



The University of Texas at San Antonio
Knowledge Enterprise

Investigator Manual

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Investigator Manual

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What is the purpose of this manual?

This document is designed to guide you through policies and procedures related to the conduct of human subjects research that are specific to this organization.

General information regarding human subjects research protections and relevant federal regulations and guidance is incorporated into the required human subjects protections training. For additional information see below: “What training does my staff and I need in order to conduct human subjects research?”

What is human subjects research?

“POLICY: Human Research Protection Program (HRP-010)” defines the activities that this organization considers to be “Human Subjects Research.” Use this document for guidance, keeping in mind that the IRB makes the ultimate determination in questionable cases as to whether an activity constitutes human subjects research subject to IRB oversight.

You shall not conduct human subjects research without prior IRB review and approval. If you have questions about whether an activity is human subjects research, contact the IRB Office who will provide you with an assessment. If you wish to have a written determination, submit an IRB application through Cayuse, our online submission portal.

If you have questions about whether an activity requires IRB review, contact the IRB Office.

What is the Human Research Protection Program?

A Human Research Protection Program or HRPP is an organization-wide system to protect human subjects in research. It is described in “POLICY: Human Research Protection Program (HRP-010).”

What training do my staff and I need to conduct human subjects research?

All members of the research team involved in the design, conduct, or reporting of the research must complete training.

Investigators and staff conducting human subjects research must complete the Collaborative Institutional Training Initiative (CITI) human subjects online training program. The Social/Behavioral Research Course or the Biomedical Research Course are acceptable. Please note the Responsible Conduct of Research courses do not meet the UTSA training requirement. Investigators and staff conducting research must also update their Conflict of Interest Training and Disclosure (COI).

The CITI site can be accessed at <http://www.citiprogram.org/>.

The COI site can be accessed at <https://oric.utsa.edu/coi>.

CITI training is valid for a three-year period, after which time the training must be repeated.

COI Training and Disclosure must be updated every January 1st.

This section describes the training requirements imposed by the IRB. You may have additional training imposed by other federal, state, or organizational policies.

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Members of the research team who have not completed human subjects research protections training may not take part in aspects of the research that involve human subjects.

What are the obligations of individuals who conduct human subjects research?

The obligations of individuals who conduct human subjects research can be found in these documents:

- INVESTIGATOR GUIDANCE - Investigator Obligations (HRP-800)
- INVESTIGATOR GUIDANCE - Prompt Reporting Requirements (HRP-801)
- INVESTIGATOR GUIDANCE - Informed Consent (HRP-802)
- INVESTIGATOR GUIDANCE - Documentation of Informed Consent (HRP-803)
- INVESTIGATOR GUIDANCE - Additional DOD Obligations (HRP-810)
- INVESTIGATOR GUIDANCE - Additional DOE Obligations (HRP-811)
- INVESTIGATOR GUIDANCE - Additional DOJ Obligations (HRP-812)
- INVESTIGATOR GUIDANCE - Additional ED Obligations (HRP-813)
- INVESTIGATOR GUIDANCE - Additional EPA Obligations (HRP-814)
- INVESTIGATOR GUIDANCE - Additional FDA Obligations (HRP-815)
- INVESTIGATOR GUIDANCE - Additional ICH-GCP Obligations (HRP-816)

How do I submit new human subjects research to the IRB?

PIs will submit their study through our online IRB submission portal, [Cayuse](#). If you have not used Cayuse before, please email IRB@utsa.edu with your name, UTSA email and network ID (abc123) and an account will be created for you. If you are a student, you will need to add your faculty sponsor as a Co-PI. If their name is not available in the search results, they will need to email the IRB Office to have an account created for them as well.

How do I write an Investigator Protocol?

All protocol questions will be asked in Cayuse. Based on the answers to your questions, additional questions may populate within the online application. Be as thorough as possible so the reviewer understands what your study objective is. This will help the review process run quicker. You will need to upload documents, such as recruitment flyers, survey outlines, consent forms, etc. Please upload those in PDF format.

Once all required sections are completed, all staff listed as PIs or Co-PIs will “Certify” the study and submit it to the IRB Office. Your study will be placed in a queue and reviewed in the order in which it was received. All correspondence will go through the Cayuse website once you have successfully submitted your study.

How do I create a consent document?

You may use “TEMPLATE Consent (HRP-500)” or “TEMPLATE Consent Not Requiring Signature (HRP-501)” to create a consent document. Date the revisions of your consent documents to ensure that you use the most recent version approved by the IRB.

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What are the different regulatory classifications that research activities may fall under?

Submitted activities may fall under one of the following five regulatory classifications. The criteria to determine which classification an activity falls under can be found in 45 CFR 46. Contact the IRB Office for help determining which category your research falls under, if necessary.

- Not “Human subjects Research”: Activities that do not meet the organizational definition of “Human subjects Research” do not fall under IRB oversight.
- Human subjects research that does not engage the institution: Some human subject research requires review by an IRB, but is not the responsibility of the organization. human subjects
- Exempt: Certain categories of human subject research may be exempt from regulation but require IRB review. It is the responsibility of the organization, not the investigator, to determine whether human subjects research is exempt from IRB review.
- Review Using the Expedited Procedure: Certain categories of human subject research are not exempt but may qualify for review using the expedited procedure, meaning that the project may be approved by a single designated IRB reviewer, rather than the convened board.
- Review by the Convened IRB: Non-exempt human subject research that does not qualify for review using the expedited procedure must be reviewed by the convened IRB.

What are the decisions the Convened IRB can make when reviewing proposed research?

The IRB may approve research, require alterations to the research to secure approval, table research, or disapprove research:

- Approve: Made when all criteria for approval are met. See “How does the IRB decide whether to approve human subjects research?” below.
- Conditionally Approve: Made when IRB members require specific modifications to the research before approval can be finalized. The IRB describes the required modifications and their reasons, and gives the investigator an opportunity to respond to the IRB in person or in writing.
- Defer: Made when the IRB determines that the board is unable to approve research and the IRB suggests modifications the might make the research approvable. The IRB describes the recommended modifications and their reasons, and gives the investigator an opportunity to respond to the IRB in person or in writing.
- Disapprove: Made when the IRB determines that it is unable to approve research and the IRB cannot describe modifications the might make the research approvable. The IRB describes its reasons for this decision and gives the investigator an opportunity to respond to the IRB in person or in writing.

How does the IRB decide whether to approve human subjects research?

The criteria for IRB approval for human subjects research can be found in 45 CFR 46.

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What will happen after IRB review?

The IRB will provide you with a written decision indicating that the IRB has approved the human subjects research, requires alterations to secure approval, or has disapproved the human subjects research.

- If the IRB has approved the human subjects research: The human subjects research may commence once all other organizational approvals have been met. IRB approval is good for one or three years, which is noted in the approval letter. You will be required to submit a request prior to the study expiration date to maintain ongoing IRB approval.
- If the IRB conditionally approved your research and you accept the alterations: Make the requested alterations and submit them to the IRB. If all requested alterations are made, the IRB will issue a final approval. Research cannot commence until this final approval is received. If you do not accept the alterations, write up your response and submit it to the IRB.
- If the IRB deferred the human subjects research: The IRB will provide a statement of the reasons for deferral and suggestions to make the study approvable, and give you an opportunity to respond in writing. In most cases if the IRB’s reasons for the deferral are addressed in an alteration, the human subjects research can be approved
- If the IRB disapproved the human subjects research: The IRB will provide a statement of the reasons for disapproval and give you an opportunity to respond in writing.

In all cases, you have the right to address your concerns to the IRB directly at an IRB meeting.

How do I submit an ongoing IRB approval request?

If your study was approved prior to October 2020, contact the IRB Office to inquire about which form is necessary. The IRB office will notify you if you need to complete “FORM: Continuing Review (HRP-202)” or the informal Administrative Annual Check-in procedure. Attach all requested documents and provide to the IRB Office. Maintain electronic copies of all information submitted to the IRB in case revisions are required.

If your study was approved in Cayuse, navigate to the Study Details page, select “New Submission” and then select “Renewal.” Complete the Annual Check-in section. All members of the research team involved in the design, conduct, or reporting of the research must have current training. See above: “What training does my staff and I need in order to conduct human subjects research?”

If the ongoing IRB approval request is not received by the date noted in the approval letter, you will be restricted from submitting new human subjects research until the completed application has been received. Studies that expire will be closed and all research procedures must cease.

How do I submit a modification?

If your study was approved prior to October 2020, complete the “FORM: Modification (HRP-203),” attach all requested documents, and provide to the IRB Office. Maintain electronic copies of all information submitted to the IRB in case revisions are required.

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If your study was approved in Cayuse, navigate to the Study Details page, select “New Submission” and then select “Modification.” Complete the Modification section and make necessary changes to the previously approved study. Update all documents as necessary.

How do I close out a study?

If your study was approved prior to October 2020, complete the “FORM: Closure Request (HRP-202).” Maintain electronic copies of all information submitted to the IRB in case revisions are required.

If your study was approved in Cayuse, navigate to the Study Details page, select “New Submission” and then select “Closure.” Complete all questions on the Closure Request section. The IRB will process your request and provide you with a closure letter for your records.

If you fail to submit “FORM: Closure Request (HRP-202)” or request through Cayuse to close out human subjects research, you will be restricted from submitting new human subjects research until the completed application has been received.

How long do I keep records?

Research documents and data must be kept a minimum of 3 years after the study is complete and officially closed by the IRB office. Maintain signed and dated consent documents for at least three years after completion of the research.

Maintain signed and dated HIPAA authorizations and consent documents that include HIPAA authorizations for at least 6 years after completion of the research.

If your human subjects research is sponsored, funded, or FDA-regulated there may be additional requirements. Contact the sponsor, funding agency, or IRB for additional information.

How do I get additional information and answers to questions?

This document and the policies and procedures for the Human subjects Research Protection Program are available on the IRB Web Site at <http://research.utsa.edu/research-funding/human-subjects/>.

You may contact the IRB Office at:

IRB Office
The University of Texas at San Antonio
One UTSA Circle
San Antonio TX 78249
irb@utsa.edu