TEXAS A&M UNIVERSITY
SAN ANTONIO

IRB STUDENT HANDBOOK

A GUIDE TO HUMAN RESEARCH PROTECTION IN RESEARCH

September 2025

Table of Contents

Table of Contents

1. INTRODUCTION TO THE STUDENT HANDBOOK

A Guide to Human Research Protection in Research

Texas A&M University-San Antonio (A&M-SA), is legally and ethically bound to protect the rights and welfare of humans participating in research conducted by its faculty, staff, and students. Federal regulation, state law, university policy, and professional standards of the investigator's academic discipline demand compliant, ethical and responsible conduct of social, behavioral, educational, and biomedical research involving human subjects. We offer this Handbook to help students meet their regulatory and ethical responsibilities when conducting research involving human subjects. We answer many of the questions students new to research may have about working with an IRB and identify where to find additional resources.

The A&M-SA Office for Research Compliance (ORC) recognizes the value of student participation in the research process. It is a valuable learning experience that helps ensure future social benefit from the efforts of well-trained researchers. We encourage students to contact us directly if they need help navigating the IRB process. Contact the A&M–SA IRB office either by visiting our Institutional Review Board or by sending an email: irb@tamusa.edu**.** An IRB staff member will contact you to assist.

2. WHAT IS AN IRB?

An **Institutional Review Board (IRB)** is a committee designated by an institution to review, approve, and conduct periodic post-approval reviews of human research studies that fall within its scope of authority, as required by federal or state regulation and university policy. The committee is composed of respected scientists, non-scientists, community members, staff, and a variety of specialists from diverse fields of study.

The primary purpose of IRB review is to protect the rights and welfare of individuals involved in human subjects' research conducted by faculty, staff and students of the institution. Many other countries also require IRB review and approval of proposed human research studies but, outside of the U.S., such committees may be called "Privacy Boards" or "Research Ethics Boards".

3. WHAT REGULATIONS, POLICIES AND PRACTICES APPLY TO HUMAN SUBJECTS' RESEARCH?

Federal regulation, state law, university policies and industry best practices shape what constitutes appropriate conduct of research involving human subjects.

Regulatory Authority

Federal, state and local laws and regulations may require human subjects' research to be conducted in particular ways. The university requires its researchers to be knowledgeable about and comply with the laws and regulations of the country and state in which they are conducting research, and all research documents must reflect compliance with such laws and regulations.

Federal Regulation

By federal regulation, U.S. institutions, companies and organizations that receive federal funding and conduct human subjects' research such as A&M-SA and its affiliated hospitals and clinics must use an IRB and follow specific review and approval [45 CFR 46] 45 CFR 46 | HHS.gov.

Institutions, companies and organizations that do not receive federal funding—such as pharmaceutical and medical device companies but conduct human subjects' research with Food and Drug Administration (FDA) regulated products (drugs, devices, biologicals and nutraceuticals) that require FDA approval before sale to consumers must also use an IRB and abide by its determinations [21 CFR 50, 21 CFR 56] Regulations: Good Clinical Practice and Clinical Trials | FDA.

Further, investigator-initiated clinical trials conducted by A&M-SA investigators that meet clinical trials registration requirements under the FDA Amendments Act of 2011 (FDAAA) must register their clinical trial on the website. For a subset of clinical trials, investigators are also required to fulfill the FDAAA requirements for reporting results and adverse events on the site at the end of the research.

Federal agencies that fund research, such as National Institutes of Health (NIH), National Science Foundation (NSF), Department of Education, Department of Defense, and others, may publish additional regulations with which researchers must comply. Depending on research design, FDA regulations, the funding agency, or research activities occurring at non-U.S. study

sites, research may need to comply with the International Council of Harmonization Good Clinical Practices ICH Official web site : ICH.

Institutions, companies and organizations not bound by regulation—such as foundations and other types of private funding agencies may require IRB review as a best practice to safeguard subjects' rights and welfare.

All institutions and organizations, regardless of funding, are bound by the Privacy | HHS.gov which regulates the use of subjects' personally identifiable health information found in patients' electronic medical records [See **HIPAA Privacy Rule** in Section 7].

State Statutes:

States may have laws and regulations beyond what is federally required to safeguard rights and protection for their residents participating in research. You are responsible to know and comply with the applicable laws in the countries and states in which you conduct your research.

A&M–SA Policy and Organizational Support:

Committed to protecting the rights and welfare of human subjects involved in research, The university requires all human subjects' research to be conducted in compliance with applicable Federal and State laws, requirements of public and private funding agencies, and the university's internal policies and procedures for the solicitation and management of externally sponsored programs and for the allocation of internal research (see **A&M–SA Policy Library,** System regulation 15.01.01 and 15.01.01.01.01 Rules : Policies and Regulations. All research that meets the definition of human subjects' research must be reviewed by a university-sanctioned IRB before research activities may begin. Once approved, investigators must comply with IRB decisions and instructions, and communication requirements until such time as the IRB deems the project closed. Later in this document we review the various types of IRB decisions, instructions and communication requirements.

The university's **Office of Research Compliance (ORC) is organized to support the research activities of faculty, staff and students 15.99.05**. ORC oversees research compliance to ensure the conduct of research promotes the integrity of the scientific record, including training and

certification. The **Human Research Protection Program (HRPP)** which provides oversight for the **IRB** (research with humans), **IACUC** (research with animals), **IBC** (research with biosafety), **FCOI** (financial conflict of interest in research), **Export Control** (oversight to regulate the export of certain research goods and knowledge to/from persons, companies, or entities residing in non-U.S. locations), and **Research Integrity** (ensuring high ethical standards in the conduct of research through research training programs and activities related to such research training), are its principle areas of responsibility.

Publication Best Practices

Irrespective of legal, regulatory, university and grantee requirements, most major journals national and international require proof of IRB review and approval of interventional research involving human subjects as a condition of publication.

4. WHAT ETHICAL PRINCIPLES APPLY TO HUMAN SUBJECTS' RESEARCH?

The **Belmont Report**, published by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research in 1979, provides the ethical foundation which guides federal research regulations and IRB review of human subjects' research. The Belmont Report | HHS.gov highlights three basic ethical principles:

Respect for Persons incorporates at least two ethical convictions: "first, that individuals should be treated as autonomous agents, and second, that persons with diminished autonomy are entitled to protection." The Report clarifies, "respect for persons requires that subjects, to the degree that they are capable, be given the opportunity to choose what shall or shall not happen to them." The cornerstone of protecting respect for persons is **the informed consent process**, whereby the researcher provides individuals with the details about the study and their rights as study subjects, anticipated harms and benefits, alternatives to participation, and an opportunity to ask questions before deciding whether to participate in the study. The Belmont Report | HHS.gov

Beneficence incorporates at least two obligations: "first, do no harm and (2) maximize possible benefits and minimize possible harms." Regarding particular projects, researchers must design projects in ways that ensure anticipated risks of harm from the research are minimized, possible benefits are maximized, and harms and benefits are proportional to one another. The Belmont Report | HHS.gov

Justice demands that society's members share equally the benefits and burdens of research. In other words, the selection of subjects should be justified by the scientific question(s) being asked and not as a matter of convenience or bias. Further, the principle requires that the communities of people who undertake the burdens of research are likely to benefit from the research. The Belmont Report | HHS.gov

Later sections in this guide highlight what study design elements and documents the IRB reviews to determine that the three ethical principles outlined in The Belmont Report have been appropriately applied to the proposed research.

5. WILL MY RESEARCH NEED IRB REVIEW?

Your proposed project may or may not require IRB review depending on whether

(1) it qualifies as *research*,

(2) involves *human subjects*.

(3) Self-determination is not allowed at A&M-SA

All criteria must be satisfied for a study to be deemed human subjects' research requiring IRB review. Definitions of relevant terms are found in this section followed by a description of how the criteria are applied to different types of research activities.

Is It Research?

The first question that must be considered is whether a project fits the regulatory definition of research. The federal regulations define research as "a **systematic investigation**, including development, testing and evaluation, designed to develop or contribute to **generalizable knowledge**" [45 CFR 46.102(d)] 45 CFR 46 | HHS.gov

- A ***systematic investigation*** is not a federally defined term but typically involves the collection of data in an organized and consistent way and analyzed in some scientifically reliable fashion permitting conclusions to be drawn.
- ***Generalizable knowledge*** is not a federally defined term but typically considered as the learned/collected information **expressed in** theories, principles, and statements of relationships that **can be applied more widel**y than the specific site and individuals participating in the research project. With this said, generalized knowledge in qualitative research typically regards

transferability, especially for those who are consuming their work so that another may transcribe and transfer the findings into practice.

The requirement that a proposed project involves systematic investigation is usually met because observation and data collection methodologies are, by their very definition, systematic. That the proposed project seeks to generate knowledge that has applicability beyond the context of the single study, on the other hand, may not always be the case as you will see when you review the different types of research examples provided later in this section

Rule of Thumb:

If you are **presenting at a conference**, **writing for a journal**, **publishing a thesis**, or **writing a dissertation**, your work may require **IRB approval**. Always verify **before starting** to avoid delays or rejection.

Does My Project Involve Human Subjects?

The second question that must be considered is whether the proposed research involves human subjects. The federal regulations define a human subject as "a **living** individual **about whom** an investigator conducting research obtains

(1) **information** or **biospecimens** through **intervention** or **interaction** with the individual, and **uses, studies, or analyzes** the information or biospecimens

(2) Obtains, uses, studies, analyzes, or **generates identifiable private information** or **identifiable biospecimens [**eCFR :: 45 CFR Part 46 -- Protection of Human Subjects**]**.

Several concepts are relevant to whether the project is considered to involve human subjects:

- **Living individual** refers to data (information or specimens) collected from *living* persons
- **About whom** means the information collected is personal information *about a person (*information collected solely about an organization or its processes is not human subjects research)
- **Intervention** includes physical procedures by which data are gathered (e.g., blood draw, cheek swap, saliva sample) and manipulation of the subject or

subject's environment that are performed for research purposes

- **Interaction** means communication or interpersonal contact between researcher and subject
- **Private information** means information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, information in their medical record)
- **Identifiable private information** means the identity of the subject is or may readily be ascertained by the researcher or associated with the information collected. [See HIPAA Privacy Rule]
- **Identifiable biospecimen** means that a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

If the project meets the definition of research **AND** involves human subjects, the project must be reviewed and approved by the IRB before it is conducted.

IMPORTANT: IRB approval **CANNOT** be backdated. If you begin your project without IRB approval and later learn that your study required IRB approval, the research activities you conducted without IRB approval CANNOT be used to fulfill degree requirements or published in most peer-reviewed journals.

What if my study does not meet the definition of human subjects' research?

Your faculty advisor is responsible to contact the IRB in writing and receive the approval for the study. The researcher is responsible for the initial assessment as to whether an activity constitutes human subjects research based on the federal definitions. If one or more of the criteria listed above to define human subjects research is not met, the project **does not require IRB review.**

When you submit your project for an IRB determination, you must:

(1) be sure to provide sufficient information about your proposed project in your IRB application in order for a determination to be made accurately and swiftly (such as,

study purpose and design so the IRB can determine whether it is research—and what data will be collected, how it will be collected and from whom—so the IRB can determine if human subjects will be involved in the research)

(2) state that you believe your project does not qualify as human subjects' research

The U.S. Department of Health and Human Services offers a decision-tree to help IRBs determine when projects constitute human subjects research. You might find it helpful. Human Subject Regulations Decision Charts | HHS.gov.

What If I Am Not Sure If My Project Involves Research with Human Subjects?

Determining whether a project constitutes human subjects research can be tricky because of the multiple criteria at play and when more than one methodology is employed to collect data. Your faculty advisor and the IRB are available to help you think through whether your project does or does not qualify as human subjects' research requiring IRB review.

What Are Some Research Project Examples to Help Me Think About Whether My Project Is Human Subjects' Research?

Following are some examples of different types of projects and a discussion about what activities do/do not qualify them as human subjects' research. Reviewing them may help you determine whether your project is human subjects' research.

Analysis of Bio-specimens

Bio-specimens range from tissue samples to blood, sputum, urine, sweat, and bone marrow. Some research studies propose to prospectively collect fresh specimens from individuals; others propose to use archived samples that were originally collected during a necessary clinical procedure or another's research and is now stored in laboratories of hospitals, medical centers, or tissue repositories. Assuming the project is deemed research (systematic and generalizable), the key to determining if analysis of bio- specimens constitutes research with human subjects is found in the answers to 3 questions:

(1) **Are the specimen donors living?** If none of the specimen donors are living

individuals, your project *does not* constitute human subjects' research per the Common Rule. However, HIPAA regulations may apply [See **HIPAA Privacy Rule**]

(2) **Who is collecting fresh specimens?** If you or members of your research team are interacting with the subjects from whom the specimens will be collected, it *is* human subjects' research because intervention or interaction by study staff with subjects will occur. If persons unrelated to the study are interacting with individuals to collect the specimens (e.g., clinic staff), and who will then forward the samples to study staff, it *may not* be human subjects' research because no intervention or interaction by study staff will occur. ***But*** we cannot be sure until we answer Question 3.

(3) **Will private identifiable information about the subject be affixed to the specimen vials or slides or included in documents that may accompany them?** If the answer is yes, then it *is* human subjects' research because individuals' private identifying information is being collected for research. If the answer is no—the identity of the subject donating the specimen remains anonymous, and no intervention or interaction with study staff will occur—then the research *is not* human subjects' research. [To learn more about private identifiable information, see **HIPAA Privacy Rule**].

Classroom Exercises

Most exercises assigned to students in research methodology classes are designed to teach skills and provide students the opportunity to practice research methods such as observation, interview or survey techniques, tissue or data analysis, or environmental testing. Typically, exercises are limited in scope, designed exclusively to teach students and not to develop or contribute to generalizable knowledge, and are not undertaken with that goal in mind. In such cases, IRB review is not necessary. However, when exercises are designed to develop or contribute to generalizable knowledge, then IRB review is required.

Responsibility for determining whether classroom exercises require IRB review/approval

rests with the IRB. Faculty will find guidelines and the appropriate form to submit to request an IRB review of class-based research assignments to determine if the activities constitute human subjects research at Identifying Human Subject Research A&M-SA Research SOP 200. The A&M–SA Faculty member can submit an IRB application for a Non-Human Research Determination by logging into IRB to create an initial submission cayuse
Regardless of whether projects require IRB review, both faculty and students should follow federal guidelines and university policy when designing and conducting class exercises with human subjects to protect the rights and welfare of human subjects.

Quality Assurance (QA)/Quality Improvement Projects (QI). PAM SOP 9
Quality Assurance, Quality Improvement, Program Evaluation, Evidence-Based Practice, and Benchmarking activities that are designed to determine whether aspects of an *organization's existing practices* are being performed in line with *established standards* are called Quality Assurance (QA).

Quality Improvement (QI) extends that process to continuously evaluate and learn from organizational experience in a cycle (i.e., plan-do-study-act). In general, QA/QI activities are not research because they evaluate existing practices against established standards (not untested practices), and the results are not generalizable beyond the organization. Further, the activity does not increase risks of harm because, ostensibly, QA/QI works to reduce risks of harm in the organization by its efforts. As a result, standard QA/QI projects are not deemed human subjects' research and do not need IRB review/approval.

Research Using Data Sets

- **Public databases** are data files prepared by investigators, data suppliers, organizations or governments with the intent of making them available for public use. The data available are usually not individually identifiable, are not maintained in a readily identifiable form, or are identifiable without expectation of privacy. A&M–SA library has access to an extensive array of public databases (see Databases| A&M-SA available for student research. Research with public databases is not considered human subjects research and **does not generally require IRB**

approval, **unless** you plan to merge data from different datasets which may result in (re) identification of individuals. If the study plans to merge data sets, IRB review/approval may be necessary. However, submit information to IRB office to make self-determination.

Private or Restricted-Access databases are data files prepared by investigators, organizations or governments with the intent of making them available for internal use or available on a restricted- access basis only. Data may or may not be individually identifiable or maintained in a readily identifiable form by completing the data holder's authorization form. Access to restricted-level data requires an application for IRB review and approval. Unless the data holder requires a specific level of review, then the Researcher can request Exemption Review The organization providing the private database must provide written confirmation that no identifiers or links to identifiers will ever be shared with the researcher. Submit to IRB to make the final determination.

Surveys, Questionnaires and Focus Groups

The most often used methodological strategies students employ to collect data for research are surveys, questionnaires and focus groups. Depending on whether there is interaction between the researcher and subjects or collection of subjects' identifying information determines whether the proposed research constitutes human subjects research requiring IRB review. The IRB will look closely at how you propose to interact with subjects (if applicable) and your data collection plan to make sure your study is designed using the least invasive data collection procedures necessary to accomplish the research goals and that subjects' privacy and confidentiality are adequately protected. Your faculty advisor can guide you in designing your study in a way that minimizes potential privacy and confidentiality harms to subjects.

Thesis and Dissertations

Student research activities include, but are not limited to, projects that result in undergraduate honors thesis, masters' thesis, or doctoral dissertations. IRB approval is generally required if the intent of the research is to develop new or expanded generalizable knowledge **AND** human subjects are involved, either directly or through use of identifiable data about them.

Students must work with a faculty advisor(s) to prepare and submit their research to the IRB during the proposal stage of the thesis or dissertation. This requirement applies regardless of funding or funding source. Start this process early to assure you have sufficient time to complete the project and satisfy the necessary department, IRB, and other university requirements and reviews.

Work on Faculty IRB-Approved Research

Students may serve as researchers on a faculty member's existing project that already has IRB approval. In such cases, the faculty principal investigator must submit a modification request to the IRB to add the student to the existing project. Students may not engage in research activities until the modification is IRB approved.

Depending on the scope and purpose of the student's part in the research, the IRB may require the project to be submitted separately as new research. Remember, no human subjects' research activities may begin without IRB review and approval. Regardless of whether the activity is human subjects' research or not, your project must be executed in a manner that is ethical and respects the rights and welfare of the people in them.

6. WHAT ARE THE DIFFERENT TYPES OF IRB REVIEW?

All research that meets the definition of human subjects' research must obtain IRB approval or an exemption determination from them. IRB review and approval must occur prior to the initiation of any research activities, such as contact or recruitment of subjects or collection of tissue samples or data. Research involving human subjects cannot be initiated until IRB approval is granted. The IRB cannot grant retroactive approval after research has been initiated or completed.

The different types of IRB review—exempt, expedited and full board—is outlined below.

Exempt Review

Federal regulations permit certain studies which present little or no risk of harm to subjects to

be exempt from continuing review once the IRB has approved it. That means the study must be initially reviewed by an IRB member, but it **does not require ongoing IRB** oversight after study approval is granted. If a researcher wishes to change the research plan after obtaining an exemption, the IRB must re-review the project before changes can be implemented.

Except for research involving certain vulnerable populations and for FDA-regulated research, the IRB may grant exempt status if it meets federal exemption criteria:

1. when the study holds minimal risk of harm to subjects; AND
2. subject selection does not include persons who are vulnerable; AND
3. adequate provisions exist to protect the privacy interests of subjects and the confidentiality of subject data.

Expedited Review

Not all research that requires IRB review warrants review by the full IRB at a convened meeting. Federal regulations permit certain types of research to be reviewed by a designated member of the IRB or a subcommittee, thereby, 'expediting' the IRB review process. A designated member of the IRB will then periodically review the research—no less than once a year—to monitor its progress. Two general categories of research can qualify for expedited review:

(1) The research must involve no greater than minimal risks of harm to subjects. Regulations define minimal risk to mean 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 the daily life or during the performance of routine physical or psychological examinations or tests" of normal, healthy persons [45 CFR 46.102(i) and 21 CFR 56.102(i)].

(2) minor changes in previously IRB-approved research during the period for which approval is granted. That is, if you/your Faculty Advisor request modifications to your IRB-approved research and the proposed changes do not increase risks of harm to subjects, the modification may qualify for expedited review.

Full Board Review

> Studies that involve greater than minimal risk of harm, such as testing experimental chemicals or devices on humans, employing complex research designs (e.g., randomized control or placebo), or researching sensitive topics (e.g., infectious disease, illegal drug use, genetic predisposition to disease) require IRB full board review. Projects posing no more than minimal risks of harm to subjects but that involve vulnerable persons, such as, children, pregnant women, fetuses, prisoners, persons lacking decision-making capacity, and others may require full board review.

Last, projects that do not or no longer qualify for exempt or expedited review or the complexity of study design exceeds the expertise of an individual reviewer, may also be reviewed by the full board at a convened meeting.

The schedule of IRB full board meeting dates, including submission deadlines, for the current year may be found online.

IRB Office Support

Prior to any type of IRB review, a designated IRB Office staff member conducts an initial administrative review of each application. The staff reviewer may request clarification, changes or additional materials if the application or supporting materials are incomplete or unclear. Once the staff member determines the submission packet is complete, the application is forwarded to an IRB member or the full board for review.

After review, the IRB will correspond with you/your Faculty Advisor to advise that your study has been approved, approved with minor changes, approval with stipulations or approval is deferred until revisions to the study are made. Any IRB-required changes will be outlined in the correspondence.

Revisions must be re-reviewed by the IRB and approved before research may be initiated. Depending on the type of review, number of clarifications needed, the scope of changes or revisions required, if any, and the promptness of your/your Faculty Advisor's responses to such

requests, a proposed project may take up to four weeks for IRB review. Due to the complexity of laws and customs, IRB review of proposed international research may take longer. Please plan your research deadlines accordingly.

IMPORTANT: You MAY NOT initiate any research activities until you/your Faculty Advisor receives a written notice of IRB approval of your research, or a Non-Human Subjects' Research Determination.

7. WHAT DOES THE IRB CONSIDER IN THEIR REVIEW?

When the IRB reviews proposed research, it must determine that the research meets federal regulation, state law and university policy, and appropriately applies the ethical principles outlined in the Belmont Report—respect for persons, beneficence, and justice. In what follows, two important federal regulations that regularly apply to student research are outlined, The Common Rule and the Health Insurance Portability and Accountability Act.

Common Rule – General Protections

U.S. Dept. of Health and Human Services [45 CFR 46] Section 46.111 of the **Common Rule** outlines eight criteria that must be satisfied to protect subjects in research before an IRB may approve proposed research 45 CFR 46 | HHS.gov. The **FDA** requires satisfaction of the same criteria, plus more, when conducting clinical research leading to the development of drugs and devices, [21 CFR 50, 21 CFR 56] Food & Drug Administration | HHS.gov.

Risks of harm to subjects are minimized [*Beneficence*].

- Use only procedures which are consistent with sound research design and do not unnecessarily expose subjects to risk of harm; and
- Whenever appropriate, use only procedures already being performed on the subjects for diagnostic or treatment purposes.
- Consider possible economic, legal, physical, psychological and social harms that may occur to subjects because of participating in the research.

Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects [*Beneficence*].

- Assure there is a fair balance between the risks of harm or burden to subjects that may result from study participation and any anticipated benefits of participation or the knowledge to society that is expected to result from it.

Selection of subjects is equitable [*Justice*].

- Selection of subjects should be justified by the scientific question(s) being asked and not as a matter of convenience or availability. Pay special attention to problems that may arise when involving vulnerable populations in research.

Informed consent will be sought [Respect for Persons].

- Researchers must obtain the informed consent of the subject or the subject's legally authorized representative before enrolling them in research.

- The IRB looks closely at the offer of participation outlined in proposed research protocols to ensure the consent process supports an environment where individuals **voluntarily decide**, and are not unduly influenced or coerced, to participate in research. The IRB also looks closely at consent documents to determine if **adequate information** is provided about the proposed study and whether it is written in a fashion that the target audience can easily **understand**.

- Consent documents must contain specific types of **information** about the proposed research. Go to the A&M – Research Compliance site to learn about what informational elements are required for your proposed research

- If the proposed study includes a **non-English speaking population** or a **vulnerable population**, such as children, prisoners, persons lacking decision-making capabilities, economically disadvantaged or educationally disadvantaged, additional protections apply [See **Common Rule - Vulnerability in Research** in this Section].

- Under certain circumstances, the IRB may waive the need for written consent, authorizing oral consent instead.
- The IRB may **waive specific required elements of consent. It may also waive the requirement to obtain informed consent** under certain circumstances. Go to the applicable HRPP|IRB site to learn more about waivers

Informed Consent will be appropriately documented (respect for persons).

- Researchers must document informed consent using a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. A copy must be given to the person signing the form. The IRB may waive the requirement to document consent under certain circumstances.

Research plan makes adequate provision for monitoring data to ensure subject safety (beneficence).

- Some studies must monitor the quality of data collection and management, and the accumulating outcomes to assure subject safety and the scientific integrity of the study. Studies that require data safety monitoring are complex and pose greater than minimal risk to subjects. Such risky research usually requires faculty to serve as the principal investigator and coordinate oversight by a qualified data monitoring board. For learn more about data safety monitoring.

Adequate provisions are made to protect the privacy of subjects and to maintain confidentiality of their data (beneficence)

- Privacy is defined in terms of a person having control over the extent, time, and circumstances of sharing oneself or a part of oneself with others. The IRB will look closely as the study methods used to identify and contact potential subjects, whether the setting(s) in which the researcher and subject meet afford(s) privacy, what methods are used to obtain private information about subjects whether the justification for its collection is sound, and that the minimum amount of information is collected to meet the needs of the research.

- Confidentiality is a duty to protect the data that was collected or generated about the subject during the research. The IRB will assess the research plan—what private information about the subject will be collected or generated—and the security plan— what measures will be taken to protect the data from improper disclosure, such as not collecting identifiers, de-identifying data after collection, coding research data and storing the links to identifiers in a separate location, encrypting data files, etc...

Additional protections exist to safeguard the rights and welfare of subjects vulnerable to coercion or undue influence (respect for persons).

- When some or all of the subjects are likely to be vulnerable—lack the capacity, skills, status, or resources needed to protect their own interests--the protocol plan must outline additional steps that will be taken to protect these subjects' rights and welfare, such as, a need for a parent or surrogate to help may decisions, provide more information or provide it in a culturally or linguistically accessible way, offer the research at a location more accessible to the subjects, etc.

Common Rule – Vulnerability in Research Special regulatory and ethical considerations apply when research involves vulnerable persons. Vulnerability in research means that, due to contextual and/or relational circumstances, persons lack the freedom or capability to protect their self-interests when deciding whether to enroll, decline to enroll or withdraw from research. The Common Rule [45 CFR 46, Subpart B-D], FDA [21 CFR 50 & 56] and The Belmont Report identify some groups they deem vulnerable: **pregnant women, human fetuses, neonates, prisoners, children, persons with physical handicaps or mental disabilities**, persons who are **disadvantaged economically or educationally**, **racial minorities**, the **very sick** and the **institutionalized**. Additionally, some individuals may be situationally vulnerable because of the type of research or an offer of participation in it.

For example, persons may feel obligated or coerced to enroll in research because of real or

perceived differences in role relationships (such as, between **students** and teachers in school research; **patients** and caregivers or providers in health care research; **employees** and supervisors in organizational research, **prisoners** and wardens in prison research, to name a few). As a result, additional design elements often need to be built into the protocol plan, the recruitment plan, and/or the consent (or assent/parental permission) process to protect persons' autonomy to make decisions in their self- interests.

Your Faculty Advisor and IRB staff are available to help you think through what appropriate additional strategies are necessary to protect vulnerable persons in your research, if applicable.

HIPAA Privacy Rule

The Common Rule requires researchers to protect subjects' private information, regardless of the data source—from whom or where—the information was obtained. However, another federal regulation also exists to protect subjects' private information, but it is narrowly focused on just one data source—**patients' electronic medical records**. The "HIPAA Privacy Rule", demands researchers protect the confidentiality and security of patients' personally identifiable health information found specifically in **patients' electronic medical records**. Among other things, HIPAA regulates when researchers may access and use such information also known as **Protected Health Information, or PHI**.

To qualify as **protected health information, or PHI,** the information must possess three qualities:

- it must include one of 18 identifiers deemed capable of identifying an individual

- it must relate to a person's health, health care, or payment of health care

  Examples of health information would include any information in a patient's medical chart, lab values, results of diagnostic testing or imaging, psychological tests, biological specimens, billing documents, etc.

- it must exist in an institution, organization or business that electronically transmits such health information to accomplish a health-related transaction

Examples of covered entities include hospitals, health care clinics or business entities that support the services of a hospital or health care clinic care clinic. To access PHI, researchers must obtain an individual's **authorization** (permission) to access their electronic medical record.

HIPAA allows the requirement to obtain subject authorization to use PHI to be waived by a Privacy Board under certain circumstances. HIPAA also allows a covered entity to disclose a limited data set to a researcher if a data use agreement is in place. A&M-SA IRB serves as the institution's Privacy Board, so any request for a waiver of authorization or proposed use of a limited data set must be submitted to the IRB.

Other Regulations May Apply

Depending on research design or the population targeted for inclusion in the research, other regulations may apply. A list of other regulations, laws, policy relevant to human subjects' research may be found at HRPP link. It is the responsibility of the researcher to identify and be knowledgeable about all applicable laws and regulations that may apply to their research.

8. WHAT STUDY DOCUMENTS DO I NEED TO SUBMIT TO THE IRB?

The IRB will review the following project documents to determine if your proposed research meets regulatory compliance and ethical standards:

- Student's research plan (the protocol)
- Consent or assent documents, as applicable
- Data collection tools (including surveys, questionnaires, etc.)
- Recruitment materials (including flyers, tear-off sheets, ads, etc.)
- Evidence of CITI completion by all study staff
- Conflict of Interest forms completed by all study staff
- Site approvals, as applicable
- Other documents, as applicable or requested by the IRB
- Completion of other training as directed by IRB

Helpful Study Document Templates

IRB offers a variety of **protocol**, **consent** and **assent**, as well as other **document** templates to

help students craft the study documents necessary for IRB review. Go to IRB Website. A list of templates relevant to your research will appear. Contact your faculty advisor if you have questions about which templates best fit your proposed research aims and why.

9. DO I NEED SPECIAL TRAINING?

Yes. All persons planning to conduct human subjects' research—faculty, staff, students, and faculty advisors of students must complete an online research ethics and compliance education program, prior to IRB approval of proposed human subjects' research, including research that may be deemed exempt. The online program is called Collaborative Institutional Training Initiative (CITI Training). Study personnel may not participate in human subjects' research until their CITI training is completed. CITI Certification is valid for a three-year period, after which time refresher training must be completed. Contact IRB Office for more training details.

Additional training may be required by other Federal or State regulators or funding agencies. For example, NIH requires completion of a Responsible Conduct of Research course.

10. WHAT ARE MY RESPONSIBILITIES AS A RESEARCHER?

Student researchers have an obligation to protect the rights and welfare of human subjects participating in their research. To that end, following is a list of student researcher responsibilities aimed at affording such protections:

Research projects undertaken by students should be appropriate to their educational level and be commensurate with their training.

- Speak with your advisor about your previous experience and coursework to determine if it is appropriate and adequate for the research you are proposing and the risk(s) of harm you are proposing for your research subjects.

Students must conduct research in an appropriate manner, consistent with ethical standards for their discipline and in accordance with federal requirements, state law, and university policies.

- You must be knowledgeable about and comply with laws, regulations, policies and standards. Coursework, CITI training, Faculty Advisor guidance, and IRB

support will help you identify and comply with them. As a student, you are held to the same ethical and regulatory standards as faculty and staff of the university and are responsible for ensuring the rights and welfare of human subjects in the research.

- If you suspect other(s) have failed to maintain ethical standards in research, you must report such misconduct to the appropriate university authorities. Guidance on what constitutes research misconduct and how to report it may be found in the Policy section.

Students must comply with all IRB requirements for research review (initial and continuing), its conduct and study closure. The student researcher is expected to follow all current IRB policies, procedures and deadlines for IRB initial approval, continuing review, change requests, and other protocol matters.

Students must maintain adequate and timely communication on all research matters with faculty advisors, IRB and other committees, university officials, and funders, if any.

Students must identify a university faculty member to serve as their faculty advisor on the research.

Students must protect the research data from unauthorized disclosure.

Students must complete all training.

11. MAY I SERVE AS THE PRINCIPAL INVESTIGATOR (PI)?

No. A principal investigator is the individual who assumes full responsibility for a research project, including the supervision of any co-investigators, research assistants, house staff and students. Undergraduates may participate on a research project, but not as the principal investigator. Graduate students may not serve as principal investigators at A&M-SA.

Some funding agencies require the student to be listed as the Principal Investigator of Record. A&M-SA IRB will work with the student, School or Department, and the Office of Sponsored Research (ORSP) when such requirements apply.

12. DO I NEED A FACULTY ADVISOR?

Yes. You must identify a full-time A&M - SA faculty member to serve as your faculty advisor. Ideally, your advisor should be familiar with conducting research involving human subjects. Your advisor must complete CITI training.

Your faculty advisor will work closely with you to design, submit and conduct your research. They will assess whether you possess adequate qualifications to conduct the proposed research in a way that safeguards the rights and welfare of subjects. They will monitor your progress throughout the research to ensure it complies with necessary policies and procedures, laws and regulations, and ethical standards of your discipline. Your faculty advisor will help you close the study when completed. When you have questions, your advisor should be the first person you contact. Your advisor will assist you with submissions and communication with the IRB and will help you close the study when completed.

13. HOW DO I APPLY FOR IRB REVIEW OF MY RESEARCH?

All human subjects research is reviewed using the A&M–SA electronic submission system, known as CAYUSE. Students cannot be PI'S on protocols. Faculty members can submit IRB proposals in CAYUSE on behalf of students. Training is available in blackboard. Contact irb@tamusa.edu to enroll.

14. WHAT ARE MY RESPONSIBILITIES TO COMMUNICATE WITH THE IRB?

You and your Faculty Advisor hold joint responsibility to communicate with the IRB when certain milestones or events occur in the conduct of the research. Obligations to communicate with the IRB do not end until the IRB accepts your/Faculty Advisor request to close the study.

Initial Review

Of course, you/your Faculty Advisor must provide sufficient information to the IRB so they can determine if the proposed research is regulatory-compliant and ethically sound. Once reviewed, the IRB will notify you/your Faculty Advisor of any changes you must make or

additional documents you must provide to them before they are able to approve the proposed research, if any. Follow their instructions.

Continuing Review

In the Notice of IRB Approval, the IRB will advise you/your Faculty Advisor if or how often your study must be re-reviewed by the IRB.

Changes to the Research Plan

You/your faculty advisor must notify the IRB of any change(s) you wish to make to an IRB-approved protocol. This includes any request to add to, revise, or remove elements from any document previously approved by the IRB (such as the application, protocol, consent document, recruitment materials, data collection tools, etc.). For example, if a member of the study team changes (such as who serves as your Faculty Advisor) or you wish to change a study design element, you/your Faculty Advisor must submit a modification request and submit it to the IRB and receive their approval ***before*** you make any changes.

Unanticipated Events or Protocol Deviations

If an unexpected or adverse event occurs (such as unexpected subject discomfort…or…your laptop holding research data is stolen), or you notice that you have deviated from the protocol plan (such as failing to secure consent from a subject…or…overlooking a step in protocol plan), you/your Faculty Advisor must submit a report to the IRB that outlines the details of the event or deviation as soon as possible after it occurs. The report must also outline what corrective action(s) you/your Faculty Advisor took and any changes to the protocol you propose to assure the problem(s) does not repeat. If research documents containing subjects' identifiers or your laptop storing research data are misplaced or stolen, report incident to IRB via adverse event form.

Study Closure or Study Withdrawal

You/your Faculty Advisor must submit a request for **study closure** to the IRB when you wish to close the study: (1) because you have completed data gathering and will no longer interact with subjects or hold their private information, or (2) determine you are unable to complete the

research once activities have commenced. If you conducted the research to satisfy degree requirements, do not close out the study until your faculty advisor(s) confirm you have successfully defended your honors project, thesis or dissertation and no further analysis of your research data will be necessary.

You/your Faculty Advisor must submit a request to **withdraw your IRB-approved study** if, for whatever reason, you change your mind about conducting the research before any research activities were initiated (such as recruitment, consent, specimen or data collection).

Data Storage after Study Closure

Your research responsibilities do not end when your study closes. Data retention is an important part of the research process. Research data must be preserved for a set period to comply with federal law, university policy, and funding agency requirements. The data must be well organized and accessible for any reason, including audits.

Your project's data retention requirements depend on the type of data involved. At a minimum, the university requires research data to be retained for 3 years after study closure. If you collected Protected Health Information (PHI), the HIPAA Privacy rule requires research data to be retained for 6 years after study closure. Your Academic School/Department and/or the agency/organization funding your research (if you received funding for your project) may require data to be retained even longer. Please check with your School/Department and funding agency (if applicable) and comply with the longest time required. You may keep your data longer, but not shorter than required.

Some federal (such as FDA) and funding agencies may require investigators to retain subject identifiers for long periods of time for safety reasons. Other studies may retain subject identifiers because, by design, they need long term follow-up or future contact with subjects. In such cases, in addition to details about the length of data storage, the IRB will review in the protocol you submit to them how you will protect any data elements you retain that can identify subjects in the study. You will need to outline where such identifiers will be stored and who/how it will be protected from unauthorized access.

If there is no regulatory agency requirement, funding agency demand or study design justification to retain identifiers, it affords greater protections to destroy identifiers as soon as

possible after the data is collected. In such cases, the protocol should detail when identifiers will be removed from the data collected and how you will destroy identifiers and/or the key codes that can re-identify subjects. While you may destroy the identifiers early, you must still retain the de-identified data for the number of years required consistent with federal law, University policy, or funding agency demands, as outlined above.

When you graduate or leave the university, for any reason, you must arrange to leave a copy of the research data with your advisor; they will *also* retain your research records for the required period of time. If you conducted your research at a non-A&M–SA facility and your data is being stored there, you must ensure that A&M–SA can have access to the data upon request.

15. WHAT OTHER THINGS SHOULD I CONSIDER?

Site Approvals, Other Sites' IRB Approvals and Authorization Agreements

If you plan to conduct research at a **non-A&M-SA institution or organization**, such as an elementary school, community center, or clinic, you must obtain *written permission* (called Site Approvals or Letters of Cooperation) from an authority of the site (Principal, Director, etc.), as identified by the site (not by you) to conduct the research on their property or using their data or samples.

Approvals/Letters of Cooperation must be submitted to the IRB before IRB approval of the research may be granted. A Letter of Cooperation needs to be completed contact IRB office for details.

If you plan to have employees of the non-A&M–SA site 'engage in the research' with you [that is, they will *intervene for research purposes* with any of the subjects of the research, such as, obtain subjects' identifiable information or identifiable biological specimens, perform invasive or noninvasive procedure, interact with subjects to collect research data or obtain research consent, etc.], you must obtain IRB approval from **both** the A&M–SA IRB and the site's IRB.

Sometimes institutions will work together and craft an agreement, called an **IRB Authorization Agreement or Reliance Agreement**, to recognize one site's IRB as the lead review to cover research at both institutions. If a site asks you if they can cooperate with A&M – SA IRB to set up an Authorization Agreement, coordinate a conversation between the site

and the A&M–SA IRB.

Non-A&M-SA site approvals, other institutions' IRB approval, and Authorization Agreements can be tricky. To best help you, it is important that your protocol plan clearly outlines which research tasks will be delegated to members of our university, and which will be delegated to members of the non-A&M-SA institution or organization, if any. If you plan to conduct research at an A**&M-SA-owned or operated site** written permission from the site is not required by the IRB. However, you/your faculty advisor should coordinate your activities with the site before its conduct.

Please note, approvals and authorizations take time. Plan your research timetable accordingly.

Research Opportunities at Other Institutions and IRB Approval

A&M-SA students may engage in human subjects' research through collaboration with researchers at other institutions. However, regardless of IRB review/approval obtained at the other institution, A&M - SA students must also submit the research to a A&M–SA IRB and secure their approval before engaging in research with the other institution.

International Research

The university is committed to protecting people who participate in human subjects' research whether the work is conducted domestically or internationally. If human subjects' research will take place outside of the United States, there are additional requirements, so the IRB process should be started as soon as possible. It is essential that researchers have sufficient knowledge of country laws, regulations and the local research context to be able to design and conduct research in a way that protects the rights and welfare of the subjects and respects their customs and practices.

Students who conduct international research must comply with export controls and IT requirements.

Please Note: the movement of equipment and data stored on laptops and other electronic devices the student may use in the research, as well as shipping materials to/from the international site are regulated by federal export control laws. Visit the Export Control website to learn more about research rules and responsibilities around export control at Export Control

| A&M - SA Research.

Sponsored Research

The A&M–SA Office of Research and Sponsored Programs (ORSP) provides a range of services to faculty and staff seeking funding from public and private non-for-profit sponsors. Services include guidance on proposal submission and award set-up, interpreting sponsor guidelines, and meeting compliance requirements, to name a few. The IRBs work with researchers and ORSP to ensure human subjects' research compliance requirements are met, as well as appropriate and timely coordination of IRB review of funded research. Visit SRS and website SOP's to learn more about the services they provide.

Research Using Social Media

Conducting research using social media requires special considerations, particularly around issues of privacy and confidentiality. All studies, including those using computer and internet technologies, must

(a) ensure that the procedures fulfill the criteria for informed consent: voluntariness, adequate information, and comprehensibility of the information provided.

(b) maintain the confidentiality of information obtained from human subjects.

(c) adequately address the possible risks of harm to subjects, including psychosocial stress and related risks.

(d) equitable representation of the population from which subjects will be recruited to participate.

Research Using Mobile Devices

Conducting research using mobile devices also requires special considerations around issues of privacy and confidentiality, especially when communicating with subjects, storing subject data, and transporting subject data.

Conflict of Interest

Per System Regulation 15.01.03 and A&M-SA Rule 15.01.03.01 all university faculty, staff, and students who conduct research, funded or unfunded must disclose financial information

that may influence or may be perceived to influence their work. The policy is intended to promote objectivity in research with the reasonable expectation that the design, conduct, and reporting of the research will be free from
bias resulting from research conflict of interest.

Clinical Trials Registration

ClinicalTrials.gov (Home | ClinicalTrials.gov) is a public database that offers up-to-date information for locating federally and privately supported clinical trials for a wide range of diseases and conditions. Researchers conducting clinical trials that meet certain federal requirements must register their clinical trial at this site. The responsibility to register rests with the principal investigator.

Post Approval Monitoring

Consistent with its mission to create a culture of research integrity and compliance, the ORC team conducts random, periodic audits of university research involving human subjects. Your research may (or may not) be subject to an unannounced quality assurance audit sometime before study closure.

16. IN CLOSING

We all share responsibility for assuring that the rights and welfare of the individuals involved in university research. The university, your School or Department, your Faculty Advisor and IRB staff stand ready to help you navigate the IRB process to make the research experience meaningful and rewarding to you and further the research mission of the university. Our collaborative efforts to work as partners in research serve to minimize the burdens to human volunteers and maximize the benefits to science and society. Good Luck in your research endeavors!

17. NOW WHAT?

Follow this checklist to get started on your goal to conduct meaningful and compliant human subjects' research.

- ☐ Read the Student Handbook: A Guide to Human Research Protection in Research.
- ☐ Complete all courses your School/Department deems pre-requisite to conducting human research.
- ☐ Identify a faculty advisor.
- ☐ Register with CITI and complete your online training.
- ☐ Work with your faculty advisor to identify and review relevant regulations, laws, institutional policies and discipline practices that inform how you must conduct the research you imagine responsibly and compliantly.
- ☐ With Faculty Advisor oversight, draft the research documents you need for the IRB submission packet (i.e., protocol, consent documents, data collection tools, etc.).
- ☐ Secure written Site Approval and/or IRB Approval from institutions where you propose to conduct research activities, if any.
- ☐ Submit financial disclosure form/documents to the Conflict-of-Interest Committee.
- ☐ Ensure you have completed all documents required by the A&M–SA Office of Sponsored Research and the grantor if your research is funded.
- ☐ Coordinate your efforts with A&M–SA Export Control if you propose international research.
- ☐ Work with your advisor to complete an IRB application, append required research documents and permissions, and submit the packet for IRB review when you have completed the steps above.

IMPORTANT: Remember, you may not engage in any form of human research, including reviewing patient charts, recruiting or enrolling human subjects or analyzing databases until written IRB approval is secured or a Non-Human Research Determination is made.