryption, hashing of data, password protection, authentication of computer systems, utilization of secure servers, internet security software that protect against viruses, spyware, etc.).

C. Certificates of Confidentiality

Another mechanism to protect the confidentiality of sensitive higher-risk data is to obtain a Certificate of Confidentiality (CoC). CoCs are issued by the National Institutes of Health (NIH), as well as other HHS agencies to protect identifiable research information from forced disclosure. They allow the investigator and others who have access to research records to refuse to disclose identifying information on research participants in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level. CoCs may be sought for all studies (regardless of funding) collecting information that, if disclosed, could have adverse consequences for subjects or damage their financial standing, employability, insurability, or reputation. To obtain a Certificate of Confidentiality, a request can be submitted at https://humansubjects.nih.gov/coc/apply .

Note that as of October 1, 2017, the National Institutes of Health (NIH) revised its policy for issuing Certificates of Confidentiality (CoCs) to persons engaged in NIH-funded research in which identifiable, sensitive human subject information is collected. NIH now provides Certificates of Confidentiality automatically to any NIH-funded recipients conducting research applicable to the Policy, including studies commenced or ongoing after December 13, 2016. Researchers must inform study participants of the protections and the limits to protections provided by a Certificate issued by this Policy in the Informed Consent Document. See the full policy here: https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-109.html

D. Collection of Social Security Numbers

Any study that plans to collect social security numbers (SSNs) should include a justification for the collection and a detailed plan on how SSNs will be protected from a potential breach of confidentiality.

In general, SSNs should not be collected for research studies. However, the UT Arlington IRB recognizes that the collection and use of SSNs is essential for the conduct of some research activities (e.g.,

epidemiological studies collecting mortality statistics) and is required for processing payments to subjects (e.g., reimbursements or compensation for participation). The IRB must review the planned collection of SSNs for any research purpose other than compensation/reimbursement to subjects.

Release of SSNs outside of UT Arlington increases the potential risks to subjects, as well as legal risks to UT Arlington. If SSNs will be shared with individuals outside of the UT Arlington study team (i.e., the sponsor), an additional justification for such a release must be provided in the IRB submission. A Data Use Agreement may also be required to ensure that the external entity will implement sufficient safeguards to protect the data including SSNs from unauthorized disclosure.

XVI. IRB Post-Approval Study Monitoring & Quality Assurance Processes

A. Post Approval Study Monitoring

In addition to standard Continuing Reviews, the IRB may require or initiate additional monitoring of approved research at its discretion on both a for-cause and a not-for-cause basis. The method for post-approval monitoring will be at the discretion of the IRB and may include activities such as protocol audits, laboratory visits, observation of the consent process, audit of some or all consent forms and / or collected human subject data, or meeting with the Principal Investigator and protocol personnel. Post-approval monitoring will be performed by the IRB or its designee. Monitoring that identifies non-compliance will comply with the established procedures for non-compliance outlined in Section VIII, part 4.

1. For-Cause Post Approval Study Monitoring

When complaints or concerns are raised regarding the conduct of the study or potential risks to subjects that may have changed that the IRB or designee cannot satisfactorily resolve with the investigator, the IRB may verify whether or not material changes may have occurred in the conduct of the research since the last review by the IRB. The IRB may verify such concerns by requesting an audit of the research, reviewing the audit report that may have been conducted by an external entity or requesting additional information from sources other than the investigator that may address the concerns. The IRB may also choose to utilize any other method listed under Section XVI, A.

2. Not-For-Cause Post Approval Study Monitoring

To ensure compliance with approved IRB protocols, the IRB may, at its discretion, require additional monitoring of studies using any method listed in Section XVI, A without cause or prior notification to the Principal Investigator. Examples of types of research that may be subject to additional IRB monitoring requirements include, but are not limited to:

- Greater than minimal risk / full board research;
- Research involving vulnerable populations;
- Federally funded research;
- FDA regulated research;
- Complex projects involving multiple collaborating institutions or complex study interventions;
- Research in which investigators have or may have a conflict of interest;
- Research studies with previous IRB findings of non-compliance, or research involving investigators with previous IRB findings of non-compliance.

The IRB may choose a risk-based approach to select studies for monitoring, or may choose to employ a random selection process. In either case, the investigator will be informed of the IRB's request for routine study monitoring with sufficient time to compile any needed documentation prior to the monitoring visit.

B. IRB Quality Assurance Process

The UTA IRB utilizes an external consultant, PEER Consulting Group, LLC, which is under contract to provide regular assessments of our HRPP. Our professional relationship with PEER Consulting began in late 2015 and is ongoing.

XVII. Reporting & IRB Review of Non-Compliance

Non-compliance is defined as a failure on the part of the PI or any member of the study team to follow: (1) federal regulations, state laws, or institutional policies relevant to human subjects research; or (2) the requirements and determinations issued by the reviewing Institutional Review Board (IRB), including failure to comply with the approved IRB protocol. A *protocol violation* is defined by the UT Arlington IRB as a divergence from the approved IRB protocol by the PI and/or research team without the prior IRB approval of a study modification request for the specified change. This divergence may reduce the completeness or quality of the data collected; may make the information presented to participants in the Informed Consent inaccurate; or may impact the safety, rights, or welfare of the human subjects. Protocol violations are considered non-compliance with the federal regulations and/or institutional policies for the protection of human subjects.

Information regarding non-compliance in research studies involving human subjects may come to the attention of the IRB through several pathways. These include internal monitoring of research projects, information contained in new applications, continuing reviews, adverse experience reports, and reports from collaborators, employees, subjects, or others.

A. Reporting of Protocol Violations and/or Allegations of Potential Non-Compliance to the IRB

All UT Arlington Faculty, employees, and students are responsible for promptly reporting (**within five business days) potential serious or continuing noncompliance to the IRB**.

The following protocol violations must be reported to the IRB **within five business days**:

- An incident or event that may have increased harm to subjects;
- An incident or event that affected the integrity of the study;
- An incident or event that involved a breach of confidentiality;
- An incident or event that involved the collection of sensitive data that was not described in the protocol.

All other protocol violations should be reported at the next continuing review to the IRB. For studies where continuing review is not required, an email to RegulatoryServices@uta.edu to document the circumstances of the violation will be uploaded to the protocol as documentation.

B. Non-Compliance Allegations or Self-Reported Findings

Initial reports can be either allegations or findings of non-compliance. Allegations of non-compliance that have yet to be proven are reviewed and investigated. An allegation determined to be true based on a preponderance of the evidence becomes a finding. Generally, self-reported instances by investigators will be accepted as a finding of non-compliance.

C. IRB Review of Protocol Violations and/or Allegations of Potential Noncompliance

All reports of noncompliance are initially evaluated by the IRB Staff as the designee of the IRB. A report will either be designated as minor and not requiring further action by the IRB, or will be escalated for review and/or action by the IRB if the non-compliance may be serious or continuing in nature.

Serious non-compliance is defined as non-compliance with federal regulations or institutional policies and procedures that, in the judgment of the reviewing IRB, affects the rights and welfare of subjects, or may cause a significant risk to enrolled subjects or others.

Continuing non-compliance is defined as a pattern of noncompliance (serious or non-serious) that results in multiple findings of noncompliance over time for similar protocol violations (either on the same protocol, or for the same investigator across multiple protocols) despite prior communications from the IRB attempting to address and correct the violation(s); continuing noncompliance could also result from repeated failures of the investigator to respond to or resolve previous allegations or findings of noncompliance.

1. Minor Findings of Non-Compliance Requiring No Further IRB Action

A report may be deemed minor and may not require further action by the IRB if the non-compliance is:

- A factual assertion of noncompliance (generally self-reported by the investigators);
- Neither serious nor continuing; and
- Addressed by the investigator through a corrective action plan to remedy the problem.

If a report of non-compliance is found to be minor and does not require further action, IRB staff will document the incident and corrective action plan in writing and store all relevant documentation in the electronic protocol file, and the finding will be reported to the IRB at the next convened meeting. Findings of possible serious or continuing noncompliance are referred to the IRB for review.

2. Allegations or Findings of Non-Compliance Requiring Additional Investigation

If an initial report of alleged or potential noncompliance is determined to have merit, and the circumstances do not fit the criteria for a minor finding of non-compliance, the Director of Regulatory Services or designee will review the report and choose one of the following courses of action in investigating the allegation:

1. Conduct the investigation alone.
2. Conduct the initial investigation in coordination with the IRB Chair.
3. Delegate some of the investigation review to IRB Staff.
4. Delegate all of the review to IRB Staff.
5. Empanel a reviewing investigation subcommittee of the IRB.
6. Request that legal counsel provide advice and conduct the investigation.
7. Request assistance from others at UT Arlington (e.g., Office of Internal Audit, Office of General Counsel, or outside consultants) in the conduct of the investigation.

The individual(s) or subcommittee conducting the investigation may take any of the following actions necessary to determine whether allegations are true, and to determine the seriousness or number of

occurrences of the actions: (1) Review written materials, (2) Interview knowledgeable sources, and (3) Collect relevant documentation.

Allegations which, in the opinion of the Director or delegate and the IRB Chair, are supported by the preponderance of evidence are determined to be findings of noncompliance. Any draft written report that is prepared from a review or investigation of the alleged noncompliance will be forwarded to the PI for his/her review for accuracy of facts prior to forwarding the draft report to the IRB or administrative officials for consideration. Any other researcher(s), who allegedly performed any noncompliance will also be given an opportunity to review the draft report for accuracy during the same period as the PI. If the noncompliance is neither serious nor continuing, the Director or delegate, alone or with the IRB Chair, will examine whether the Investigator understands the non-compliance and has an adequate corrective action plan. If so, the decision and corrective action plan are documented and filed; otherwise a written report is referred to the IRB (the convened IRB, the IRB Chair, or their delegate) for additional review. Findings of possible serious or continuing non-compliance are referred to the IRB for review.

3. IRB Review of Potentially Serious and/or Continuing Non-Compliance

If the acts of noncompliance appear to be serious or continuing, the IRB Staff will notify the Chair, and the issue will be discussed at the next available convened IRB meeting. If necessary or appropriate, an emergency meeting may be scheduled. At the convened meeting, the IRB will review the circumstances regarding the incident and will determine if the alleged practices appear to: (1) cause injury or any other unanticipated problems involving risks to subjects or others, or (2) constitute serious or continuing noncompliance with IRB determinations or federal regulations.

As a result of this review, the following actions may be taken:

1. The IRB may determine that additional information is needed and request that such information be obtained before further action is taken.
2. The IRB may determine that noncompliance did not occur or that noncompliance occurred but was neither serious nor continuing, and either take no further action or require or recommend an appropriate corrective action plan.
3. The IRB may determine that noncompliance occurred and that it was serious or continuing. In this case, the IRB will: (1) Take action appropriate for the situation (see possible actions below), (2) Follow the reporting procedure required by federal regulations and/or funding agency requirements, and (3) Notify the Institutional Official.

For concerns not within the IRB's purview (e.g., research misconduct), the IRB will refer the matter to the appropriate official at the University. IRB determinations and actions will be recorded and communicated as appropriate to the relevant, involved individual(s), normally including the Investigator. If the UTA IRB is the IRB of record, the Relying institution(s) will be promptly notified of a Serious and/or Continuing Non-Compliance determination.

4. Possible IRB Corrective Actions for Serious and/or Continuing Non-Compliance

In considering actions for serious and/or continuing non-compliance, the IRB seeks to:

1. Correct the non-compliance.
2. Deter it from occurring again (e.g., hold the relevant individuals accountable for their actions and provide education on how to comply), and
3. Attempt to mitigate any adverse effects on participants.

The IRB will consider:

1. Suspension or termination of the protocol pursuant to 45 CFR 46.113. The IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator, appropriate institutional officials, the relevant regulatory or funding agencies, and Relying institutions.
2. Notification of current subjects (required when such information may relate to subjects' willingness to continue to take part in the research).

Other possible IRB actions include, but are not limited to, the following:

3. Monitoring of the research;
4. Monitoring of the consent process;
5. Referral to other organizational entities (e.g., legal counsel, risk management, institutional official);
6. Modification of the research protocol;
7. Modification of the information disclosed during the consent process;
8. Provision of additional information to past subjects;
9. Requiring re-consent of current subjects to continue participation;
10. Modification of the continuing review schedule;
11. Participation by research team members in additional training or education;
12. When appropriate, applying any corrective action to all similar protocols.

D. Reporting to Federal Oversight Agencies

The Institutional Official or designee notifies the Office for Human Research Protections (OHRP) of any changes to the Federalwide Assurance Statement and IRB Registration. When applicable, the Institutional Official or designee reports to OHRP, FDA, and/or any applicable funding agencies for instances of serious and/or continuing non-compliance, any unanticipated problems involving risks to subjects or others, or suspension or termination of IRB approval.

XVIII. Appeal of IRB Decisions

Investigators may appeal the IRB's approval decision, the IRB's requirement for specific changes in the protocol and/or consent document(s), or a determination regarding a noncompliance case. An investigator may appeal to the IRB for a formal re-review of a decision in the instances below:

- there have been multiple unsuccessful efforts by the investigator and the IRB to resolve a disagreement; and,
- the investigator believes that the IRB's decision is due to: inadequate or inaccurate information; or, IRB non-compliance with UT Arlington policy, state law, or federal regulation.

At the discretion of the IRB Chair, the investigator may make such an appeal in person and/or in writing to the IRB. The appeal request consists of sending the IRB Staff a cover letter outlining the basis for the appeal and documents that support the appeal. The IRB Staff reviews the appeal request to determine whether an appeal is appropriate. This may include consultation with the investigator, the Institutional Official, the IRB Chair, and select members of the IRB, as needed. The IRB Staff informs the investigator by email of whether the request has been accepted for review.

The appeal is heard at an IRB meeting. This may be a regularly scheduled IRB meeting, or it may be a meeting convened for this specific purpose. If the decision being appealed was made by a full IRB committee: that same IRB will hear the appeal. Or, if the decision being appealed was made by the Expedited or Exempt (both minimal risk) process: the IRB Chair will hear the appeal.

During the IRB meeting:

1. The IRB Chair may hold a closed session without the researcher, prior to the appeal portion of the meeting, to establish the key issues and questions to consider.
2. The researcher is invited to present information and rationale to the IRB.
3. There is a question-and-answer session with the researcher.
4. The researcher leaves the meeting room.
5. The IRB members and other meeting attendees discuss the appeal.
6. The IRB Staff prepares anonymous written ballots to distribute to the members for voting when the discussion has ended. After voting, the ballots are read by the IRB Chair.
7. The IRB moves and then votes whether to take one of the following actions: (1) Approve the appeal and modify the original decision; (2) Disapprove the appeal and uphold the original determination; or, (3) Defer the appeal and obtain additional information or consultation in order to make a final decision.

The IRB's appeal determination, and any other considerations or requirements associated with it, are communicated to the researcher in a letter within 10 business days of the IRB's determination. If appropriate, the determination may also be communicated by email or telephone call with follow-up email by the IRB Staff.

A decision by the IRB to disapprove, suspend, or terminate a project is not subject to reversal by the VPR or any other officer/agency of UT Arlington, state, or federal government. Only one appeal will be allowed on a given matter. The concluding IRB decision of an appeal is final and cannot be appealed.

XIX. Education and Training

The IRB and Office of Research Administration provide services to inform the research community on issues related to use of human subjects in research and ethics in research, and to make researchers aware of applicable Federal regulations and institutional policies. Regulatory Services maintains an internet website that contains detailed information on the human subjects research review process as well as links to federal regulations and regulatory agencies, the OHRP Institutional Review Board (IRB) Guidebook, and other guidance documents.

A. Educational Activities Aimed at the Research Community at Large

UT Arlington Office of Research Administration maintains an internet website that contains detailed information on the human participants review process as well as links to federal regulations and regulatory agencies, the OHRP Institutional Review Board (IRB) Guidebook, and other guidance documents.

1. Office of Research Administration also maintains a small library of materials that includes the OHRP Institutional Review Board (IRB) Guidebook, federal regulations, and other books and videotapes discussing ethical and regulatory issues relating to human participants research.
2. Application materials are provided with appropriate guidance (e.g., templates, instructional documents, internet links) as a means of educating investigators regarding the proper process for conducting research with human participants.
3. Office of Research Administration schedules and advertises numerous educational workshops throughout the calendar year directed at investigators and their research associates. These workshops cover topics that include UT Arlington policies and procedures as well as federal regulatory requirements.
4. Members of the IRB or Office of Research Administration Staff may present information at meetings in academic departments or give scheduled lectures to emphasize selected aspects of human subject research, and to keep various constituencies abreast of activities of the IRB.

B. Educational Activities for Members of the IRB

At the time of induction of a new member, the IRB Chair and/or a professional Staff member from Office of Research Administration provides the individual with the procedures of the IRB and the general regulatory framework from which procedures and policies are derived.

UT Arlington provides opportunities for IRB members to participate in continuing education/training, and to attend conferences/workshops on human participant issues in research. Upon return, these individuals will be expected to provide relevant information to all board members and, as appropriate, the rest of the University community.

C. Required Researcher Education and Training

Prior to conducting human subjects research, investigators will be provided training in the relevant ethical principles and federal regulations pertaining to the protection of human subject research participants.

Training will also include subject matter pertaining to institutional policies for protection of human subjects, and policies/procedures of the UT Arlington IRB. Training may be offered online or in person by the IRB Chair or designee.

Trainings that may be required based upon the type of research to be conducted may include:

1. **Human Subjects Protection Training** - All investigators and IRB protocol personnel engaged in human subjects research reviewed by the UTA IRB or designee are required to complete Human Subjects Protection (HSP) Training; this training must be retaken every 3 years. The link to this training for UTA-affiliated personnel is available on the Regulatory Services IRB website. Non-UTA Collaborators must also provide a certificate of completion for Human Subjects Protection Training through CITI, NIH, OHRP, or another approved method. An email may be sent to RegulatoryServices@uta.edu if a free option is needed.
2. **Responsible Conduct of Research (RCR) Training** - NSF-funded projects require all protocol personnel complete Responsible Conduct in Research Training**,** which is located in our Profiles IRB System. It must be retaken every 4 years.
3. **Good Clinical Practices (GCP) Training** - Studies meeting the NIH Definition of a Clinical Trial and FDA regulated projects require all protocol personnel complete **Good Clinical Practice Training;** requirements are located on our IRB Website for GCP Training**.** It must be retaken every 3 years.
4. **HIPAA Training**-Studies that include a HIPAA authorization or waiver of HIPAA authorization require all protocol personnel complete health privacy training through CITI. The module is named "IPS for researchers". The training is completed once and does not need to be retaken.

The IRB may require additional trainings as deemed necessary for specific protocols & procedures.

XX. Multi-Site and Collaborative Research Projects

Modern research studies often involve collaborations between two or more participating institutions. For these collaborative research projects, a single institution is often able to serve as the designated "IRB of record" for all (or some) of the study sites engaged in the research project. The IRB of Record assumes the primary responsibility for the IRB review and approval of all human subject research procedures for the study, including those at the IRB's home institution as well as those taking place at the external relying institutions. When two or more institutions enter into an agreement to allow one institution's IRB to serve as the IRB of Record for a collaborative study, this is called "reliance."

UTA is often willing to serve as the IRB of Record for projects and may also serve as a Relying IRB depending upon the procedures and circumstances of each specific study and the funding source(s) involved. For NIH funded projects, the Final NIH Policy on the Use of a Single IRB for Multi-Site Research requires that all NIH-funded studies must select one institution to serve as the IRB of Record, unless an exception is met under the Policy. For projects that are subject to the Common Rule, cooperative research projects must rely on a single IRB.

The two main methods of facilitating institutional reliance upon a single IRB of Record include standing reliance arrangements through existing reciprocity agreements, and situational requests for reliance through IRB Authorization Agreements.

A. Reliance through Standing Reciprocity Agreements

UT Arlington is a participating institution in the UT System Statewide Master IRB Reciprocity Agreement, and is also a participating institution on the NIH SMART IRB Online Reliance System. Per the terms of these executed agreements, reliance upon any of the participating institutions for IRB review is acceptable; however, before a collaborative project can begin, both the Reviewing IRB and the Relying Institution(s) must agree that the Reviewing IRB will serve as IRB of Record for each project and IRB protocol where reciprocity is requested. This agreement may be documented via the SMART IRB Online Reliance Portal, by email between participating IRB Offices, or by another equivalent method, such as by the PI's submission of the UT Centralized IRB Review form along with the initial IRB application.

B. Situational Requests for Reliance through IRB Authorization Agreements

In most cases where an executed IRB Reciprocity Agreement is not already in place between UTA and another institution, it is possible to request reliance through an IRB Authorization Agreement (IAA) between the UTA IRB and another institution's IRB when both are engaged in a collaborative research project. Each individual study will be considered for reliance on a case by case basis; UTA can serve as either the IRB of Record for a collaborative study or may rely on another institution to serve as the IRB of Record. When the UTA IRB will serve as the IRB of Record, reliance through an IAA is required when the study meets the definition of human subject research at all sites and is non-exempt research subject to the Common rule, NIH-Policy, or FDA Regulations. In either case, in order for the reliance to be effective,

both the Reviewing IRB and the Relying Institution(s) must agree that the Reviewing IRB will serve as IRB of Record for the research procedures at all sites as described in the approved IRB protocol. This agreement may be documented via an executed IRB Authorization Agreement or another equivalent effective method, such as via email exchange between participating IRB Offices.

C. Acknowledgement Submission Process for UTA Researchers Engaged in External IRB Approved Research

All UTA researchers who are engaged in research which has received IRB approval from an institution other than UT Arlington must submit the approval letter for each externally approved study in the electronic submission system as a new protocol for official acknowledgement. Other approved study documents such as the IRB protocol and consent form must also be provided to Regulatory Services upon request.

D. External Investigators Engaged in UT Arlington IRB Approved Research

UT Arlington researchers may add researchers who are not affiliated with UTA as study personnel on their IRB protocols when necessary (i.e., when the non-UTA researcher will be interacting or intervening with the human subject participants for the purposes of the research study, or when they will be granted access to identifiable human subjects data collected under the UTA IRB protocol). All non-UTA researchers must be clearly listed on the IRB protocol application forms and must complete and sign the Non-UTA Letter of Collaboration Form, which should be attached as part of the IRB protocol application. Additionally, the UTA investigator must attach a copy of the non-UTA collaborator's certificate of completion for Human Subjects Protection Training taken within the past 3 years. The certificate may be through the collaborator's home institution, CITI, or the free online OHRP training course found here:

https://www.hhs.gov/ohrp/education-and-outreach/online-education/human-research-protection-foundational-training/index.html

1. Individuals at Non-Assured Institutions Engaged in UT Arlington IRB Approved Research

For non-UTA researchers listed on a UTA IRB protocol who are not affiliated with an institution that holds a Federalwide Assurance (FWA) for the Protection of Human Subjects with OHRP, UT Arlington is willing to extend the coverage of our FWA to cover the individual investigator provided that the non-UTA researcher has read, completed, and signed the Non-UTA Letter of Collaboration Form; has provided documentation of current Human Subjects Protection Training; and he/she understands and accepts the responsibility to comply with the standards and requirements stipulated in (a) *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research;* (b) the HHS regulations for the protection of human subjects at 45 CFR part 46; (c) the terms listed on the second page of the Non-UTA Letter of Collaboration Form; and (d) the UT Arlington IRB Standard Operating Procedures posted on the Regulatory Services website.

2. Individuals at Assured Institutions Engaged in UT Arlington IRB Approved Research

For non-UTA researchers listed on a UTA IRB protocol who are affiliated with an institution holding a Federalwide Assurance (FWA), the UT Arlington IRB Office will reach out to the IRB Office at the non-UTA researcher's home institution in an attempt to initiate the reliance / reciprocity process. However, it is ultimately the responsibility of the non-UTA researcher to comply with the policies and procedures of his/her home institution regarding the engagement of researchers in collaborative projects that have received IRB approval at an external institution.

XXI. Recordkeeping and Retention of Records

A. Recordkeeping

Regulatory Services is responsible for ensuring that all IRB records and documents described below are maintained in accordance with these procedures.

Documentation of the following IRB activities and regulatory requirements are maintained:

1. Copies of all research proposals reviewed;
2. Scientific evaluations, if any, which accompany the proposals;
3. Approved consent documents;
4. Statements of significant new findings provided to subjects as required by 45 CFR 116(b)(5), 21 CFR 50.25(b)(5);
5. Copies of all modifications or amendments to protocols;
6. Reports of unanticipated problems;
7. Records of continuing review activities;
8. Progress reports submitted by research investigators;
9. Minutes of IRB meetings;
10. IRB review (e.g., in Notes, correspondence, IRB reviewer form), including actions taken by reviewer or Board, approval and expiration dates), determinations (e.g., waiver of informed consent, waiver of documentation of informed consent, Subpart-specific determinations), restrictions (e.g., suspensions, contingencies), and reviewers;
11. Correspondence between the IRB and the research investigators;
12. List of Board members and their alternates identified by:
    a. Name;
    b. Earned degrees;
    c. Representative capacity;
    d. Indications of relevant experiences such as board certifications, licenses, etc.;
    e. Information sufficient to describe each member's chief anticipated contributions to the IRB deliberations;
    f. Any employment or other relationship between the member and the institution;
13. Board member curriculum vitae, appointment letters, and other relevant correspondence involving member service;
14. Reports submitted to the IRB regarding injuries to subjects;
15. Exemption determinations, including category of exemption;

16. Reviews conducted under an expedited review process, including category, actions taken by the reviewer such as returns or approval, and required determinations;
17. Investigations related to allegations of noncompliance;
18. Not-for-cause audits;
19. Interactions with federal regulatory agencies regarding compliance matters.

B. IRB Files

Each protocol is assigned a unique number and is maintained within an individual record in the electronic IRB submission system. All associated files, modifications, continuing reviews, and correspondence are maintained electronically as part of the electronic protocol record.

C. Record Retention Term

Records relating to a specific research activity, including research records collected by investigators and IRB records, must be maintained for at least three years after completion of the research (45 CFR 46.115(b); 21 CFR 56.115(b)). This minimum retention period applies whether or not any subjects were enrolled in the study.

1. FDA regulated research

An investigator involved in the research of drugs being tested in humans for FDA approval shall retain records for a period of 2 years following the date a marketing application is approved for the drug for the indication for which it is being investigated; or, if no application is to be filed or if the application is not approved for such indication, until 2 years after the investigation is discontinued and FDA is notified (21 CFR 312.62(c)).

An investigator involved in the investigation a device shall retain records for a period of 2 years after the latter of the following two dates: The date on which the investigation is terminated or completed, or the date that the records are no longer required for purposes of supporting a premarket approval application, a notice of completion of a product development protocol, a humanitarian device exemption application, a premarket notification submission, or a request for De Novo classification (21 CFR 812.140(d)).

Records should be retained until there is written confirmation from the sponsor or FDA granting permission to destroy them.

2. HIPAA Requirements

If the research involves written HIPAA authorization, the investigator must retain the permission (i.e. consent form or authorization) to use the Protected Health Information (PHI) for 6 years from the completion of the research (45 CFR 164.530(j)(1)).

IRB records documenting a waiver of HIPAA Authorization must be retained for 6 years from the completion of the research.

Protocol-specific IRB records, and IRB records that are not protocol specific (e.g., minutes, rosters, or correspondence not related to a specific study), will be maintained within the electronic IRB filing system. The records/information that are kept electronically will be maintained on backup media throughout the time that IRB electronic records, protocol submission/tracking system are maintained. If the electronic records are superseded by another electronic system, and all data are not transferred to that system, the data will be retained electronically for a period thereafter of at least three years after the last federal grant recorded in that system has been completed.

D. Confidentiality of Records

IRB records, including records relating to specific research protocols, are kept confidential to the extent possible and allowed by law. However, authorized representatives of sponsors, federal regulatory agencies, UT Arlington officials, IRB staff, University staff with legitimate access, and IRB Board members may review, inspect, and/or copy records.

E. Inspection of Records

IRB records are accessible for inspection and copying by authorized representatives of the Food and Drug Administration (FDA), the Office for Human Research Protections (OHRP), and other agencies, when appropriate jurisdiction exists, at reasonable times and in a reasonable manner (45 CFR 46.115(b); 21 CFR 56.115(c)). Requests for photocopying and release of any IRB records must be received in writing and approved by the Director, Regulatory Services.