

The University of Texas at El Paso

Institutional Review Board (IRB)

Investigator Manual



Human Research Oversight and Compliance Office

A division of

The Office of Research and Sponsored Projects

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Purpose of this Manual

This manual provides guidance on the protection of human research participants in accordance with applicable laws, regulations and UTEP's policies and procedures to research investigators and study personnel engaged in human research. Investigators are required to abide by procedures as described in this manual.

All research involving human participants conducted at UTEP or any other entity for which UTEP is engaged in research must be submitted to the UTEP IRB prior to initiating the study. Further guidance and information can be found at the [Human Research Compliance and Oversight website](#)

Human Subjects Research: A Definition

The UTEP IRB has the sole authority to determine whether an activity meets the definition of "Human Subject Research" by considering whether the activity either:

- Meets the DHHS definition of "research" and involves "human subjects" as defined by DHHS

OR

- Meets the FDA definition of "research" and involves "human subjects" as defined by the FDA.

Research

Research is defined as any systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge [\[45 CFR 46.102\(d\)\]](#).

Human Subjects

Federal regulations define human subjects as: living individual(s) about whom an investigator (whether professional or student) conducting research obtains [\[45 CFR 46.102 \(f\)\]](#):

- (1) Data through intervention or interaction with the individual; or
- (2) Identifiable private information.



The IRB **does not** have the authority to grant **retroactive** approval should a research study be **initiated without prior** IRB review.

Human Research Oversight & Compliance Program (HROC)

The Human Research Oversight & Compliance (HROC) Program's mission is to promote compliance awareness for personnel involved in conducting human subject research through continuous outreach and education.

HROC is guided by the ethical principles regarding research involving human subject participants as set forth in the [Belmont Report](#). HROC assures that all UTEP research involving human participants will comply with the Terms of its' Assurance for Protection of Human Subjects for Institutions within the United States (<http://www.hhs.gov/ohrp/assurances/index.html>).

Research conducted outside of the UTEP IRB's jurisdiction in which UTEP is "engaged" is also subject to the same ethical and regulatory requirements, in addition to country/region specific requirements. This fundamental commitment to the protection of human participants applies to all UTEP research involving human participants, regardless of the funding source and location of the research.

Ultimately, the UTEP IRB ensures to protect the rights, dignity, welfare and privacy of human research participants.

HROC Contact Information

The HROC program is located in Kelly Hall, 7th Floor-East Wing. You may contact HROC by phone at (915) 747-7693 or by e-mail at irb.orsp@utep.edu.

IRB Administrator:
Christina Ramirez
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(915) 747-7693

Coordinator:
Bernice Caad

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(915) 747-8841

IRB Chair
Dr. Lorraine Torres
lorit@utep.edu
(915) 747-7282

What is subject to review?

Any faculty, student or staff engaged in projects that involves or collects data from human participants, whether funded or non-funded, needs to be submitted to the UTEP IRB for review and issuance of a determination letter prior to initiating the conduct of the project.

The Institutional Review Board at UTEP (IRB)

UTEP has one registered Institutional Review Board (IRB) that reviews research conducted by UTEP faculty, staff, students and/or other affiliated investigators. The purpose of the IRB is to review research with the sole purpose to ensure the protection of the rights, safety, and well-being of human participants recruited to participate in research activities conducted under the auspices of the University. Additionally, the UTEP IRB reviews all human research conducted at UTEP or affiliated entities (as established by an IIA or required through sIRB).

The UTEP IRB will not provide or publish the names of the members of the IRB except to Federal regulatory agencies requiring specific disclosure. Others, such as industry sponsors, may request a list of IRB members identified by initials, area of specialization, and gender.

Submissions are accepted year-round and will be determined by HROC regarding the level of review necessary. If a submission will require Full Committee Review, it must be received by the 1st Monday of the month.

The UTEP IRB is scheduled to meet on the 3rd Monday of each month (exceptions are official Monday holidays). Refer to the IRB website at www.research.utep.edu/irb for more information of meeting dates and submission deadlines.

The responsibilities of the Institutional Review Board are:

- To protect human subjects from undue risk and deprivation of human rights and dignity.
- To disapprove studies which are unethical or of no scientific merit (Belmont Report – Respect of Persons).
- To ensure that participation by subjects is voluntary, as indicated by a voluntary and fully informed consent.
- To ensure equitable selection of subjects (Belmont Report – Justice).
- To maintain an equitable balance between potential benefits of the research to the subjects and/or society and the risks assumed by the subject (Belmont Report – Beneficence).
- To determine that the research design and study methods of a protocol are appropriate to the objectives of the research and the field of study.
- To assist the investigator by providing peer review and institutional approval.
- To ensure compliance of protocols with the regulations of DHHS, FDA and other funding agencies when appropriate.
- The IRB has the authority to approve, require modifications of, or disapprove all human research that falls within its jurisdiction. Research that has been reviewed and approved by the IRB may be subject to further review and disapproval by the UTEP IRB. However, as stated in [45 CFR 46.112](#), UTEP officials may not approve research if it has been **disapproved** by the UTEP IRB.
- The IRB conducts project verification biennially or annually as required by funding agency
- The IRB has the authority to inspect research facilities and obtain records and other relevant information relating to the use of human subjects in research.
- The IRB has the authority to observe or have a third party observe the consent process
- The IRB takes actions to comply with federal regulations or other applicable laws, including action to suspend or terminate approval of research.
- The IRB must report to appropriate UTEP and federal government officials and any funding agency:
 - Any suspension or termination of research
 - Any unanticipated problems involving risks to subjects
 - Any serious or continuing noncompliance with IRB requirements

Who should submit to the UTEP IRB

All UTEP faculty, staff and students are eligible to submit to the UTEP IRB. Any study recruiting UTEP students, accesses UTEP data, (to include Private Identifiable Information (PII)), UTEP property and/or services must be submitted to the UTEP IRB. All studies involving human subjects carried out on UTEP premises require the approval or acceptance of the UTEP IRB.

UTEP policy prohibits officials, investigators, employees, and sponsors from attempting to or using undue influence with the UTEP IRB, any of its members or staff, or any other member of the research team to obtain a particular result, decision, or action. "Undue influence" means attempting to interfere with the normal functioning and decision making of the UTEP IRB or to influence a IRB member or staff, or any other member of the research team outside of established processes or normal and accepted methods, in order to obtain a particular result, decision, or IRB action.

Affiliated Entities or Collaborative Partners

The UTEP IRB also reviews research for "affiliated entities". These "affiliated entities" are separate facilities or institutions that have designated the UTEP IRB on their Federalwide Assurance with DHHS and *have a contractual relationship with the UTEP IRB*.

UTEP provides IRB review for human subjects research conducted at these entities under a DHHS IRB authorization agreement. Research reviewed for these entities receive the same level of IRB review as those conducted at UTEP.

The UT System has also created an IRB Reciprocity Agreement for collaborating institutions within the UT System to document reliance for collaborating projects. This agreement also includes several institutions in Texas outside of the UT System.

As per the revised Common Rule in an attempt to reduce IRB review redundancy and administrative burden, single IRB (sIRB) review will be required and in effect January 2020. At this time, lead Investigators will have to name the lead IRB of record and coordinate efforts between the collaborating institutions.

Non-UTEP Students

Non-UTEP students wishing to recruit and/or conduct a research project at UTEP will be required to submit to the UTEP IRB for review and determination. A letter of determination from their home institution IRB will also need to be included in the submission.

Required Training to Conduct Human Subject Research

All UTEP principal investigators, co-investigators, research staff, and IRB members as well as collaborating investigators are required to complete a training course to conduct Human

Subjects Research. Additional training may be imposed by other federal, state, or institutional policies.

Principal Investigators are responsible for ensuring their personnel engaged in human subject research complete the required training course prior to beginning work on any study.

CITI Training

Training is provided through the Collaborative Institutional Training Initiative (CITI) human subjects online training program.

In order to complete [CITI](#) training, visit the [IRB webpage](#) for specific instructions. Once successfully registered and completion of the course, you will be able to download a course transcript. UTEP will also be notified of your successful completion of the course.

If applications submitted to the UTEP IRB have co-investigators or research staff from schools or hospitals that are not formally affiliated with UTEP, the UTEP IRB retains the right, at their discretion, to request documentation of training regarding the rights and protection of human subjects in research, or, in its absence, require the unaffiliated co-investigators or research staff to take UTEP required training prior to final IRB approval. Other forms of human research training may be approved at the discretion of the IRB administrator. A description of the training and a copy of a completion certificate shall be provided by the Investigator.

Training Renewal Requirements

All personnel involved in the conduct of human subjects research is required to renew their training every three (3) years. Determination letters may not be issued if training requirements are not up-to date.

IRBNet Training

IRBNet is an internet-based system used by the UTEP IRB to review and track research studies at UTEP. All submissions must be submitted through [IRBNet](#) for IRB review. Training on the use of the system is available through the IRB office or through available online tools located at: <http://research.utep.edu/Default.aspx?tabid=73250>

Additional requirements

All study personnel conducting research activities and/or invasive procedures must be appropriately trained, to perform the tasks to which they are designated. The IRB strongly recommends individuals performing such tasks be certified and/or be able to demonstrate proficiency to the IRB. Study personnel found to be acting outside of their scope of practice will be reported to Institutional Compliance Office.

Responsibilities of the Principal Investigator

The Principal Investigator (PI) is ultimately responsible for the conduct of the study and for assuring compliance with Institutional Review Board (IRB) policies and procedures and with Federal regulations. Even though a PI may delegate specific tasks to other members of the

research team, he or she cannot delegate the responsibility for ensuring that those tasks are completed according to institutional and Federal regulations.

Financial Interest Disclosure

All individuals involved in the design, conduct, or reporting of research are required to disclose financial interests.

- On submission of an initial review
- Annually through the [Outside Activity Portal](#) during Disclosure Season (Jan-Mar), if applicable
- Within 30 days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new financial interest.

Investigators that fail to appropriately disclose financial conflicts of interest will be referred to the Office of Institutional Compliance. For more information on Outside Activity and Disclosure policy and procedures, please visit [Office of Research Conflict of Interest](#)

Approvals Needed before Submission

In addition to securing IRB approval for Human Research you may need to secure other institutional approvals. The IRB Office may ask you to obtain other approvals not listed below on a case-by-case basis depending on the specifics of your research. Site Specific Authorizations are required when your research involves any organization or entity that is not part of UTEP. This includes public schools or other educational settings, private clinics, hospitals, nursing homes, government agencies or any other outside business or field site. Written approval from the organization's authorized individual is required. In certain cases, contracts or other agreements may be required.

Internationally Conducted Research Projects

Human subject research (biomedical and behavioral) conducted internationally by U.S. investigators is subject to the same ethical guidelines and regulations as human subject research conducted within the United States. Under 45 CFR 46.101(a), research "conducted, supported, or otherwise subject to regulation by the Federal Government" that takes place outside the United States must be conducted with ethical oversight and human subject protections that are at least equivalent to those provided by the U.S. regulations, in addition to any foreign laws or regulations which may otherwise be applicable and which provide additional protections to human subjects of research.

Local investigators who wish to lead or participate in the conduct of human subject research conducted outside of the United States are required to secure the proper local and international approvals prior to commencement of the proposed project. The UTEP IRB requires additional review for human subject research projects where some or all of the study subjects are located outside of the United States.

Please note that if the proposed research receives any Federal funding, the Office of Research and Sponsored Projects will work collaboratively with the funding agency and sites to ensure the proper documentation and assurances have been secured to document that the international institution/performance site will conduct the research in accordance with US Federal policy.

When submitting an International Human subject Research Proposal to the UTEP IRB investigators should include the following:

- 1) All protocols that will recruit and enroll subjects and/or conduct research procedures in countries other than the U.S. must include the following additional information:
 - Explanations of cultural differences that have influenced the study design or consent process
 - Rationale for conducting the study with an international population.
 - Specifics about the population being recruited and social norms in the specific area in the host country to clarify issues regarding recruitment, informed consent, age of majority (for enrollment of minors) and acceptability of the research procedures proposed.
 - Include information and a description of any vulnerable populations (e.g. children, women, refugees etc.) that maybe recruited for the research study and how their rights and welfare will be protected
 - Information regarding the literacy level and native language(s) of the expected subjects and how this may affect the informed consent process.
 - A description of the informed consent process including methods for minimizing the possibility of coercion or undue influence in seeking consent and safeguards to protect the rights and welfare of vulnerable subjects.
 - If remuneration is given to subjects, a justification for the amount of money or goods and how this relates to the average annual income of people in the host country. Information regarding the host country's IRB, Ethical Review Committee, or equivalent institution.

2) Letter(s) of agreement from the local host institution(s) to cooperate in the proposed research: The appropriate authorities of the host country, including a national or local ethical review committee or its equivalent, should also review and approve the proposed research within the context of their own ethical requirements. Documentation of approval from the host country should be included with the IRB submission (via IRBNet) as soon as it becomes available. The IRB may also require meeting minutes from the committee in the host country.

3) Informed consent documents and other study materials: All consent forms and associated documents to be used with potential research subjects must be translated into the appropriate local language. The investigator must provide the name and brief description of the qualifications of the individual or the service that was used to translate the informed consent documents. If a certified translation service is used, and proof of translation is provided, the IRB will accept the proof of translation as verification of accuracy. Alternatively, the foreign IRB that reviews the study can verify the translation by indicating this on the approval letter. As a general policy the IRB does not require independent back translation of consent documents. Submission of both the English version of the informed consent document (and other study materials) and the foreign language version simultaneously is encouraged; however the IRB will review and approve English-only versions in an effort to prevent investigators from having to obtain multiple translated versions prior to final IRB approval. If the foreign language translated documents are

not included as part of the initial IRB review and approval, once the translation is complete, the documents may be submitted separately as a modification to the currently approved protocol.

Subject Compensation

The IRB does not view compensation as a benefit to offset research risks in deciding whether a protocol should be approved. Risks that are otherwise unacceptable cannot be made acceptable by offering increasing amounts of money to participants. The IRB will consider the cultural, financial, and educational status of potential participants when determining whether proposed compensation plans are appropriate.

Determining Appropriate Subject Remuneration

If a study offers compensation in exchange for participation in the research study, the compensation offered is not considered a benefit of research but is for the time and effort devoted to participation in research by individuals. Payment amount, including the timing and method of payment must be specified in the protocol and consent form at the time of initial review. Investigators may compensate participants provided undue inducements and inequitable selection are avoided.

The consent document must list what is being paid for, when and in what manner the participant will be paid, including the total amount the participant will receive. Any change in the payment to participants must be submitted to the IRB as an addendum to the protocol with appropriately modified consent/assent forms.

Subject payments should generally be made upon completion of each study visit, unless justified in the research protocol. In certain circumstances it may be acceptable to withhold some or all of the payment until the end of the study. If a subject withdraws from the research study or is discharged from the study, any payments that have accrued as a result of participation must be provided promptly unless the application and consent form states otherwise.

Extra Credit as Remuneration

Students must always be informed if participation in research is a course requirement and they must be offered an alternative activity if they choose not to participate. The syllabus shall clearly describe proposed participation in research activities for course credit and the alternative means of earning the course credit, which must be an equivalent amount of time and effort. The IRB shall review:

- That consent for participation is sought only under circumstances which minimize the possibility of coercion or undue influence
- That methods used to maintain confidentiality are clearly identified and
- That genuinely equivalent alternatives to participation are available

If extra credit or partial course credit is offered as remuneration for student participants, it must be clearly stated in the protocol and in the consent form. Additionally, the PI must ensure that

credit can be provided to all participants (project conducted across colleges). The PI must also ensure the IRB that the credit being offered is without undue influence or coercive in nature.

Remuneration in Research Involving Minors

In protocols involving minors as participants the division of payment for time and discomfort between the parent and child must be age appropriate and stated in the protocol and consent/assent forms. Payments should never be so large as to induce a subject to submit to research that they might otherwise reject.

Documentation of Payments

The PI must keep documentation of payment(s) made to each subject in study files. All records shall be made accessible for inspection and copying by authorized UTEP representatives, including UTEP Compliance personnel, UTEP auditors, ORSP, and federal regulatory officials.

Finder's Fees

Due to the conflict of interest created by offering such incentives, the UTEP IRB will not allow the use of any form of compensation to individuals (including faculty, staff, students, family members, etc.) who identify and/or recruit subjects for participation in a research study.

Appropriate Recruitment and Advertisement Methods

Recruitment of study subjects is an essential part of the research protocol and must be presented in sufficient detail to allow the IRB to fully assess the investigator's project. Recruitment of participants must be equitable and include racial, ethnic, educational, socioeconomic, and gender diversity appropriate to the condition that is studied. Exclusion of any specific group (e.g., women of child-bearing potential) must be justified in the protocol. Both the benefits and risks of research participation must be equitably distributed.

All research studies are approved to recruit only the number of subjects indicated on the IRB application. If the Investigator finds that actual recruitment is approaching the maximum limit, an amendment should be submitted requesting an increase in the number of subjects to be enrolled in the study.

All recruitment efforts must respect personal rights to privacy and confidentiality. The recruitment plan must avoid coercion of participants. Financial compensation, reimbursement for expenses, or other inducement for participation must not be coercive and should be reasonable for the expenses, discomfort, or inconvenience of participating. In addition to IRB requirements, the HIPAA regulations put further restrictions on research recruitment activities. This is important to note if recruitment will occur in a HIPAA covered entity.

The following methods of recruiting subjects at UTEP are generally acceptable: Advertisements, flyers, information sheets, notices, UTEP email (with approval), internet postings and/or media. Referrals may come from outside professionals that were provided general information letters or through snowball sampling methods for minimal risk social and behavioral research. You must include a description of your recruitment methods in the application, or in the protocol, you upload in IRBNet. The IRB must approve the recruitment plan and the text of the recruitment

materials, before initiating the study. All approved recruitment materials will be stamped electronically with the IRBNet ID Number and the Approval Date and available for download from IRBNet. These IRB-stamped approved documents from IRBNet must be used for recruitment.

For recruitment materials that are distributed to potential participants through electronic means for which you cannot feasibly use the stamped document, the study's IRB ID number and IRB approval date must be included in the following format: UTEP IRB# XXXXXXXX-X Approved: XX/XX/XXXX.

Classroom Based Research Projects

The University of Texas at El Paso (UTEP) requires that all research involving human subjects conducted by faculty, students, or staff affiliated with the university, be reviewed and approved by the IRB prior to initiation, regardless of the source of funding and regardless of its federal status as an exempt, an expedited, or a full review project. Investigators may not solicit subject participation or begin data collection until they have received written approval from the IRB. The IRB further requires that all student research activities are supervised by a faculty member, but some types of student research activities may not require IRB review above and beyond faculty supervision. UTEP supports a wide range of both undergraduate and graduate student research projects using human subjects -- from course-related research exercises to Ph.D. dissertation studies. Generally, student research involving human subjects falls into one of two categories:

- Independent research projects
- Research methods training

Independent Research Projects

Independent research projects are those that employ systematic data collection with the intent of contributing to generalizable knowledge. **Thesis** and **dissertation** projects involving human subjects are considered research as defined by 45 CFR 46 and always require review by the IRB. The IRB considers results to be generalizable if they are expected to be submitted for publication in a journal or magazine, published in a newspaper or on the World Wide Web, published in bound volumes such as theses or dissertations, presented at a professional conference or otherwise widely distributed.

Research Methods Training/Curriculum

Research projects for which the overriding and primary purpose is a learning experience in the methods and procedures of research to acquire knowledge and skill is typically not subject to IRB review. Curriculum projects in which students conduct research involving human subjects need not be reviewed by the IRB if the following conditions are satisfied:

1. The project(s) involve **minimal risk** to subjects; and
2. The research does not involve **sensitive topics** or **confidential information** that could place a participant at risk if disclosed;
3. The research does not involve **vulnerable populations** or individuals who are unable to give consent;

4. The research must involve the **voluntary participation** of individuals without any coercion or pressure being placed upon them by the researcher; and

5. **The results of the research will never be distributed** outside the classroom and/or institutional setting (including poster or showcase session or oral presentation to instructors and peers) or used for publication. If there is even a remote chance that the data or the report/manuscript will be used in the future for an off-campus conference presentation, or submitted for publication, the research should go through IRB review.

If the results of the student project will be published or otherwise distributed off campus, in any form of media, the project must be reviewed by the IRB. If in doubt, it is wise to have the project reviewed or to ask for specific advice from the HROC office before the project begins. The IRB **cannot** grant post facto approval. More information is available on the Human Research Oversight and Compliance website for further guidance on classroom based projects.

Internet Based Research Projects

Internet communication is extensively used and provides access to an enormous amount of information to “Internet communities.” Access to these communities and the information associated with them raises a number of ethical questions and challenges for researchers and IRBs. Perhaps the biggest challenges that are faced relate to privacy and informed consent. Below is a list of recommendations for improving “the quality of Internet research while promoting adherence to sound ethical research practices” and take privacy and informed consent concerns into consideration.

In the research application/protocol, Investigators should, at a minimum describe:

- The Internet methods and technology that will be used to interact with “Internet communities.”
- Potential risks and benefits of the research and how risks will be minimized.
- The informed consent process that will be used, i.e., how Internet community members will be informed that research data is being collected, how community members can “opt-out” of having their data collected, etc. or justify why a waiver from the requirement to obtain informed consent is appropriate.
- Methods used to assure protection of privacy for subjects and how confidentiality of the data will be provided.

Proposals for Internet research may meet criteria for exemption from IRB review. However, other issues may dictate a higher, more stringent level of review such as:

- The complexity of reducing potential risks.
- Protecting privacy and confidentiality.
- Obtaining true informed consent.
- Justifying a waiver.

Research Projects using De-identified, Secondary Data

Research projects utilizing pre-existing, de-identified data may qualify for exemption if the data:

- Is publicly available

- May be purchased from a private entity
- Permission has been granted to use the data
- Is completely anonymous

Various entities in El Paso will provide data for UTEP; faculty, staff and students upon request and with IRB approval (this list is not inclusive):

- CIERP at UTEP
- University Medical Center (UMC)
- The Hospitals of Providence
- Local School Districts

A slippery slope may exist when an employee has access to potential data and feels it can easily be obtained to be used for research purposes without permission. In these cases, permission should be obtained from the appropriate person(s) and then the requested data may be de-identified and provided to the requestor. This should be clearly outlined in the IRB application for review and determination prior to obtaining the data.

Certificates of Confidentiality

A [Certificate of Confidentiality \(CoC\)](#) is an assurance issued to protect subjects' privacy and ensure the confidentiality of their data. The Certificate prevents researchers from having to release identifying information about human research subjects in any Federal, State or local civil, criminal, administrative, legislative, or other proceedings. This protection is afforded by the Public Health Service Act 301(d), 42 USC 241(d).

Any person engaged or intending to engage in research that will collect identifiable and "sensitive" information about participants should apply for a Certificate. Sensitive identifiable information includes all information that identifies an individual or "...For which there is at least a very small risk, that some combination of the information, a request for the information, and other available data sources could be used to deduce the identity of an individual..." (Source: <https://humansubjects.nih.gov/coc/background>). Sensitive information specifically consists of includes (but is not restricted to):

- Information regarding sexual practices or preferences
- Information regarding the use of alcohol, illegal drugs or other addictive products
- Information concerning illegal behavior
- Information that can be destructive to the subject's financial standing, employability or reputation within the community or might lead to social disgrace or prejudice
- Information regarding the subject's psychological state or mental health
- Genetic information or tissues samples

The NIH has recently updated their [CoC policy](#) for NIH funded studies. All CoCs issued in the past or in the future, regardless of funding sources, must comply with the requirements of the CoC policy, especially the new disclosure requirements and restrictions. The new disclosure requirements prohibit disclosure of the name of research subjects or any identifiable research information, document, or biospecimen to anyone not connected with the research except under very specific circumstances as detailed in the CoC policy.

- Effective October 1, 2017 CoCs will be issued automatically for any NIH-funded project using identifiable, sensitive information that was on-going on/after December 13, 2016
- The CoC will be issued as a term and condition of award
- There will be no physical certificate issued

The National Institute of Justice requires a Privacy Certificate if you are working with prisoners.

The NIJ Privacy Certificate guidelines can be found at:

<http://www.nij.gov/funding/humansubjects/pages/privacy-certificate-guidance.aspx>.

The Privacy Certificate is not the same as a Certificate of Confidentiality and it is important to complete the application to comply with the confidentiality regulations found in 28 CFR Part 22.

If you are able to obtain a Certificate of Confidentiality or a Privacy Certificate, the IRB will consider that information as part of its review.

Data Use Agreement/ Plan

A data use agreement is the means by which entities and/or researchers obtain satisfactory assurances that the recipient of the data will use or disclose the data only for specified purposes.

The Data Use Agreement should contain the following provisions:

- Specific permitted uses and disclosures of the data by the recipient consistent with the purpose for which it was disclosed (a data use agreement cannot authorize the recipient to use or further disclose the information)
- Identify who is permitted to use or receive the data.
- Stipulations that the recipient will not use or disclose the information other than permitted by the agreement or otherwise required by law.
- Use appropriate safeguards to prevent the use or disclosure of the information, except as provided for in the agreement, and require the recipient to report to the providing facility any uses or disclosures in violation of the agreement of which the recipient becomes aware.
- Hold any agent of the recipient (including subcontractors) to the standards, restrictions, and conditions stated in the data use agreement with respect to the information.
- Not identify the information or contact the individuals.

Quality Improvement Plans

Institutions engage in “quality improvement” projects or activities which are designed to evaluate outcomes and determine appropriate institutional practices. In most cases, these activities do not qualify as “human subject research” under the Federal Regulations. However, in some cases quality improvement activities are designed to accomplish a research purpose as well as the purpose of improving the quality of care. In these situations, prospective IRB approval is needed prior to engagement in the activity. Investigators CANNOT assume that their protocol is “quality improvement” simply because the ultimate goal of their research is to improve the quality of specific aspects of patient care.

Activities that are strictly “quality improvement” will require IRB submission and review prior to engagement. Quality improvement activities are generally limited to: (a) implementing an evidence-based practice to improve the quality of patient care, and (b) collecting patient or provider data regarding the implementation of the practice for clinical, practical or administrative purposes. Quality improvement activities are intended to apply to those patients who are being treated within the QI initiative, and are not intended to be generalized to those beyond the protocol. Quality improvement activities include protocols which provide the same treatment to all subjects- these may be “bundled” interventions or single interventions, but the key point is that subjects (patients) are not randomized to differing treatment groups. Quality improvement includes those interventions (or “bundles” of interventions) which research has previously demonstrated to be beneficial.

Chart Review(s)

Research activities involving the use of chart reviews or discarded tissues/biospecimens must be reviewed and approved by the IRB prior to beginning. The IRB's main concern with chart reviews for research is the possible invasion of privacy and the use of confidential and privileged data or information. For any study to qualify as a chart review all the data accessed must have been collected (or will be collected) as part of routine clinical care. As with discarded tissue/biospecimen studies, it must have been collected as part of routine clinical care only and not for research purposes.

Case Studies

A case study is when an investigator develops a case report that he/she wishes to present, publish, or use to fulfill the requirement for scholarly activity. A case report that includes information from 3 or fewer patients generally does not meet the definition of a “systematic investigation leading to generalizable knowledge” and therefore does not meet the definition of “research” (45 CFR 46.102(f) or 21 CFR 56.102(e)). If the case report does not qualify as human subject research, the IRB will return a formal determination indicating such.

An investigator must ensure that the case report does not include any of the following participant identifiers:

- Personally identifiable private information about a living human person
- Any of the 18 protected health information identifiers (PHI) noted in the HIPAA regulations unless authorization from the individual(s) has been obtained.

Research Projects using Human Bio-specimens: *in progress*

Identified and de-identified: *in progress*

Genetic Materials: *in progress*

Vulnerable Populations

Minors

For children who are potential research participants, it is the responsibility of the principal investigator and the study team to obtain permission from the parent(s) and/or guardian(s). Documentation that shows a person is the legal guardian of a person is required.

Obtaining and documenting assent

The child should be given an explanation of the proposed research procedures in a vocabulary and language that is appropriate to the child's age, experience, maturity, and if applicable, their medical condition. This explanation should include a discussion of any discomforts and inconveniences the child may experience if he or she agrees to participate in the study.

If assent is solicited, the investigator must respect the child's decision. If the child is asked for assent and refuses, the child's parent(s) or guardian may not override the child's decision. To obtain valid written assent, the investigator must use the current IRB approved and stamped assent or consent form. Assent expires when a child becomes an adult. At that time the subject must sign the IRB approved adult consent form for the study.

Parent(s) and/or guardian(s) are encouraged be present during the process of obtaining assent but not required unless the child is aged 7 and under. Parent(s) and/or guardian(s) are encouraged to be present during the research procedures, especially if a young child will be exposed to significant discomfort or if the child will be required to spend time in an unfamiliar place.

Age Guidelines for Assent

1) 7 Years of Age or Younger, Verbal or Written Assent Is Usually Not Required

Consent is based on the permission of the parent or guardian, and no assent is required. A brief verbal explanation of the research procedures should be provided to the child. A verbal script is an option for explaining the research to the child and can be submitted to the IRB for review.

2) Ages 7 to 13; a Separate Assent Form Is Required

In addition to the parents' consent form, a separate assent form is required for the child. It should be in language appropriate for children 7-13 years of age, typically at 2nd-3rd grade reading level. The assent form should outline what is involved for the child, and emphasize the voluntary nature of the study. Depending on the research study, it will usually be one to two pages in length. Each assent process must at a minimum involve communication of the information in the assent form to the child, a comfortable opportunity for the child to ask questions, and obtaining of the child's verbal agreement to participate in the study. The plan to obtain and document the assent process must be fully described and justified in the protocol/research plan. The IRB will make the final determination of the assent process.

3) Ages 14 to 17; a Consent or Assent Form May Be Used

Children 14 to 17 years old may give assent after the information in the assent form has been communicated to them and the child's verbal agreement to participate in the study has been provided. The IRB may determine that the child can sign the Informed Consent document that has been signed by the parent(s) or guardian. A separate assent form may also be provided to the child if the investigator believes it would better describe the information provided to the child

about the nature of the study. This would most likely apply to 14 or 15 year old subjects in very complex studies, or children with mild cognitive impairment. The plan to obtain and document the assent process must be fully described and justified in the protocol/research plan. The plan should describe how the minor will be encouraged to ask questions and attain an understanding of what is involved in research participation, and of the purpose of the research. The IRB will make the final determination of the assent process.

4) Assent for Minors with intellectual disability or limitations to decision-making

If a minor (of any age <18 years) has intellectual disability, or a medical condition that includes cognitive limitation, the assent process must respect this. Assent may then need to be primarily verbal, and use props such as plush toys or picture boards, to provide explanation. It may be appropriate to waive assent on an individual case by case basis but careful justification is needed and the IRB will make the final decision. Assessment of the individual's abilities in order to plan the assent process may include use of formal school-based testing results such as an Individual Educational Plan or other testing results, and the parents'/guardian's knowledge about the child, including reading level and comprehension and learning style, should be incorporated into the assent plan.

Research Projects including Wards

In general, children who are wards of the state may participate in research either because the research (1) relates to their status as wards, or (2) is conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards. For research designated as 45 CFR 46.404 or 45 CFR 46.405 that incidentally or purposely includes a ward of the state, the minor's DCFS (Department of Children and Family Services) worker can be contacted in order to assist in identifying the individual who will represent the state as that minor's legal guardian (to provide parental/legal guardian consent and parental/legal guardian permission to approach the child). Children who are in the custody of a state agency, or are in foster care, are generally referred to as wards of the State. Parents of children in the custody of the state may, and most often do, retain the right to consent to participation by their child in research. Since these situations are complex, investigators who wish to enroll wards should contact the IRB and/or the legal department for guidance in complying with all federal and state regulations pertaining to the inclusion of wards in research.

Request for Waiver of Assent (45 CFR 46.408 & 46.116 Subpart A)

There are circumstances in which the IRB may determine that assent is not a requirement for children to be enrolled in a research protocol. In determining whether children are capable of assenting, the IRB shall take into account the ages, maturity, and psychological state of the children involved. This judgment may be made for all children to be involved in research under a particular protocol, or for each child, as the IRB deems appropriate. **The investigator must specifically justify why obtaining assent is not appropriate, in the protocol/research plan.**

Waiver of Parental Permission

Under the federal regulation 45 CFR 46.408(c) for DHHS funded research, if the IRB determines that a research protocol is designed for conditions or for a child subject population in

which parental or guardian permission is not a reasonable requirement to protect the child subjects (i.e.; neglected or abused children), the research is not subject to FDA regulations, and the waiver is not inconsistent with applicable federal, state or local laws, then the IRB may waive the consent requirements. However, the investigator must provide an appropriate mechanism for protecting the children who will participate as subjects in the research as a substitute.

Under the FDA regulations (21 CFR 50.55) the FDA does not permit such a waiver of parental permission.

If the IRB determines that a research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects, it may waive the consent requirements, provided an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted, and provided further that the waiver is not inconsistent with federal, state, or local law. The choice of an appropriate mechanism would depend upon the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and their age, maturity, status, and condition.

If the IRB determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research, the assent of the children is not a necessary condition for proceeding with the research. Even where the IRB determines that the subjects are capable of assenting, the IRB may still waive the assent requirement under circumstances in which consent may be waived in accord with 45 CFR 46.116, Subpart A.

Cognitively/Decisionally Impaired Individuals

For studies proposing to include adult subjects with impaired decision making capacity the following principles always apply:

- Decisionally impaired subjects must comprise the only appropriate population and the research question must focus on an issue relevant to this subject population. If the research question can be answered using non-impaired subjects, then subjects with impaired decision making capacity cannot be studied.
- If the research involves greater than minimal risk, the risk must be commensurate with the degree of potential benefit to the individual subject.

Problems obtaining Consent

Because decision-making capacity is task specific, some decisionally impaired individuals remain capable of making informed decisions for themselves regarding research participation. The capacity to obtain informed consent should be assessed in each individual, for each research protocol being considered.

Procedures should be developed to enhance the possibility that subjects can consent for themselves. The setting in which consent is sought and the person seeking consent should be conducive to promoting a potential subject's ability to comprehend what is being asked.

Because there are no generally accepted criteria for determining capacity to consent to research, the investigator must propose criteria for assessing potential subjects, and the criteria must be reviewed by the IRB.

There have been several approaches proposed to assess a subject's ability to give informed consent. Whatever approach is taken, it is essential to document the plan in detail in the research protocol.

Examples may include:

- A screening standard mental status examination, such as the MINI-Mental Status Exam (MMSE).
- The development of a decision-making capacity assessment tool that is specific for the research project.
- A post-consent quiz documenting the subjects' knowledge of critical elements in the informed consent form (i.e., voluntary nature of participation, ability to withdraw at any time, possible risks and benefits of participation, procedures involved, time required, confidentiality, and whom to call with any questions).
- The study investigators may ask a physician/psychologist outside the research team to evaluate the potential subject's decision-making capacity.
- Investigators and the IRB may also consider involving an independent person or witness to observe or monitor the consent process as an additional safeguard for a specific protocol, especially if the protocol is complex, difficult to understand or involves increased risk as compared to benefit.

Participation in research is essentially an optional activity and even an uninformed or uncomprehending refusal should usually be respected. In the case of research involving more than minimal risk, the objection of an adult subject with limited decision-making capacity should be binding, except in rare cases when the IRB makes and specifically documents that the intervention is expected to provide a direct health benefit to the subject and the intervention is available only in the context of the research.

Pregnant Women, Human Fetuses and Neonates

As pregnant women, fetuses and neonates are considered vulnerable populations as set forth by the Department of Health and Human Services (DHHS) regulations ([45 CFR 46 Subpart B](#)), additional protections are in place for this population to be included as research participants.

Typically for Social and Behavioral Research (SBR), if the interaction and/or intervention does not affect the pregnancy status or increase the risk to either pregnant women, neonates or human fetuses, these populations may participate in research activities.

Please check with the Human Research Oversight and Compliance Office for more information on including pregnant women in research.

Prisoners

The inclusion of individuals in a research protocol who are considered “prisoners” involves special ethical considerations and requires meeting additional regulatory requirements to safeguard prisoners’ interests and protect them from harm. Prisoners constitute a research population who are at risk for coercion due to their legal status or confinement. Prisoners may be under constraints because of their incarceration, which could affect the ability to make a truly voluntary decision with respect to participation as subjects in research.

A research protocol is considered to include prisoners when:

- Prisoners are the target population that will be recruited; or
- The subject is a prisoner at the time of enrollment; or
- A currently enrolled subject becomes incarcerated during the course of the trial.

Permitted research involving prisoners includes those studies that aim to examine conditions, practices and antecedents specifically relevant to prisoners, prisons and incarceration (see 45 CFR 46.306). When a research protocol involves the inclusion of prisoners, the IRB will review the research in accordance with institutional policy, with OHRP and FDA regulations, and with respect to 45 CFR 46 Subpart C (additional protections pertaining to research involving prisoners). Additional rules as determined by Federal, state, county, and local regulations may also apply. If a prisoner is pregnant or a minor, IRB policy regarding these vulnerable populations (45 CFR 46 Subparts B and D respectively) also applies.

It is important to know that prisoners cannot be involved in emergency research where the requirement for informed consent has been waived by the Secretary under the authority of 45 CFR 46.101(i) 45 CFR 46.101(i).

Research Subject becomes a Prisoner

If a subject becomes a prisoner after enrolling in a research study, the investigator is responsible for immediately reporting the event in writing to the IRB through submitting a “Reportable New Information” form. The investigator should provide detail on the subject and the incarceration, as well as the extent of the subject’s participation in the research trial up to becoming a prisoner, what remaining study activities the subject has to complete and the plan for either inclusion or exclusion of the subject from further research activities.

All research interactions and interventions with, and obtaining identifiable private information from the prisoner must cease and the participant withdrawn from the study.

In special circumstances in which the investigator asserts that it is in the best interests of the subject to remain in the research study while incarcerated, the subject may continue to participate in the research until the requirements of subpart C are satisfied in the protocol and approved by the IRB.

Protected Groups

Although there are no specific regulations governing the inclusion of other groups of at risk persons in research, these populations may be approached for enrollment in research protocols. A protected group is one in which there is potential for real or perceived coercion or undue influence for subjects to enroll in the study or the subjects may be incapable of fully understanding the potential risks of the research. In all cases, the IRB must consider the

possibility and justification for including these subjects in the proposed research and safeguards to protect their rights and welfare.

Non-English Speaking Participants

Participants who do not speak English must be given an informed consent document written in a language understandable to them. A person who is fluent in both English and the participant's language must participate in the informed consent process. If the person authorized to obtain informed consent in the research protocol is not fluent in the participant's language, an interpreter or interpreter service may be obtained.

Students and Employees

Justification of the intention to enroll UTEP students, staff, or faculty must be provided in the protocol. The actions to prevent coercion or undue influence must also be detailed in the protocol. Anyone with an employment or academic relationship to UTEP must be informed that their participation in a study, or refusal to do so, will in no way influence their grades, employment, or subsequent recommendations. Employees must never be made to feel that their job, promotion, salary, or status in any way depends on participation in research studies.

The Principal Investigator or any co-investigator may not be responsible for directly recruiting and/or obtaining informed consent from any person under his or her direct supervision. Direct recruitment may be undertaken using IRB approved recruitment methods.

A Principal Investigator may not enroll his or herself into his or her own research protocol unless provisions are made in the research protocol to allow for the enrollment. In these cases, the IRB may allow the inclusion if the study outcomes are objectively measured and provisions are there with respect to recruitment, consent, and affirmation of eligibility (e.g., by a study co-investigator).

Native Americans

Native Americans are considered a protected group and special precautions must be taken when conducting a research project involving Native Americans. If the project will be conducted on Tribal Land, permission must be obtained. Once approval has been obtained, the submission may be submitted to the UTEP IRB for review and determination. Further information may be obtained from the [US Department of the Interior Indian Affairs](#). If the population being researched does not specifically target Native Americans and is not conducted on Tribal Land, then it is permissible to recruit Native Americans for the research project as appropriate to the inclusion criteria and the potential participant is properly consented.

Participants Who Are Mentally Capable of Consenting But are Physically Unable to Sign the Consent Document

The IRB allows participants that are mentally capable of consenting to research studies but are physically unable to sign the consent document to participate in research as long as a witness is present. The witness must verify that the informed consent process has taken place and sign and date the consent document. In addition, if participants are capable of doing so, they must

place a mark or cross on the signature line of the consent document, to confirm their participation in the research study. This process must be documented in the research file. If the reason that prevented signing the consent form resolves, the participant should be asked to sign and date the consent form. Protocols actively enrolling individual participants who are physically unable to sign the consent document should include a witness line on the consent document.

Completion of a Protocol Template Document

HROC provides a protocol template/application to assist Investigator's as a starting point for drafting a new protocol. The application references the instructions in italic text for the information the IRB looks for when reviewing research. Here are some key points to remember when developing an Investigator Protocol:

- For any items described in the sponsor's protocol or other support document submitted with the application, investigators may simply reference the page numbers of these documents within the application rather than repeat information.
- When writing an Investigator Protocol, always keep an electronic copy. You will need to modify this copy when making changes.
- Note that, depending on the nature of your research, certain sections of the template may not be applicable to your Investigator Protocol. Indicate this as appropriate.

Completion and Required Elements of a Consent/Assent Document

Use the Consent/Assent document templates posted on the HROC website to create consent/assent documents. Each different template contains information that is *generally* relevant for each type of research category. You may ultimately need to edit sections to fit the type of research proposed.

Note that although you may edit the forms to fit your research, all consent documents must contain all of the required elements of informed consent and all appropriate additional elements in accordance with regulations and policies.

We recommend that you note the version of your consent document in the lower left corner to ensure that you use the most recent version approved by the IRB. The HROC Office will also stamp the consent/assent documents in the lower right corner with IRB approval dates. You may only use the latest version approved by the IRB. Once a new version of the consent is approved, all other versions become invalid and may not be used.

General consent requirements

The IRB requires that all informed consent documents include the [eight basic elements](#) of informed consent listed below (45 CFR 46.116(a) and 21 CFR 50.25(a)). The IRB may also require any or all of the [six additional elements](#) of informed consent (45 CFR 46.116(b) and 21 CFR 50.25(b)), depending on the nature of the research.

As per the the revised Common Rule, consent forms are required to include key information at the beginning of the form and be presented to the participant at the onset of the consent

discussion to ensure that participants are provided/presented the research information in an easy-to-understand and clear manner.



As per the revised Common Rule clinical trial informed consent posting requirement (45 CFR 46.116(h)), federally funded projects must post the approved consent form no later than 60 days after the last study visit on a federal website. The two currently approved websites are www.clinicaltrials.gov and [ORHP Consent Posting Site](#).

There may not be discrepancies within the informed consent documents, the IRB application, or other supporting documents. The Informed Consent document must be in a language understandable to the participant or the participant's legally authorized representative (45 CFR 46.116 and 21 CFR 50.25), 8th grade reading level is highly recommended for adults. The consent form must be written in non-scientific language that is easily understood by all subjects. Consent must always be obtained before initiation of any study procedures.

The investigator must provide a detailed description of the intended method for obtaining informed consent in the protocol. All informed consent documents (full written documents, oral scripts, assent forms, etc.) must be submitted for review and approval by the IRB prior to use. Any changes in the informed consent documents must be submitted as an amendment to the IRB for review and approval prior to use.

No informed consent, whether written or oral, may contain any exculpatory language through which the participant or their legal authorized representative is made to waive or appear to waive any of the participant's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

Obtaining Consent

Waiver or Alteration of Informed Consent Requirements

The IRB may approve a consent procedure that eliminates or alters the required elements of informed consent, or to waive the requirement to obtain informed consent altogether. Alteration or Waiver of Informed Consent is defined as a variation from the traditional informed consent process. However, this process still includes a considerate and thorough discussion of the study with the participant and verification that the participant understands the study and will participate voluntarily. The IRBs may alter or waive the requirement for informed consent of participants. In order to approve such a waiver or alteration, the IRB must find and document the following:

- The research involves no more than minimal risk to the participants;
- The waiver or alteration will not adversely affect the rights and welfare of the participants;
- The research could not practicably be carried out without the waiver or alteration;
- Whenever appropriate, the participants will be provided with additional pertinent information after participation

An investigator who requests a waiver of informed consent for a project will include a justification of the four requirements presented here in his/her initial submission for IRB review.

The request will be reviewed and if approved, will be documented in the IRB meeting minutes and on the IRB approval letter.


Study Information Sheets (SIS)

In cases in which the project qualifies for exemption, documentation of consent requirement is not required. The IRB highly recommends the Investigator provide participants with a written statement regarding the research. HROC has provided a template to assist Investigators and includes the basic elements of consent. The difference between a consent form and an SIS, is the SIS does not require a written signature/documentation for participation.

Deceptive Studies and Debriefing

The IRB may allow the alteration of informed consent in research involving no more than minimal risk, which can only be conducted when participants are less than fully informed and the missing information does not increase participant risk (e.g. behavioral studies). In these situations, the IRB may determine that consent, which does not disclose information about all elements of informed consent, can be obtained for initial enrollment. However on completion of the research, or after participation, each participant must be informed of the true nature of the study and be offered the ability to decline participation.

The records must document why the IRB judged that each criterion listed above was met for the protocol. Research that includes participant deception may be eligible for limited or flexible review.

 Please note that any IRB committee member may call any submission for Full Committee Review (FCR).

Electronic Consent

Investigators are able to obtain consent electronically, and this process may substitute for paper-based informed consent. The eIC (electronic informed consent) must contain all elements and meet all regulatory criteria for informed consent as stated above. The eIC may contain hyperlinks and other electronic strategies to enhance comprehension, but must be easy to navigate with sufficient time allowed for understanding, and the potential subjects' electronic literacy must be considered.

Assent may also be obtained electronically but the capabilities of the child to assent using electronic methods must be considered. The process of informed consent requirements still apply with electronic consent, and the following must be included in the protocol:

- Measures to ensure that subjects have access to all the consent related materials
- Plan to ensure all hyperlinks are active and working
- Plan for providing subjects with a copy of the consent form, if requested

“IRBs, investigators, and sponsors may rely on a statement from the vendor of the electronic system used for obtaining the electronic signature that describes how the signature is created and that the system meets the relevant requirements contained in 21 CFR part 11.”

Protected Health Information (PHI) and HIPAA

UTEP is not a covered entity and does not abide by [The Privacy Rule](#) also known as HIPAA. However, specimens obtained at a HIPAA covered entity and brought to UTEP for research purposes should have mechanisms written into the protocol to ensure the privacy and confidentiality as well as detailing the protection of the data to minimize potential breach or loss.

The Rule requires appropriate safeguards to protect the privacy of personal health information (PHI), and sets limits and conditions on the uses and disclosures that may be made of such information without patient authorization.

Submission of New Human Subjects Research to the IRB

All applicable documents should be complete and electronically submitted via [IRBNet](#). Complete instructions and training tools for submission are available on the HROC website located under [IRBNet information](#). If the PI is a student, the student must share the submission with their Mentor/Chair/Advisor so that person may electronically approve and sign off on the submission.

Upon submission for initial review, the PI will verify in the application that:

- They have reviewed this protocol and acknowledge their responsibilities as Principal Investigator.
- The information in this submission accurately reflects the proposed research.
- They accept responsibility for assuring adherence to all applicable Federal, State, and local research regulations and policies in carrying out this research.

Study Withdrawal for Lack of Response

The study team has 30 days to respond to a request for modifications, clarifications, or deferral requests. If a submission response has not been received in 15 days, the HROC office will send out courtesy reminders. If a response is not resubmitted within 60 days, the IRB Administrator and/or Director will withdraw the submission. The study team will be notified when the submission is withdrawn. At that point, a new study or submission must be created if the study team wishes to move forward. If there are unusual circumstances that prevent a timely response to requested changes, the principal investigator can request an extension of time to respond.

Regulatory Classifications for Research

The Revised Common Rule went into effect on January 21, 2019. As a condition of our Assurance, we must apply federal regulations to research that is federally funded. Therefore, the UTEP IRB will only apply the new regulations to federally funded projects involving human subjects research.

However, the IRB has flexibility in determining appropriate protections for human research participants that do not fall under federal oversight. The UTEP IRB has adopted a flexible review process which allows for a streamlined review for those projects not supported by federal funding.

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

- Not human subject research: Activities must meet the institutional definition of human subjects research to fall under IRB oversight.
 - Quality Assurance projects may fall under this category
- Exempt: Certain categories of human subjects research may be exempt from regulation but require IRB review. It is the responsibility of the IRB, not the investigator, to determine whether human subjects research is exempt from IRB review.
- Limited Review: Provides an alternate path of review for studies otherwise qualifying for exemption but working with identifiable information or biospecimens. An IRB member must conduct limited IRB review for these federally funded studies.
- Flexible Review: Provides the same path of review as Limited Review but applied to projects that are not federally funded. The review may be conducted by the IRB Chair, Designated Reviewer(s), or HROC staff (as designated by the Chair).
- Expedited Review: Certain categories of non-exempt human subjects research may qualify for review using the non-committee procedure, meaning that the project may be approved by one or two designated IRB reviewer(s), rather than the convened board.
- Full Committee Review (FCR): Non-Exempt human subjects research that does not qualify for any of the above categories must be reviewed by the convened IRB.

Determinations Made by the IRB

The IRB may approve research, require modifications and/or clarification to the research to secure approval, conditional approval, defer research, or disapprove research:


- Approval: Made when all criteria for approval are met.
- Conditional Approval: Made when all criteria are met but a minor correction(s) is requested or approval is pending from a collaborating facility
- Modifications/Clarifications Required to Secure Approval: Made when IRB members require specific modifications/clarifications to the research before approval can be finalized.
- Deferred: Made when the IRB determines that the board is unable to approve research and the IRB suggests modifications that might make the research approvable. When making this motion, the IRB describes its reasons for this decision, describes modifications that might make the research approvable, and gives the investigator an opportunity to respond to the IRB.
- Disapproval: Made when the IRB determines that it is unable to approve research and the IRB cannot describe modifications that might make the research approvable. When making this motion, the IRB describes its reasons for this decision. Any further proposals would have to be part of a new submission.

Review Processes and Timelines

Upon submission, HROC receives the submission and provides a preliminary review within 72 hours, for completeness and accuracy. If HROC finds more information is required before the submission can be forwarded for review, the submission will be unlocked and the PI notified via IRBNet mail outlining the information needed within the documentation. The PI has 30 days to respond or the procedures stated above for Lack of Response will be followed.

Review timelines to receive a determination are as indicated below:

- Exempt or Flexible review: approximately 7-14 days
- Expedited or Limited Review: approximately 3-6 weeks
- Full Committee Review: approximately 4-8 weeks

 These are approximate timeframes. HROC is inundated with submissions at the beginning of each semester and review times may take a bit longer than expected. Please plan accordingly and submit as early as possible.

After IRB Review

After review, the IRB will provide you with a written decision indicating that the IRB has made a determination. The determination letter can be obtained under Board Documents within IRBNet.

- If the IRB has approved the human subject research, the project may commence. IRB approval is for a period of time which is noted in the determination letter.
- If the IRB requires modifications/clarifications to secure approval: Make or address the requested modifications/clarifications and submit them electronically to the IRB via IRBNet. If the IRB determines that all requested modifications have been addressed, final approval will be issued. Research cannot commence until this final approval is received. If you do not accept the modifications, submit a response through the system justifying your disagreement with the request.
- If the IRB defers 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 a modification, the human subjects research may be approved.
- If the IRB disapproves the human subjects research: The IRB will provide a statement of the reasons for disapproval and notify the Institutional Official.

Appealing an IRB determination

The UTEP IRB may determine that some or all of a proposed research activity cannot be approved, or the IRB may require the researcher to make changes to the research in order to obtain IRB approval. Per federal regulation, these IRB decisions may not be reversed by any official or agency, including another IRB. However, a researcher may appeal to the IRB to do a formal re-review of a decision if, after repeated interactions with the IRB, the researcher believes that the IRB's decision is due to inadequate or inaccurate information, a misunderstanding, or IRB non-compliance with UTEP policy, state law, or federal regulation.

Appeal Procedures

The investigator will submit an IRB Appeal outlining the decision(s) being appealed and providing information supporting his or her position. The form will be reviewed by the IRB during a convened meeting. The Institutional Official (IO) may also be present but is not a voting member.

At the meeting, the committee will focus on the unresolved issue(s), but will review the issue(s) in the context of the entire project. The IRB Chair will present the protocol and issue(s) at hand. The committee members will present relevant information from the Board's prior discussions and decisions.

The researcher is invited to present information and rationale to the Committee. There is a question-and-answer session between the Committee members and the researcher. The researcher and any guests/colleagues leave the meeting room during discussion and deliberation.

After hearing the information and reviewing the documents, the Committee will discuss and voting to reach a final decision by majority vote to either agree or disagree with the original IRB decision regarding the procedure, wording, or plan as proposed by the investigator. The following decisions may be rendered:

- If the IRB has approved the human subject research, the project may commence. IRB approval is for a period of time which is noted in the determination letter.
- If the Committee disagrees with the original decision, the protocol will be transferred to an outside IRB Board for full review, at the researcher's expense.
- Defer the appeal and obtain additional information or consultation in order to make a final decision. In all cases, the findings of the Committee will be provided to the investigator and in writing. The Institutional Official and investigator's Chairperson will be copied on the written communication. The minutes and the letter will become part of the IRB file.

After final disposition of a case prompting an Appeals Process, the Committee will review the case and its findings in light of current policies and procedures to determine whether clarifications, changes in practice, new guidelines or SOPs are needed.

Reportable New Information

Unanticipated Problem Involving Risks to Participants or Others, include any incident, experience, or outcome that meets **all** of the following criteria:

- Unexpected (in terms of nature, severity, or frequency)
- Related or possibly related to participation in the research
- Suggest that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

Adverse Event, although not defined under either the DHHS or FDA regulations, per OHRP guidance of January 15, 2007, Guidance on Reviewing and Reporting Unanticipated Problems

Involving Risks to Subjects or Others and Adverse Events uses the term to include any event meeting the following:

Any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign, symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research. An adverse event encompasses both physical and psychological harms; and although they most commonly occur in the context of biomedical research, they can also occur in the context of social and behavioral research.

A **harm** is "unexpected" when its specificity or severity are inconsistent with risk information previously reviewed and approved by the IRB in terms of nature, severity, frequency, and characteristics of the study population.

Reportable to the IRB

A member of the study team must complete and submit the Report New Information Form within **five business days** for any of the following information items:

- 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 at 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.
- Non-compliance with the federal regulations governing human subjects research or with the requirements or determinations of the IRB, or an allegation of such non-compliance
- Audit, inspection, or inquiry by a federal agency and any resulting reports
- Major failure to follow the protocol due to the action or inaction of the investigator or research or staff
- Breach of confidentiality (loss of equipment)
- 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.
- Complaint of a subject that cannot be resolved by the research team.

Failure to report in a timely manner may be considered a compliance matter and referred to the IRB for review and a compliance determination.

Study Modifications

The IRB reviews and approves all modifications/revisions proposed to an IRB approved research protocol. Proposed changes must be added to the applicable document (s) of the latest IRB approved version, in red, italicized font via IRBNet as a new package to the existing project. The Investigator must also include the Amendment Request Form providing a summary and justification for the requested changes. **Please note that research must continue to be conducted without inclusion of the modification(s) until IRB approval is received, except**

for reasons directly related to patient safety. In these cases, please contact the IRB immediately. Below are examples of modifications:

- Administrative or editorial changes or addenda
- Changes or additions to eligibility criteria
- Changes in or addition of funding
- Changes to a procedure
- Addition of a procedure
- Revisions to consent or assent form
- Changes to study investigators
- Changes in recruitment practices
- Change in research population
- Letters to potential participants
- Notifications and/or letters to research participants
- Advertising materials
- Recruitment materials

Continuing Review and Verification

For studies approved or determined exempt under the 2018 revised Common Rule, continuing review will not be required for **some** research, including studies where the only remaining activity is the analysis of identifiable data/biospecimens.

If a study was reviewed under the pre-2018 Common Rule and was determined to require continuing review, this must be submitted to remain compliant. The revisions allow the IRB to review existing research and determine if it can transition to comply with the revised regulations.

Unless indicated that a project must have a continuing review to be compliant, continuing reviews will not be required, if applicable.

However, in order to ensure that the rights and welfare of human subjects remain protected, the HROC will request biennial verification. The aims of biennial verification are to reappraise the research to ensure:

- To review the progress of the protocol since approval and the plans for the future based on the progress to date
- All modifications to the protocol have been submitted to the IRB
- All problems that require prompt reporting to the IRB have been submitted

If continuing review is required, the Investigator is responsible for ensuring that the research is submitted to the IRB in an appropriate time frame, in order to avoid a lapse of IRB approval. The date by which a protocol must receive its continuing review is listed on the determination letter and indicates the date that the protocol is approved through. All other projects not subject to continuing review will receive automated notice for biennial verification at 60, 30 and 10 days. Upon receipt of those notices, the Investigator will need to submit the Biennial Verification form

via IRBNet. If a response is not received within 15 days, a reminder will be sent out. If no response is received within 30 days, the study will be administratively closed. If the Investigator notifies the HROC office after the closure indicating the study is still continuing, the Investigator will need to cease study activities and resubmit the project for review.

Study Closures

If all research-related interventions or interactions with participants have been completed and collection and analysis of identifiable private data (as described in the IRB-approved protocol) are finished, the study should be closed with the IRB.

Alternatively, if the study was never initiated and the Investigators no longer have plans to pursue this project then the study should be closed with the IRB. After a protocol has been closed the IRB does not accept further submissions unless they impact the rights and welfare of participants. The investigator should keep all non-reported adverse events on file for review by regulatory agencies.



Once a study closure has been submitted and processed by the IRB the study **cannot** be re-opened.

Study Record Retention

Maintain your Human Research records, including but not limited to; signed and dated consent documents for at least three years after completion of the research.

If your Human Research is sponsored the time-frame for keeping the records may be in the contract. Be sure to contact the sponsor before disposing of Human Research records.

Allegations of Non-Compliance

If an allegation of non-compliance is reported from any source (including monitoring/auditing reports, subject complaints, internal allegation or investigator self-reporting), the HROC Office in consultation with the IRB Chair or Vice-Chair, and the Director of Research Oversight & Compliance, will make an initial assessment to determine:

- whether there is sufficient information present to verify and determine if the allegation is true;
- whether additional information is needed to make a determination; and
- whether a determination of non-compliance, is serious or continuing non-compliance.

The IRB, as part of their oversight responsibilities has established procedures for the evaluation of all non-compliance with human subject protection regulations, institutional policies and the prompt reporting of any serious or continuing non-compliance with the Federal regulations. All reports of alleged non-compliance or inappropriate involvement of humans in research are investigated by the Human Research Oversight Compliance (HROC) Office.

If it is determined that the non-compliance might be serious or continuing, the IRB Chair appoints a sub-committee to further investigate the allegation. The goals of the sub-committee in investigating and managing issues of potential noncompliance include:

- Assuring the safety, rights and welfare of human subject research participants;
- Developing action plans to prevent recurrence, and promote a culture for future compliance;
- Educating research staff to assure the understanding of DHHS (OHRP) and FDA regulations and guidelines, and UHCMC IRB Policy; and
- Reporting serious or continuing noncompliance to the appropriate regulatory agencies and institutional officials
- If the research is federally funded, then notification of the non-compliance must be made to OHRP (Office for Human Research Protections).

The sub-committee will prepare a summary of the allegation and recommended corrective measures to the IRB for review and additional input and a final determination. The Investigator, the Department Chair and Institutional Official will be notified in writing regarding the outcome.

Allegation or potential instances of non-compliance may be identified during monitoring visits, known as Post Approval Monitoring and Education (**PAVE**) conducted by the Human Research Oversight & Compliance Office.

Routine **PAVE** monitoring is conducted to assess the investigator's compliance with Federal, state and local law, institutional and IRB policies. Protocols are selected for routine visits by performing a query of the IRB database, reviewing IRB minutes, or may be requested on a voluntary basis by the principal investigator, Department or Clinical Chair. The monitoring may include, but is not limited to, the following:

- Examining the entire research project
- Assigning observers to the sites where the informed consent process is being conducted
- Interviewing investigators, research staff, or research participants
- Monitoring advertisements and other recruiting materials
- Monitor conflict of interest concerns
- Assure the consent documents include the appropriate information and disclosures
- Other monitoring or auditing activities deemed appropriate

HROC will prepare a written summary of the observations and propose an action plan for the investigator. If necessary, HROC will consult with the Director of Research Compliance & Oversight, IRB Chair, or the Institutional Official.

An action plan may include any, or all of the following:

- Identifying the finding as minor non-compliance and request a thorough action plan to correct and/or prevent the event from occurring again;
- Require Education;
- Require additional monitoring

Suspension or Termination of a Study

The IRB has the authority and responsibility to suspend or terminate approval of research that is not being conducted in accordance with the IRB policies and procedures, or that has been

associated with unexpected harm to participants or others. The IRB has the ability to temporarily or permanently suspend or terminate approval for some or all research activities. Depending on the circumstances surrounding the suspension or termination action, the investigator may be required to submit a report to the IRB, detailing any adverse events and/or study outcomes that were previously unreported to the IRB for consideration. Any letter of suspension or termination of approval to an investigator must include a statement of the reasons for the action by the IRB. This letter will be provided to the Investigator, Department Chair and Institutional Official.

The IRB Chair, is authorized to suspend or terminate the enrollment of subjects; and the ongoing involvement of subjects in research, as it deems necessary to protect the rights and welfare of participants. This also includes compelling and urgent instances when subject safety is of concern. The IRB will review such suspensions and terminations at a subsequent convened meeting. A plan will be developed that takes into account the rights and welfare of currently enrolled subjects and those subjects who may need to be withdrawn from the study. If the agreed upon plan of action involves withdrawal of enrolled participants, the IRB will take into account their rights and welfare, transfer to another researcher (if possible), and continuation in the research under independent monitoring. If the IRB determines that a suspension or termination of the research will place subjects at risk of harm, the investigator will be requested to submit a proposed script or letter for participants for IRB review and approval. The IRB determines the information that is to be provided to subjects and the method of their notification e.g., in writing or by telephone. This includes appropriate subject follow-up and notification of the reasons for the action. All protocol suspensions or terminations are reviewed at a subsequent IRB meeting.

Investigator Obligations

- Do not start human subjects research activities until you have the final IRB approval letter
- Do not start human subjects research activities until you have obtained all other required institutional approvals
- Submit to the IRB any changes to the list of study personnel
- Personally conduct or supervise the human subjects research. Recognize that the Principal Investigator is accountable for the conduct of all study team members
- Conduct the human subjects research in accordance with the relevant current protocol as approved by the IRB, and in accordance with applicable federal regulations and local laws
- When required by the IRB ensure that consent or permission is obtained in accordance with the relevant current protocol as approved by the IRB
- Do not modify the human subjects research without prior IRB review and approval unless necessary to eliminate apparent immediate hazards to subjects
- Protect the rights, safety, and welfare of subjects involved in the research
- Submit an updated disclosure of financial interests within thirty days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new financial interest
- Ensure that no study personnel accept or provide payments to professionals in exchange for referrals of potential subjects (“finder’s fees.”)
- Ensure that no study personnel accept payments designed to accelerate recruitment that were tied to the rate or timing of enrollment (“bonus payments.”)

- Each investigator is required to maintain accurate and complete files for each IRB approved protocols
- Investigators must maintain original signed consent forms in their study files, if applicable
- Investigators' files must be available upon request for IRB or PAVE review
- Investigators must maintain their study files in a secured and confidential manner to protect subject confidentiality and confidential information
- Investigator records must be kept for a minimum of three years following the end of the study or as designated by the funding agency