Getting Started with Human Subjects Research: What You Need to Know

GRADUATE SCHOOL OF MEDICINE
Institutional Review Board
1924 Alcoa Hwy., U-76
Knoxville, TN 37920
Office: 865.305.9781
http://gsm.utmck.edu/irb

Contents

Introduction

The Institutional Review Board (IRB) is responsible for reviewing and approving all human subjects research conducted by anyone on premises owned or leased by the University of Tennessee Graduate School of Medicine (UTGSM), and research conducted anywhere by faculty, students, staff or others acting as representatives of the University. The goal of the Institutional Review Board (IRB) process is to protect the rights and welfare of those individuals who contribute to research by participating as subjects. The IRB is only one part of the research enterprise designated to protect research participants. The PI (Principal Investigator) and all study team members are responsible for upholding the principles outlined in the Belmont Report and following federal regulations, state laws, and institutional requirements.

Before you Begin

What Requires IRB Review?

Case Reports, Quality Improvement Projects and Projects that are Not Human Subjects Research are not required to go through the IRB review process. However, these projects should be submitted to the IRB before they begin so that the board can verify that they do not require IRB review.

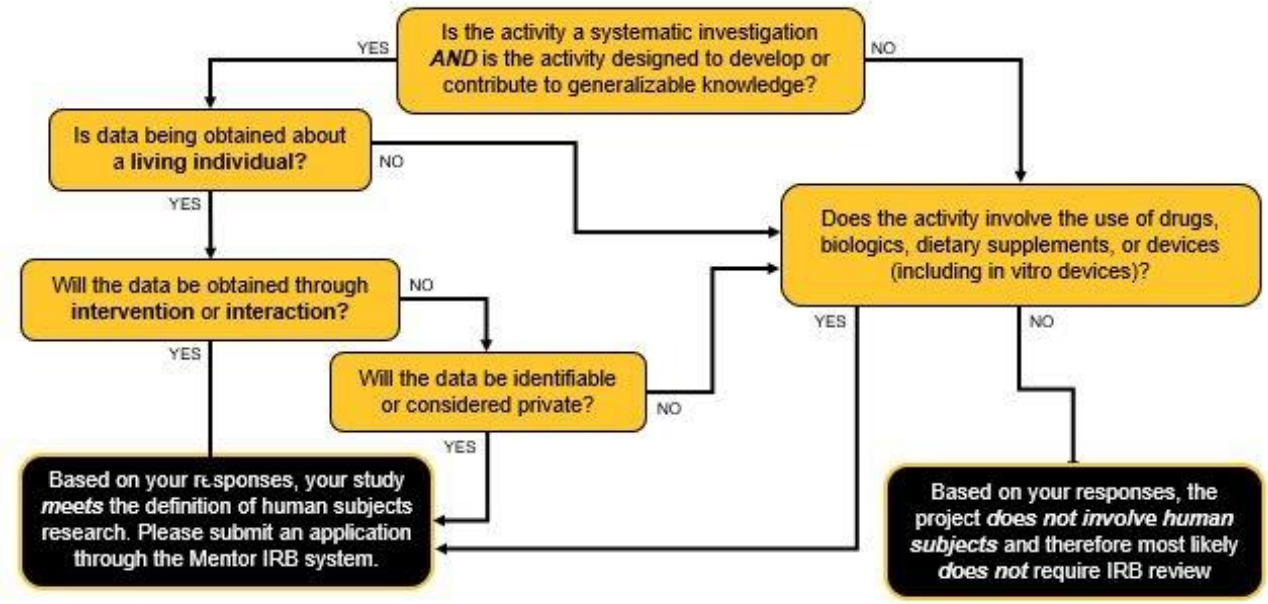
Case Reports do not require IRB review if they include descriptions of fewer than 6 patients' clinical experiences, provided that FDA regulations requiring IRB approval do not apply.

Quality Improvement or Quality Assurance (QI/QA) projects do not require IRB review. These projects are utilized to assess or improve a process or system or to improve performance as judged by accepted standards where the knowledge benefits a process and may not benefit patients. These projects create a process/system that results in greater safety, efficiency, or satisfaction.

If any of the following are true, the project is considered research and will require IRB review:

- The intent is to use the data to contribute to generalizable knowledge.
- Participants are randomized to compare outcomes.
- The activities are not normally done as part of standard operating procedures.
- Results will be used to apply knowledge to other programs outside the institution.
- The project is subject to peer review (designed to be used outside of the institution).
- The activities involve more than minimal risk to participants.

The decision tree below (reproduced with permission from Northern Kentucky University IRB) can be used to determine whether a project is Human Subjects Research and requires IRB review:



CITI Training

The IRB requires everyone involved in human subjects research to complete a training course in the protection of human research subjects (HSP). This is most often accomplished through the CITI course online. If you have completed similar Human Subjects Protection training in the last 3 years, please provide a copy to the IRB, otherwise please do the following:

- Go to www.CITIProgram.org and click “Register” (If you already have a CITI account with another institution, log into that account and underneath Institutional Courses click on "add affiliation" then continue with the instructions below. You will get credit for any matching modules you completed in the last 3 years).
- Type “Knoxville” in the search box and select University of Tennessee Health Science Center – Knoxville
- Complete the contact information screen and select your courses as described below.
- Say YES to Conflict of Interest, choose either **Group #3 Investigators and Key Study Personnel** or **Group #4 Fellows, Residents & Students**, as applicable.
    - If your research is considered a clinical trial (all industry funded, and some investigator initiated), also select Yes for **Good Clinical Practice (GCP) for Drugs & Devices, FDA focus**.
- Click “Start” next to a course name on the home page, complete the "Integrity Assurance Statement" and you will be taken to the list of required modules.

A copy of your completion report will be sent to the IRB automatically. Please contact the IRB at gsmirb@utmck.edu if you have any questions.

HSP (Groups 3 and 4) and GCP certificates are good for 3-5 years, depending on the course. Conflict of Interest training is good for 4 years. You will receive reminders from CITI and/or the IRB once your training needs to be renewed. This can be accomplished by taking the appropriate CITI Refresher course.

Review Categories

Research can undergo one of three levels of review: Exempt, Expedited, or Full Board. Decisions on the level of review are made based upon the type of research being conducted and the risk of potential harm for study participants. Exempt and Expedited research applications are typically reviewed by one or two individuals from the IRB on an ongoing basis. Full Board research is reviewed at a convened meeting of the full IRB. The deadline to submit a project for the month's agenda is the first working day of that month. If the submission is incomplete or requires numerous revisions it may be returned for correction and scheduled for the following month. Below is a chart that briefly outlines the categories of Exempt and Expedited review:

Categories of Review		
Exempt	**Expedited**	**Full Board**
Category 1... conducted in established or commonly accepted educational settings, involving normal educational practices	Category 1... some clinical studies involving drugs and medical devices	If greater than minimal risk, or If research does not fit one of the Expedited Categories even though it presents no greater than minimal risk, or If participants are particularly vulnerable, or If data are sensitive
Category 2...tests, surveys, interviews, or observations of public behavior **	Category 2... collection of blood sample by specific procedures and in limited amounts	
Category 3... benign behavioral interventions with adult subjects **	Category 3... non-invasive collection of biological specimens	
Category 4i... secondary research use of publicly available identifiable private information	Category 4... data collection using non-invasive procedures routinely employed in clinical practice	
Category 4ii... secondary research use of identifiable private information if recorded anonymously	Category 5... research involving materials originally collected for a non-research purpose	
Category 4iii... secondary research use of identifiable private information if only use of PHI is by an investigator in HIPAA covered entity	Category 6... voice, video, digital or image recordings made for research purposes	
Category 6... taste and food quality evaluation	Category 7... research on individual or group characteristics or behavior (surveys, interviews, focus groups, etc.)	
** Exempt Cat. 2 and 3 with Limited IRB Review.... ....data collected with identifiers where disclosure could reasonably place the participant at risk of criminal liability or damage their financial standing, employability, educational advancement, or reputation		

More detailed information about each category can be found on the UTK website and in the Office of Human Research Protections decision charts.

Note that some of the exempt and expedited categories for FDA regulated research are different from those for the Office of Human Research Protections. See the FDA Regulated Research and OHRP Regulated Research sections in this document for more information.

Principial Investigator Responsibilities

Protection for the rights and welfare of human subjects is achieved through a framework of comprehensive rules and regulations, independent oversight of research activities by IRBs and other responsible agencies, and the moral integrity and conscientiousness of individual investigators. In submitting a new study application for review and approval by the UTGSM IRB, the principal investigator agrees to assume important responsibilities related to the protection of human subjects. These obligations involve adhering to the approved protocol, securing and documenting informed consent, obtaining prior IRB approval for revisions, reporting in a timely fashion on the progress of the research, promptly notifying the IRB regarding unanticipated problems and serious or continuing noncompliance with regulations and policies, reporting on the completion of the study, maintaining complete study records, supervising all key research personnel and assuring their basic training in the protection of human subjects, disclosing potential conflicts of interest, and permitting inspection of all study records. To fulfill these obligations, investigators must execute them in accord with applicable laws, regulations, and local IRB policies and procedures. Because investigators and other key research personnel are the individuals who interact directly with human subjects, their fulfillment of these obligations is crucial to effective protection for the rights and welfare of human subjects.

For more detailed information on PI responsibilities, see SOP 027.

Review Process

The approval time for an application depends on the type of review (e.g., exempt, expedited, or full board) and on the completeness of the application submitted. Submitting a complete application and including all required attachments will ensure shorter review turnaround times.

Delays in obtaining IRB approval are typically due to submitting incomplete applications, insufficient consent forms, or missing survey or interview questions. Understanding what is needed in the submission can reduce the time required for review. Listed below are the issues the IRB staff most commonly see that can slow down approval times:

- Study team does not have CITI training
    - Group 3: Investigators and key Study Personnel
    - Group 4: Fellows, Residents and Students
- Selecting the wrong IRB
    - Select UT GSM/UTMC Knoxville
- iMedRIS messages going to an account you don't monitor
    - By default, iMedRIS messages go to the UT email address associated with your UT NetID (***@uthsc.edu, ***@vols.utk.edu, ***@utk.edu. ***@Tennessee.edu, etc.). If you do not monitor that account or have it forwarded to your hospital email ***@utmck.edu go to your profile in iMedris and update the email address to one you monitor. All correspondence will go to whatever address is in your iMedRIS profile.
- Failing to adequately explain what you intend to do. Make sure you read the iMedRIS questions and instructions carefullyand provide detailed information.
- Forgetting to attach supporting documents such as surveys, protocol, consents, or data collection forms.
- Forgetting to route for signatures

    - The PI and PI's Department Chair must sign off on all new submissions. If you are a student, resident or fellow, your Faculty Advisor must also sign off.
- The Department Chair or Faculty Advisor do not sign off in a timely manner
    - The IRB office does not receive your application until all signoffs are completed. You may need to send reminders to those who are required to sign off on your project.
- Not checking the status of your project
    - If it has been more than a week and you have not received a response to your submission, contact the IRB office to verify we have received your submission.

See SOPs 003, 014, and 015 for more detailed information about the review process for Full Board, Exempt, and Expedited studies.

Using Protected Health Information for Research

There are certain conditions under which a HIPAA covered entity can use or disclose protected health information (PHI) for research purposes:

- If the subject of the PHI has granted specific written permission. This written permission can be included in the study consent form. Waivers of written permission can be granted under certain circumstances. (See the next section for more details)
- To determine study feasibility or develop a study protocol if the PHI will not be re-used or re-disclosed for other purposes.
- If the PHI has been de-identified in accordance with the standards set by the Privacy Rule.
- If the information is released in the form of a Limited Data Set with certain identifiers removed and with a data use agreement between the researcher and the covered entity.

Waivers of the Authorization requirement can be granted by the IRB if the use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements:

- an adequate plan to protect the identifiers from improper use and disclosure;
- an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research
- adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity
- The research could not practicably be conducted without the waiver and;
- The research could not practicably be conducted without access to and use of the protected health information.

See SOPs 009 and 010 for more information about PHI and research.

Collaborations

When research requires the collaboration of one of the hospital units listed below, GSM requires completed, signed collaboration forms or letters of support. These are due at the time of IRB submission and should be attached to the Submission Routing Form at the end of the application. Collaboration forms are available on the IRB Website at http://gsm.utmck.edu/irb/forms.

- **Infection Prevention/Control:** Letter of Support, contact Mahmoud Shorman, MD at 865-305-6175 or mshorman@utmck.edu with questions regarding support from Infection Prevention.
- **Nursing (supporting other departments):** Collaboration Form, if you need support/assistance from staff nurses at UTMC, submit a collaboration form signed by the Nurse Manager for the area where you need assistance AND Leslie McKeon, PhD, RN.
- **Nursing (Research by Nurses):** Approval letter, present your project to the Nursing Research and Evidence-Based Practice Council (NREBPC) before submitting your IRB application and attach a copy of the NREBPC approval letter with your application. Contact Leslie McKeon at LMcKeon@utmck.edu for questions regarding the review by the NREBPC.
- **Pathology:** Collaboration Form, contact Dr. Amila Orucevic at 865-305-9080 or AOrucevic@utmck.edu with questions regarding the Pathology Collaboration form.
- **Pharmacy:** Collaboration Form, contact Dr. Barbara Faircloth at 865-305-8380 or BFairclo@utmck.edu with questions regarding the Pharmacy Collaboration form.
- **Radiology:** Collaboration Form, contact Dustin Osborne, PhD at 865-305-8264 or DOsborne@utmck.edu with questions regarding the Radiation Collaboration form and review by the Radiology Research Committee.
- **Radiation Safety:** Approval Letter, contact Stephen Handley at 865-305-9664 or SHandley@utmck.edu with questions regarding review by Radiation Safety.
- **Biobank:** Collaboration Form, Antje Bruckbauer, MD, PhD at 865-387-0103 or abruckbauer@utmck.edu with questions regarding review by the Biobank.
- **Simulation Center:** Collaboration Form, contact Melinda Klar at 865-305-4626 or at MKlar@utmck.edu with questions regarding the SIM Center form.
- **Advanced Practice Providers:** Collaboration Form, contact Andrew Ward PhD at award@utmck.edu with questions regarding support from the APP Research Council

Reliance Agreements

When multiple institutions are engaged in human subjects research, a formal relationship must be established between the two parties. While there are several factors that may affect how that relationship is established and executed, a formal agreement is usually required.

Reliance Agreements are used when the external investigator is affiliated with an institution that holds its own Federalwide Assurance (FWA). Usually this means that the investigator is affiliated with a hospital or university located in the United States of America and has its own IRB.

A Reliance Agreement is a document signed by two institutions that are engaged in human subjects research that permits one institution's IRB to cede review to another institution's IRB. This requires only one IRB to conduct a full review of a research project rather than both IRBs conducting a full review. An institution is considered to be engaged in the conduct of human subjects research if an employee or agent affiliated with that institution engages in any of the following:

- Collecting data
- Obtaining informed consent
- Analyzing or accessing identifiable data
- Answering questions about the research for potential, current, or past participants
- Otherwise acting as an extension of the Principal Investigator

An Individual Investigator Agreement (IAA) is required when the GSM IRB oversees research that engages individuals who are not agents or employees of an institution with its own FWA. For example, someone who works at a hospital or clinic that does not have its own IRB. An IAA establishes that these researchers will adhere to the same policies and procedures that UTGSM researchers must follow.

The University of Tennessee Graduate School of Medicine is a member of SMART IRB, which allows for easier collaboration and more streamlined reliance agreement processing with other member institutions. SMART IRB streamlines the reliance agreement process through the execution and agreement of a Common Master Agreement that most notably defines responsibilities and communication plans for IRBs engaged in cooperative research.

If an institution is not a member of SMART IRB, the UTGSM IRB will utilize a more defined communication plan to ensure all parties are appropriately aware of their responsibilities.

The University of Tennessee Graduate School of Medicine and the University of Tennessee, Knoxville have executed a Master Reliance Agreement that streamlines the reliance agreement process between our two institutions.

iMedRIS

Account Activation

iMedRIS is the electronic system used by researchers and the IRB for the submission of new studies and the ongoing review of existing projects. You can access iMedRIS anywhere you have internet access. Logging into the system requires using your university NetID and password (not your hospital ID and password) along with DUO Mobile two-factor authentication. You must set your web browser to allow pop-ups from iMedRIS.

Submitting a New Application

New study applications should be submitted to and approved by the IRB before any study-related activities occur. For step-by-step instructions on submitting a new study application in iMedRIS, email the IRB at gsmirb@utmck.edu.

Altering an Approved Application

Investigators are required to submit an Amendment Request in iMedRIS (Form 2) for any modifications they wish to make to the study after initial approval has been given by the IRB. The amendment must be approved prior to implementing modifications to the study procedure.

If you are only adding or removing personnel who have a university NetID, then you can submit a Personnel Change Request in iMedRIS (Form 5). This form cannot be used to make any other changes to the application. To add individuals who do not have a university NetID, please contact the IRB office.

For step-by-step instructions (including screenshots) on how to submit an Amendment Request or a Change in Personnel, please email gsmirb@utmck.edu.

Continuing Review

Continuing review is required yearly for all Full Board studies and for some Expedited studies until the Principal Investigator has completed all research-related interactions/interventions and the study is

closed to enrollment. The continuing review allows the IRB to monitor the progress of the study and ensure that it continues to meet institutional and federal requirements.

The PI should receive notifications from iMedRIS at 60 and 30 days prior to expiration of the study that a continuing review form needs to be submitted. However, it is ultimately the responsibility of the PI to keep up with study expiration dates and submit a continuing review in a timely manner. If the continuing review has not been submitted and approved prior to the expiration date, the study will be administratively closed the day after expiration. If this occurs, you must halt all research activities until approval has been reinstated. Note that the IRB reviewers are busy and may not have time to review a continuing review submitted shortly before the study's approval lapses. The board recommends submitting your continuing review at least a week before the study expires for Expedited studies. For Full Board studies, review the Full Board Deadline and Meeting Dates on the IRB website to determine when your continuing review should be submitted.

For step-by-step instructions (including screen shots) on how to submit a Continuing Review, please email gsmirb@utmck.edu.

Submission Signoffs

Each submission type has different required signoffs. It is important to assign the correct individuals for signoffs because the IRB will not review your submission until all of the required signoffs have been obtained.

See the table below for more information:

Submission Type	**Signatures Required**
New submission	Principal Investigator, Faculty Advisor if applicable, Departmental Scientific Reviewer, Department Chair After approval, everyone else listed on the study gets notified they are listed as study personnel. They have 7 days to request removal.
Revision	Principal Investigator or Co/Sub-investigators
Continuing review	Principal Investigator or Co/Sub-investigators
Advertisements and other misc.	Principal Investigator or Co/Sub-investigators
Change in Personnel	Principal Investigator or Co/Sub-investigators
Protocol deviation	Principal Investigator
Serious Adverse Event	Principal Investigator

Unanticipated Problems & Adverse Events

The Office of Human Research Protections (OHRP) and the Food and Drug Administration (FDA) both require prompt reporting of any unanticipated problems involving risks to study subjects or others.

Adverse events, on the other hand, do not always need to be reported. Adverse events are defined as "any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example abnormal physical exam or laboratory finding), 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".

Some adverse events are also considered unanticipated problems, and these need to be reported to the IRB promptly so that the IRB can report them to OHRP and/or FDA as required. Unanticipated problems are unexpected events that occur in the context of research that might cause harm to participants or others. Unanticipated problems are:

- unexpected; and
- at least possibly related to participation in the research; and
- indicate that subjects or others are at a greater risk of harm than was previously known or recognized

For more detailed information about this topic, see this guidance from HHS or this guidance from the FDA. If you have any questions about whether an event needs to be reported to the IRB, ORHP, or the FDA, contact the IRB Office.

Protocol Deviations

A protocol deviation is any departure from the study procedures as specified in the IRB-approved protocol. For example, a protocol deviation may involve using an unapproved version of a consent form or recruitment flier, or it may involve implementing some other change to the study protocol without first receiving IRB approval.

In some rare instances, deviations from the protocol may be necessary to eliminate an apparent immediate hazard to a participant. However, all other protocol changes must be submitted to and approved by the IRB before implementation.

Investigators and their study staff are required to report instances of possible noncompliance to the IRB within 7 working days of discovery. Additionally, anyone may report concerns of possible noncompliance to the IRB verbally, by email, or other means. In such cases, the reporting party is responsible for making these reports in good faith, maintaining confidentiality and, unless reporting anonymously, cooperating with any subsequent fact-finding in relation to the report.

If an individual, whether investigator, study staff or other, is uncertain whether there is cause to report noncompliance, he or she may contact the IRB Director or IRB Chair directly to discuss the situation informally.

Study Closure

The completion or early termination of a study is a change in research activity that should be reported to the IRB. Studies may be closed when the involvement of human subjects ceases. This means that interventions, interactions, observations, and the gathering, use, study, and analysis of identifiable private information, including specimens, are all complete. The IRB will review study closure reports, typically by expedited review, and either approve the closure of the study or request additional information or confirmation of facts from the investigator.

For step-by-step instructions (including screen shots) on how to submit a Study Closure form, email gsmirb@utmck.edu.

FDA Regulated Research

FDA regulations apply to research that involves food, dietary supplements, drugs, medical devices, and some electronic products. The regulations apply when the intent of the research or clinical investigation is to develop a drug, device, biologic, or app that will cure, treat, mitigate, diagnose, or prevent disease in humans. Prospective IRB approval is required for all of the types of research outlined below, except where noted otherwise.

Investigational Drugs

The Investigational New Drug (IND) process begins when a sponsor of a new or marketed drug is ready to test the drug in human research subjects for a particular indication. There are typically five phases for IND studies. The preclinical phase involves lab studies in animal models. After that, there can be four additional phases of clinical trials:

- Phase 1 trials – small group of people, usually first time in humans; assess short-term safety, safe dosage range, healthy subjects
- Phase 2 trials - human research subjects who have been diagnosed with the disease targeted by the drug; used to support finding of effectiveness for a particular indication
- Phase 3 trials - obtain additional effectiveness and safety information
- Phase 4 trials - conducted after FDA approval, during post-market safety monitoring

An IND is required for any study of an investigational drug that has never been approved for use in the United States. An IND also may be required when an approved drug is being used for different (new) populations, dosing, or routes of administration.

An IND is not required in the following situations:

- When study results are not intended to be reported to the FDA in support of a new indication or significant change in labeling of the drug.
- For prescription drugs when the investigation is not intended to support a significant change in advertising for the drug.
- When the investigation does not involve a route of administration, dose, patient population, or other factors that significantly increase the risk associated with use of the drug.

Investigational Devices

An FDA-regulated device is an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is:

- recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,
- intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
- intended to affect the structure or any function of the body of man, and

- which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

There are two different routes to market for an Investigational Device that is FDA-regulated. The first is called a 510(k) determination. In this instance, the device is considered substantially equivalent to a device that was on the market as of 1976 and is cleared to join the device already on the market without demonstrating safety or efficacy.

Devices that are not eligible for a 510(k) determination require clinical data to determine safety and efficacy before they can be marketed. Before this data can be collected, an Investigational Device Exemption (IDE) must be obtained from the FDA. An IDE is not needed for diagnostic devices, if the device is:

- Noninvasive
- Does not require an invasive sampling procedure that presents significant risk
- Does not by design or intention introduce energy into a subject, and
- Is not used as a diagnostic procedure without confirmation of the diagnosis by another, medically established product or procedure
- When the device is undergoing consumer preference testing, testing of a modification, or testing of a combination of two or more devices in commercial distribution, if the testing is not for the purpose of determining safety or effectiveness and does not put subjects at risk

Expanded Access/Compassionate Use

Expanded access involves the use of an investigational drug, biologic, or medical device to treat a patient with a serious disease or condition when there is no comparable or satisfactory alternative treatment available. The purpose is to treat the patient, and the intent is to provide direct benefit to the patient. Even though the purpose is not strictly for research, expanded access or compassionate use of an investigational drug, biologic, or device must receive prospective IRB approval.

Emergency Use

Emergency use of a drug that is not FDA-approved can be used when a patient needs to be treated before a written submission can be made, for example, when there is:

- An acute medical emergency
- Time to treatment is critical
- No comparable or satisfactory alternative is available

Prospective IRB review is not required for this treatment; but the FDA requires that the IRB be notified of the emergency use within 5 days. The use of this unapproved drug applies only to an individual patient; any subsequent use of the test article is subject to IRB review.

Humanitarian Use

Humanitarian Use Devices are designed to treat a disease or condition that affects fewer than 8,000 people in the U.S. per year. Approval can be granted “notwithstanding the absence of reasonable assurance of effectiveness that would otherwise be required.” IRB approval is required prior to humanitarian use of any unapproved device.

Nonemergency Individual Patient Requests

Nonemergency individual patient treatment with an investigational new drug. This may be requested to treat just one patient. In this case, the physician is responsible for oversight of the patient and for securing IRB approval prior to administering the drug.

Compassionate use involves individual patient use of a medical device, and the same rules apply as for using an investigational new drug for just one patient. Prospective IRB approval is required for each of these uses.

OHRP Regulated Research

When research is federally funded, it must comply with the regulations set forth by the Office of Human Research Protections, known as the Common Rule. Sometimes studies will be subject to both OHRP and FDA regulations and sometimes only one set of regulations will apply.

When human subjects research is not subject to the Common Rule or FDA regulations, the Graduate School of Medicine IRB ensures that human research subjects benefit from equivalent protections by applying the Common Rule standards, with purposeful deviations that do not meaningfully diminish protections as noted within our Standard Operating Procedures.

Other Common Types of Research at UTMC

Research with Biospecimens

Research with biospecimens may be subject to OHRP regulations, FDA regulations, and/or the HIPAA Privacy Rule. Biospecimens may be collected directly from individuals for research purposes, but they may also come from biobanks or other existing repositories. Under OHRP regulations, a human subject is a living individual about whom an investigator conducting research: 1) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or 2) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens. A biospecimen is considered identifiable when the identity of the subject may be ascertained by the investigator. This means that biospecimens that have direct identifiers removed, but that are linked to a code key that allows individuals to be re-identified are still considered identifiable if the researchers have access to the code key. Biospecimen research that fits the criteria of being human subjects research with identifiable data must be reviewed and approved by the IRB.

Under FDA regulations, a human subject includes any individual on whose specimen an investigational device is used, even when the individual is not identifiable. In addition, all FDA-regulated clinical investigations must undergo IRB review, even if they are outside the scope of the Common Rule (OHRP regulations). One other difference between OHRP and FDA regulations is that when an individual withdraws from an FDA-regulated study, all of the data collected on that individual up until the point of withdrawal must be kept as part of the study data. For OHRP-regulated studies, OHRP and the sponsor may sometimes allow the destruction of all study data for individuals who withdraw from a study.

Research with Medical Records

The most common research involving medical records the UTGSM IRB reviews is retrospective chart review studies. These studies are most frequently reviewed under Exempt Category 4iii. This review

category involves only the collection or analysis of protected health information (PHI) from a covered entity. In this case, the PHI is already subject to HIPAA regulations and those apply rather than the Common Rule regulations on PHI. Typically, the IRB can grant a waiver of consent for these projects, as long as it is not practicable to collect consent and there is minimal risk to participants. It is also important to note that this exemption is only available if the data stays in or is shared with another HIPAA-covered entity. If data from medical chart reviews will be shared with a non HIPAA-covered entity, expedited review will be required. Note that not all research involving medical records will fall into this category, and depending on the data that is being shared, a Data Use Agreement may be required.

Interview or Survey Research

The other type of research the UTGSM IRB frequently reviews is research involving surveys or interviews. Surveys and interviews may qualify for Exempt Category 2 if the information obtained is completely anonymous, or if it is identifiable but disclosure of the data outside of the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation. If the research does not fit these criteria, it is typically reviewed as Expedited Category 7 or as a Full Board study. If the survey or interview is occurring online or via teleconference, a waiver of the requirement to obtain written consent may be granted under certain conditions. For online surveys, participants can be presented with a consent statement and asked to click a box to agree to continue. For teleconference interviews, participants may provide verbal consent at the beginning of the interview instead of signing a consent form.

Conclusion

We hope this guide has been useful for you as a researcher. If there is additional information you would like to see included in this guide, or if you would like to request that the IRB conduction an education presentation for your department or group, please let us know. If you have any questions or concerns about the IRB process, you may contact any of us listed below.

Kimberly C Mason, PharmD
Chair, IRB
865-305-9712
KMason@utmck.edu

Jen Engle, PhD, CIP
IRB Director
865-305-9781
jmengle@utmck.edu

Cindy Langley, RN, CIP
IRB Regulatory Specialist
865-305-6892
clangley@utmck.edu