The University of Texas Rio Grande Valley

Institutional Review Board

Student IRB Manual

January 22, 2026

[Version 1.0]

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What is the purpose of this manual?

This Student IRB Manual is designed to provide guidance for faculty advisors and student investigators through IRB review process. This manual will also assist with understanding and navigating through policies and standard operating procedures (SOPs) related to the facilitation of student led human subjects research at UTRGV.

What is Research?

Research is defined as "a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge[1]." **Student theses and dissertations by default, are designed to contribute to generalizable knowledge**. Individual projects in research methods courses may or may not fall under the definition of "Research," based on numerous variables including but not limited to the intent of disseminating results outside of the classroom, if subjects are only the class participants, the activity is presented as a learning experience to participants outside of the class, and etc. However, such activities do require notification to the IRB Office if the project involves typical research-related activities (including but not limited to: informed consent, interviews, focus groups, surveys) involving human subjects.

What is a Human Subject?

Human subjects means a living individual about whom an investigator (whether professional or student) conducting research (i) obtains information or biospecimens through intervention or interaction with the individual, and uses studies, or analyzes the information or biospecimens; or (ii) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens[2].

The faculty advisor and their student investigator are responsible for ensuring that IRB approval (or an organizational review and approval of exempt Human Research or determination of Not Human Subjects Research [NHSR]) is obtained before conducting human subjects research. If you have questions about whether a thesis or dissertation meets the definition of human subjects research, the IRB Office is available for guidance. You may contact the IRB Office any time at IRB@utrgv.edu.

How does working with the Doctoral Support Program aid student investigators and faculty advisors?

Doctoral students are highly encouraged to participate in the Doctoral Support Program. This program is designed for doctoral students, but all students are welcome to participate. The program is designed to facilitate high quality protocol submissions, reducing review time and interpreting IRB expectations throughout the review process.

The Doctoral Support Program offers the following services:

- Verifying that the doctoral student's dissertation committee approved their dissertation proposal before IRB submission.

[1] 45 CFR 46.103(d)
[2] 45 CFR 46.102(f)

The Doctoral Support Program offers the following services:

- Verifying that the doctoral student's dissertation committee approved their dissertation proposal before IRB submission.
- Tracking doctoral student's progress by collaborating with department officials to monitor IRB progress and ensure timely IRB application submission.
- Providing one-to-one sessions with doctoral students and their faculty advisors in completing their IRB application and preparing supporting documents to reduce submission errors.
- Providing in depth review of IRB applications prior to submission for consistency, completeness, and accuracy.
    - Preliminary reviews of associated documents and attachments to ensure readiness for submission.
- Providing guidance to doctoral students and faculty advisors on how to structure their research to meet ethical and regulatory standards.
- Advising on the most appropriate IRB pathway, including whether the research requires an IRB application or qualifies for a Not Human Subjects Research (NHSR) determination.
- Providing training/reference materials for doctoral students and faculty advisors.

To enroll contact Itzel Solis itzel.solis02@utrgv.edu.

Who must have a Faculty advisor?

Student research projects are reviewed using the same guidelines and regulatory requirements followed by the IRB for the protection of human subjects in general. ***All student-initiated and student-conducted human subjects research must be reviewed and approved by the IRB before initiation.*** All research projects for which a student serves as Principal Investigator (PI) require that a full-time faculty member (typically the thesis/dissertation committee chair/faculty advisor), be designated as the faculty advisor on the IRB Application. Other thesis or dissertation committee members who will be engaged in the research (recruitment, consent, study procedures, or review of identifiable data) should be listed as study team members. Post Doctoral Fellows cannot serve as Faculty advisor on student-led research.

What is the Faculty advisor's Role?

Faculty advisors are responsible for guiding student investigators through each phase of the IRB process. They must be familiar with research methods specific to the field of study and stay informed regarding the rules and regulations governing research at UTRGV. The faculty advisor should be the primary resource when student investigators have questions or need assistance with their projects. IRB personnel may also serve as a resource. Specific office hours and appointments are available to both students and faculty advisors for this purpose.

Faculty advisors are responsible for:

- Evaluating whether the student investigator has sufficient knowledge and experience

  - to conduct the proposed research, including the completion of required online human subjects' protection training (CITI) and any other relevant and protocol-specific research-related training.

- Before IRB submission reviewing all documentation compiled by the student to:
  - Verify scientific merit and appropriate study design for relevant field
  - Ensure the project meets criteria for degree satisfaction
  - Ensure field-specific codes of conduct are adhered to
- Ensuring that the proposed research is not initiated (including advertisement/recruitment/consenting) until final written approval from the IRB has been obtained.
- Providing ongoing supervision of the submission and conduct of the study, including advising the student on clarifications/changes requested by the IRB, monitoring the progress of the project and ensuring continued adherence to the protocol and regulatory requirements (e.g. timely submission of unanticipated problems, reporting issues of noncompliance, using approved documents/tools, avoiding over enrollment of subjects, and project closeout when the research is completed).
- Keeping abreast of the policies and procedures of the UTRGV IRB, the published guidelines for the ethical conduct of research relevant to the field of inquiry, and state and federal regulations; providing the student investigator with guidance on the protection of human subjects as necessary. (See appendix A)

What is the Student Investigator's role?

Students serving as Principal Investigators are responsible for:

- Participating in the Doctoral Support Program (strongly encouraged);
- Ensuring the research is not initiated until IRB final approval is received;
- Facilitating the overall design and conduct of the study, and ensuring compliance with the IRB-approved protocol throughout the duration of the research;
- Contacting the faculty advisor, Doctoral Support Program representative, and or the IRB for any questions related to the IRB submission process or the conduct of the research;
- Ensuring the conduct of the research team, including the assurance that all
  - team members read and understand the protocol and are trained on applicable study procedures;
- Ensuring the protection of the rights and welfare of human subjects including obtaining informed consent, maintaining privacy during interaction with subjects, and confidentiality of data as outlined in the protocol;
- Submission of modification(s) within online database system and awaiting IRB approval before implementing changes to the study;
- Reporting any unanticipated problems or issues of noncompliance identified by study

- team members or participants in the research to the IRB, using the
- "IRB Protocol Deviation/Possible Noncompliance Report Form" which is located on the IRB webpage; and
- Consultation with the faculty advisor and identification of protocol modifications warranted by unexpected events and circumstances.

What training do faculty advisors and Student Investigators need when conducting Human Research?

All study team members, *including faculty advisors,* must complete required human subjects training before the conduct or supervision of student research. Access the Citi Program and create an account using your UTRGV email and affiliating with UTRGV using the following instructions. Then complete two or three of the following modules:

- One of the options listed under "Human Subjects Research" and
- One of the options listed under "Responsible Conduct of Research".
- When conducting clinical research also complete the appropriate option for your research under "Good Clinical Practice"

Additional CITI training modules are required for anyone working with Protected Health Information (PHI) or student/educational records under FERPA. Human subjects training completion is pulled into the online database system from CITI. If the training does not populate into the "training" tab in online database system, please check the team member's CITI account to verify that their profile matches the online database system account profile exactly (name and @UTRGV email address). Accounts linked to email addresses other than UTRGV.edu will not link to the online database system. If the name and email address do not match, please update the CITI profile to reflect the correct information as it appears in online database system. There is also the option of uploading your CITI training certificate as an attachment in the online database system. Training must be completed before IRB approval.

If CITI training was completed at another institution, access the existing CITI account and choose "Affiliate with Another Institution." Add the UTRGV and complete the registration process. Note that there may be additional modules to complete to fulfill the UTRGV training requirements.

Training is valid for a four-year period, after which time a refresher course must be taken. All study team members should be provided with a copy of the approved protocol and be trained specifically on approved protocol requirements and processes.

What activities require IRB Review?

Activities meeting both the definitions of "research" and "human subjects" as outlined above must be submitted for review. IRB Coordinators may be contacted to provide assistance with determining the need for IRB review. Once determined to be human subjects research, any non-exempt protocol is reviewed by the IRB (or designated IRB reviewer) using the federal guidelines.

While some low-risk human research activities fall under an exempt review category a protocol is still required and is reviewed by administrative staff in the IRB Office using criteria similar to the criteria of approval.

All resources can be found on the IRB website. Faculty advisors and student investigators are encouraged to use these resources to write their Protocol in a way that addresses the criteria for approval. If you are still unsure, please contact our office for guidance.

If the faculty advisor believes the student investigator will need a formal determination letter of "not human subjects research[5]," they will need to complete an Request for Determination That a Proposed Activity is Not Research Requiring IRB Oversight application. Ensure that any supporting documents that may help with the determination are attached, in case a full review is determined to be required. Remember, student investigators may not begin any research activity involving human subjects until the IRB has issued approval correspondence specific to that activity.

What is the process for faculty advisors to support their student investigators with submitting Human Subjects Research to the IRB?

- Review all information outlined in the Getting Started section of the IRB Website.
- The student investigator and their faculty advisor will need to complete the required training on human subject protections.
- Obtain access to the online database system to complete the IRB application.

What is the process for faculty advisors to request reliance on another IRB for their student investigator?

Reliance agreements are arrangements between institutions allowing the IRB of one institution to rely on the IRB of another institution for review of collaborative or multi-site human subjects research. Sometimes student investigators choose to conduct research or gather research data at an institution where he/she works for his/her UTRGV thesis or dissertation. If this is the case, as the research is being conducted to fulfill a UTRGV degree requirement, UTRGV oversight is still required but may be able to be fulfilled through reliance on the other institution's IRB. If you have a student in this situation, please contact the IRB Office for guidance. Additional information may also be found on the UTRGV IRB webpage under Collaborative Research with External Institutions.

How does a student investigator write a Protocol?

Student investigators are encouraged to engage in discussions with their faculty advisors to refine their research question(s) and receive guidance on structuring their study in accordance with professional and ethical standards. This collaboration ensures that the research is appropriately designed to yield meaningful and valid results. Additionally, both the student investigator and the faculty advisor should thoroughly review all relevant guidance documents and reference materials available on the IRB webpage.

[5] Some journals may require this determination for publication; check journal requirements and if needed, obtain this determination prior to initiation of the research.

If further clarification is needed, they may consult with IRB staff to address any specific ethical considerations or regulatory requirements.

- If UTRGV students will be recruited as research participants, this must be identified in the protocol. In most cases, an individual with access to or influence on the student's grades may not be involved in recruitment or informed consent, or in the review of identifiable data for the study. This policy addresses the IRB requirement to avoid undue influence in subject selection. If extra credit will be offered as an incentive for participation, it may not be the only method by which extra credit may be earned in the course.

How does a student investigator create an informed consent document?

It is highly recommended that all UTRGV research use(s) the template informed consent forms located on the IRB webpage. Various versions of consent documents are available including parental permission and child assent which are required for research involving subjects under the age of 18 in the state of Texas.

Note that all consent documents must contain the required elements of informed consent as well as all additional appropriate elements defined by federal regulations.

The templates provided contain these elements.

Some studies may qualify for a waiver of documented consent (for example, low-risk survey research conducted online). In these cases, all elements of informed consent must still be provided, although physical signature is waived. In other cases (such as reviewing archival data), the consent process may be waived altogether. Both of these options require that specific regulatory criteria are met; please consult IRB staff if you need guidance/clarification on waivers/alterations to the informed consent process.

What are the different regulatory classifications of review for research activities?

Submitted activities may fall under one of the following five regulatory classifications:

- Not Research: Activities must meet the definition of "Research" to fall under IRB oversight. If a project does not meet the definition of research provided above (for example, it is not intended to generate generalizable information), a submission to the IRB is not required. Contact the IRB Office in cases where it is unclear whether an activity is Human Research. All theses and dissertations meet the "generalizable information" threshold.
- Not Human Subjects Research (NHSR): Activities must involve "Human subjects" to fall under IRB oversight. Activities that do not meet the definition above are not subject to IRB oversight or review. Additional information on NHSR can be found on the IRB webpage along with the Request for Determination Not Regulated Research Form. Contact the IRB staff in cases where it is unclear whether an activity is Human Research.

- Exempt Review: Certain categories of Human Research may be exempt from regulation but still require IRB Office/institutional review. It is the responsibility of the institution, not the student investigator, to determine whether Human Research is exempt from IRB review.
- Expedited Review: Certain categories of non-exempt Human Research defined by the regulations may qualify for review using an expedited procedure. This means that the project may be reviewed by a single designated IRB member, rather than a fully convened board.
- Review by the Convened IRB: Non-Exempt Human Research that does not qualify for expedited review must be reviewed by the convened IRB. The fully convened IRB meets monthly; submission deadlines and meeting dates can be found on the IRB website.

What are the turnaround times for submission?

When developing a research protocol and study materials, be sure to plan ahead! The process may take additional time depending on the nature of the research and the quality of the protocol submitted. Think through all the details of the research and review all guidance documents. (See Where is my IRB application?)

- Student investigators and faculty advisors should work together to discuss the protocol and research methodology before IRB submission; the faculty advisor should review the submission in full to ensure:
  - Scientific validity of the research;
  - Ensure that the project meets degree requirements; and
  - Verify that the submission is complete.
- Once the protocol has been submitted in online database system, a Pre-Review is conducted by IRB staff within 7-10 business days to verify general completeness of the application, verify training status of all research team members, ensure that study tools and consent documents are attached, and to determine review category. The IRB staff member will request modifications to areas that are incomplete before moving the protocol forward for detailed review. If a protocol is incomplete, there may be significant delays in the review process.
- If the protocol meets exempt or expedited review criteria, it is reviewed on a rolling basis in the order received (i.e., it does not get assigned to a convened meeting). This review typically takes 7-10 business days once pre-review modifications are addressed. Turnaround times may be slightly longer at peak times for student submissions. Again, please plan and submit early if possible.
  - If an application meets full board review criteria, the convened IRB meets once each month. Please see the IRB website for meeting dates if you think the application will require a convened IRB review. As these protocols are more complex or may carry a higher degree of risk, it is important to plan the timing of the submission appropriately and understand that the total turnaround time may be longer. Feedback from convened

IRB meetings will be provided 7-10 business days following the meeting.

- Almost all protocols require at least minor revisions following review (see Figure 1), many of which can be reviewed within the IRB Office. Time should be factored in to consider and respond to these revisions, and for the IRB Office to review them and provide final approval. Please respond to all requested revisions as thoroughly as possible to avoid additional delays.

The IRB may approve research, require modifications to the research to secure approval, defer research, or disapprove research.

- **Approve**: This determination is made when all criteria for approval are met.
- **Modifications Required to Secure Approval**: This determination is made when the IRB or designated reviewer requires specific, clear-cut modifications to the research before approval can be granted. This means that all regulatory review criteria have been met; however additional modifications or documents must be provided for the protocol to be considered complete (for example, minor modifications to consent forms, revision of a flyer, or completion of training). Modifications may be reviewed by the IRB Office staff.

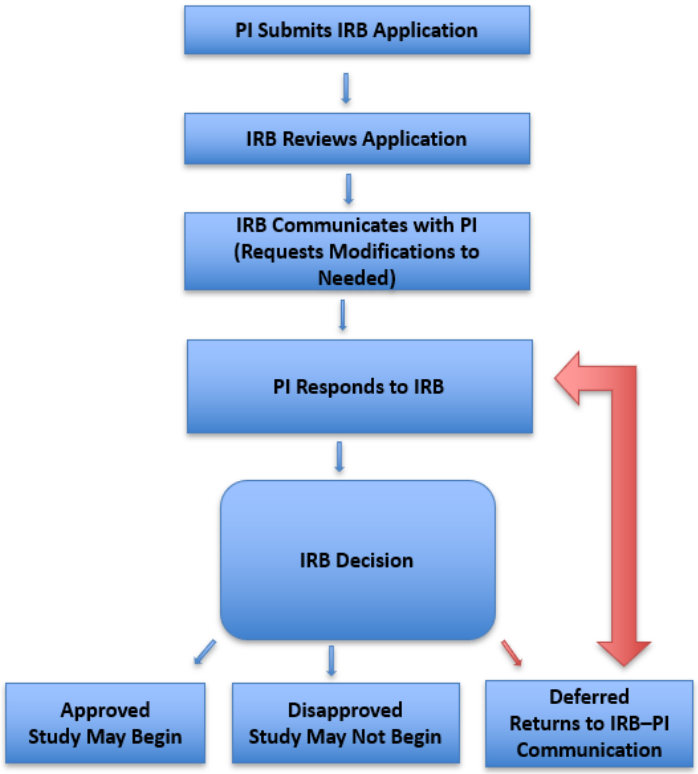

Figure 1 IRB Approval Process

- **Deferred**: This determination is made when the convened IRB determines that regulatory review criteria either have not been met, or that not enough information is provided to determine if these criteria have been met (for example, risks to subjects are unclear or not minimized, subject selection is not equitable, the consent process described is not approvable). When making this motion, the IRB describes its reasons for this decision, offers suggestions for revisions to address these concerns, and provides the investigator an opportunity to respond by providing additional information or justification to the IRB. Responses to a deferred protocol require review by the full committee at a convened IRB meeting.
- **Disapprove**: This determination is made when the IRB determines that it is unable to approve research because the protocol does not meet regulatory approval criteria and the IRB also cannot describe modifications that might make

the research approvable in its current state or design. When making this motion, the IRB describes its reasons for this decision and gives the investigator an opportunity to re-write and resubmit the protocol. The investigator may request to be allotted time in a convened meeting to discuss the issues with the board. The research may also be disapproved at an institutional level if it involves subject areas or procedures unacceptable to the university's vision or mission. The Institutional Official may not approve a study if the IRB has disapproved it. Protocols that are disapproved require a full re-design and a new submission to be reconsidered by the IRB/institution.

In all cases, faculty advisors and student investigators have the right to work directly with the IRB and IRB Office to address required corrections and their concerns regarding IRB review.

What are the faculty advisor and student investigator's obligations after IRB approval?

- Human Research activities, including advertisement and recruitment, may not commence until the student has received the final IRB approval letter.
- Human Research activities may not begin until all other required institutional approvals have been obtained.
- Ensure that there are adequate resources to carry out the research safely. This includes, but is not limited to, sufficient investigator time, appropriately qualified research team members, equipment, and space.

- Ensure that Research Team members remain qualified (e.g., including but not limited to appropriate training, education, expertise, credentials, protocol requirements and, when relevant, privileges) to perform procedures and duties assigned to them during the study.
- Personally conduct (and supervise, if additional team members are involved) the Human Research.
    - Conduct the Human Research based on the relevant current protocol as approved by the IRB.
    - Ensure that consent or permission is obtained according to the relevant current approved protocol.
    - Do not initiate modifications to research without prior IRB review and approval unless necessary to eliminate apparent immediate hazards to subjects (such

    - changes must be reported to the IRB as soon as possible with adequate justification).
    - Protect the rights, safety, and welfare of all subjects involved in the research.
- Submit to the IRB:
    - Any proposed modifications as described in this manual, including changes to study personnel. (See "How do we submit a modification?")
    - A continuing review application annually or otherwise as requested in the
    - approval letter. (See "How do we submit continuing review?")
    - A continuing review application when the Human Research protocol is to be closed. (See "How Do we Close Out a Study?")

- Report required information to the IRB promptly:
    - Information that indicates a new or increased risk, or a new safety issue. For
    - example:
        - New information (e.g., an interim analysis, safety monitoring report, publication in the literature, sponsor report, or investigator finding) that indicates an increase in the frequency or magnitude of a previously known risk, or uncovers a new risk
        - Protocol violation that harmed subjects or others or that indicates subjects or others might be at increased risk of harm
        - Complaint of a subject that indicates subjects or others might be at increased risk of harm or risk of a new harm
        - Any changes significantly affecting the conduct of the research
    - Harm experienced by a subject or other individual, which in the opinion of the investigator are **unexpected** and **probably related** to the research procedures.
- Harm is "**unexpected**" when its specificity or severity are inconsistent with risk information previously reviewed and approved by the IRB regarding nature, severity, frequency, and characteristics of the study population.
- Harm is "**probably related**" to the research procedures if in the opinion of the investigator, the research procedures more likely than not caused the harm.
    - Non-compliance with the federal regulations governing human research or with the requirements or determinations of the IRB, or an allegation of such non-compliance. Please note that instances of noncompliance, such as over-enrollment of subjects or conducting research before approval or following the expiration of the protocol (i.e., without IRB approval) may result in corrective action, including not using the noncompliant data for research purposes.
    - Audit, inspection, or inquiry by a federal agency and any resulting reports.
    - Written reports of study monitors.
    - Failure to follow the protocol due to the action or inaction of the investigator or research staff
    - Breach of confidentiality, including but not limited to loss or theft of identifiable research data.
    - Change to the protocol taken without prior IRB review to eliminate an apparent immediate hazard to a subject
    - Incarceration of a subject in a study not approved by the IRB to involve prisoners, if you wish for that subject to continue participation while incarcerated.
    - Complaint from a subject that cannot be resolved by the research team.
    - Premature suspension or termination of the protocol by the sponsor, investigator, or institution.
- Ensure team members follow the UTRGV Conflict of Interest policy in disclosing financial interests that relate to the research within 30 days of acquiring the interest.
- Follow additional requirements of federal agencies that fund and/or oversee the research (such as the Department of Education) detailed in the appendices to this document. These represent additional requirements and do not override the baseline requirements of this section.

How do we document consent?

Please keep in mind that consent is a process (see Figure 2) and not simply a document and should represent an ongoing dialogue between the study team and the subject in most cases.

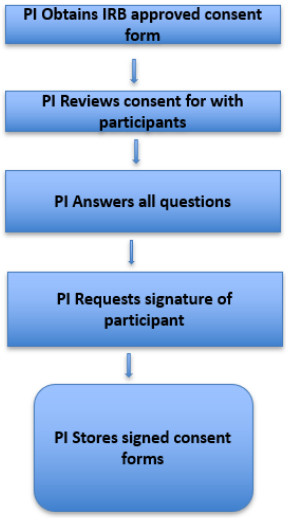

Figure 2 Informed Consent Process

The following are the requirements for long-form consent documents:

- The subject or representative signs and dates the consent document.
- Whenever the IRB or the sponsor requires a witness or for subjects who cannot read and whenever required by the IRB or the sponsor, a witness to the oral presentation signs and dates the consent document. The subject can indicate their consent by "making their mark" on the consent document.
- A copy of the signed and dated consent document is to be provided to the subject. A signed and dated copy must also be maintained in the research record and maintained separately from coded or identifiable data.

The following are the requirements for Waiver of documentation of Consent:

- This waiver is typically used when the research participants are not physically present to sign an informed consent form and the study is minimal risk.
- Faculty advisors should discuss the need and applicability of waivers of documentation with the student investigator to ensure that the regulatory requirements are met.
    - *That the only record linking the subject and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality;*
    - *That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context; or*
    - *If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.*
- The IRB application must be completed answering all questions related to informed consent and the waiver of documentation.

How do we submit a modification?

The student investigator should identify all potential change(s) to the approved and any necessary documents depending on the potential change(s). The student investigator should follow the guidelines to submit modification in the online database system. Maintain

electronic copies of all information submitted to the IRB in case revisions are required. Please note that research must continue to be conducted as approved without the inclusion of the proposed changes until written IRB approval is received. Updates to the list of study personnel will be approved administratively by office staff unless the update represents an additional modification to the research, the change is to appoint a new PI, or potential conflict of interest requires further review. New personnel will not be approved until they have completed the

Outside Activities Disclosure and CITI training requirements.

What Happens if IRB Approval Expires and How to Address Check ins?

If IRB approval of a human subjects research protocol expires, all research procedures related to the protocol must cease, including recruitment, advertisement, screening, enrollment, consent, interventions, interactions, and collection or analysis of private identifiable information.

Continuing research during a lapse in protocol approval is a violation of both federal and UTRGV policy. If current subjects may be harmed by stopping research procedures that are not available outside the research context, contact the IRB coordinator or Chair immediately and provide written justification stating how subjects can be harmed by stopping Human Research procedures and provide a list of the currently enrolled subjects this applies to. The IRB will provide further direction.

When a research project does not have an expiration date annually the PI/research team will receive notification for an annual check-in. This check-in will include three questions 1) Is the research activity ongoing? 2) Have there been any changes to your project since initial approval or the last approved modification? 3) Is the study ready for closure? This process will continue until the project is completed and closed out in the database system.

If a student investigator anticipates leaving the institution or graduating and the research will continue, the student investigator should consult with the faculty advisor and submit a modification to change the PI prior to graduation.

How do we close out a study?

Once research is complete (including analysis of identifiable data), all studies should be formally closed in online database system. Follow the guidance in the "How do I request Project Closure in tick@lab" to close a study.

How long do we keep records?

All records related to IRB-approved human subjects research, including signed and dated consent documents, must be securely maintained **on the UTRGV campus or on the UTRGV server** for at least three years following completion of the research. Maintain signed and dated HIPAA authorizations and consent documents that include HIPAA authorizations for at least six years following completion of the research. Student investigators should state within the protocol document that their faculty advisor (or other individual specifically designated by the college or department) will maintain the records on campus and list the faculty advisor's building and room number. Electronic records stored on a secure university server are also a

sufficient means of storage. If the department has a designated location for long-term storage, this location and the individual responsible for long-term storage may be listed as well.

If the student investigator's research project is sponsored and/or under the oversight of additional federal agencies (for example, NIH-funded research), additional maintenance requirements may apply. Carefully review the requirements of the sponsor and/or agency prior to disposing of research records.

What are additional services provided to student investigators and faculty advisors?

If faculty advisors and student investigators have specific questions about preparing a student protocol and/or other research-related documents, office hours are listed on the IRB website. If these hours conflict with the student investigator's schedule, you may also schedule an appointment to meet with the IRB coordinator(s). Student investigator IRB services available include:

- The opportunity to ask questions about the IRB submission and review process,

  including whether the study qualifies as human subjects research and what application materials are required
- Discussion of human subjects' issues as related to the student's specific project
- Guidance to students on the drafting of their protocol prior to submitting it to the IRB (pre-review)
- Hands-on assistance with the IRB module of the online database system online system

IRB staff are also available to provide human subjects training sessions (ethical principles, online database system instruction, case studies as applicable, and mock IRB sessions) as a guest lecture in research methods courses or lab meetings. Contact irb@utrgv.edu to schedule.

How do we get additional information and answers to questions?

This document and the policies and procedures for the Human Research Protection Program are available on the IRB Web Site at Institutional Review Board (IRB) | UTRGV

If you have any questions or concerns about the Human Research Protection Program, contact the IRB Office at:

Office of Research Compliance
MRIOB 4th Floor
701 E. Expressway 83
McAllen, TX 78501
Main IRB Office number: (956) 665-3364
IRB email: irb@utrgv.edu

The IRB has the responsibility to investigate allegations of non-compliance and require corrective actions as needed. The IRB may also suspend the conduct of a study to protect human subjects pending an investigation of noncompliance or if the risk assessment must be updated and reconsidered based on new information.

Questions, concerns, complaints, allegations of undue influence or non-compliance, or input regarding the Human Research Protection Program (HRPP) may be reported orally or in writing. Concerns may be reported to the IRB Chair, IRB Office, or Director of the Office of Research Compliance.

Faculty, staff, and students are also permitted to report concerns on an anonymous basis using the utrgv.ethicspoint.com.

Employees and students who report in good faith possible compliance issues may not be subjected to retaliation or harassment as a result of the reporting. Concerns about possible retaliation should be immediately reported to the Chief Compliance Officer.

Additional IRB Contacts:

Eric Allen
Director, Office of Research Compliance
Email: eric.allen@utrgv.edu
Phone: (956) 665-3494

Christy Richardson
Senior IRB Coordinator, CIP
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Phone: (956) 665-3598

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IRB Coordinator
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Phone: (956) 665-3378

Appendix A

Additional references/resources

Committee Charter for AI, Data, and Privacy Governance
UTRGV Artificial Intelligence Policy
TRAIGA Disclosure Guidance
Code of Ethics for Responsible AI
UTRGV Research Data Retention and Disposal Policy

Where is my IRB application?
IRB application checklist

UTRGV IRB main page: https://www.utrgv.edu/research/departments/research-integrity/research-compliance/irb/index.htm
IRB Education & Guidelines: https://www.utrgv.edu/research/departments/research-integrity/research-compliance/irb/irb-education-and-guidelines/index.htm
Trainings (CITI): https://www.utrgv.edu/research/departments/research-integrity/research-compliance/irb/training/index.htm
Researcher's Handbook (Getting Started): https://www.utrgv.edu/research/departments/research-integrity/research-compliance/irb/getting-started/index.htm
Questions to Ask (Participants): https://www.utrgv.edu/research/departments/research-integrity/research-compliance/irb/questions-to-ask/index.htm
OHRP Guidance: https://www.hhs.gov/ohrp/regulations-and-policy/guidance/index.html