********IRB Frequently Asked Questions********

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New Studies

How do I know which type of application to complete?

- ✓ It depends on your study design and how much risk is involved in the study. If the study involves:
  - ➢ Little to no risk – generally ***Exempt*** review
  - ➢ Minimal risk studies (not involving x-rays or other radiation) - generally ***Expedited*** IRB review
  - ➢ More than minimal risk studies – always ***Full Board*** (reviewed by convened IRB)
- ✓ Refer to the OIRB website for examples and application forms

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How long does it take to get approval for a new study?

- ✓ The turnaround time depends on a variety of factors such as: how well the application was prepared, complexity of the study (needing other committee/institution approvals, etc), PI/coordinator response time to OIRB and IRB questions and concerns, etc. The following are the average turnaround times:
  - ➢ ***Exempt –*** approximately 1-3 weeks
  - ➢ ***Expedited –*** approximately 2-4 weeks
  - ➢ ***Convened IRB –*** approximately 6-8 weeks

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Amendments

What types of changes need IRB review?

- ✓ All changes require IRB review unless the change is implemented to eliminate an immediate hazard.

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How do I make a change to my IRB approved study?

- ✓ You must submit an amendment to the IRB office and receive IRB approval before you may implement any changes (unless your study was determined exempt). To submit an amendment you need to:

  1. Complete the amendment form: http://research.uthscsa.edu/irb/Amendments.shtml
  2. Revise any approved application forms or documents (using tracked changes so the IRB can see what was added/deleted)
  3. Sign Form A-1 and scan it (or sign it electronically)
  4. Save all forms (amendment form, Form A-1, and any revised forms) and email your submission to IRBMail@uthscsa.edu.

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How long does it take to get approval of an amendment?

- ✓ ***Expedited*** – The average turnaround time for an Expedited Amendment is one week. If your amendment is especially simple (changing study staff) you may receive approval in as little as 2 days. If your amendment is extremely complicated (i.e., many changes including new procedures and revised study design), or not completed correctly, approval may take 2 weeks or longer.
- ✓ ***Convened IRB*** – Full Board amendments submitted within the posted guidepost dates (http://research.uthscsa.edu/irb/dates.shtml) will go to the next appropriate meeting (no more than 34 days after submission). You can expect to learn about the Board's decision within ten days following the meeting

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Continuing Review

How to determine when my study expires?

- ✓ The original approval letter provides the study's' IRB expiration date.

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When is my progress report due?

- ✓ The progress report is due 45 days prior to the expiration date.

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What is required in my continuing review submission?

- ✓ The Progress Report Form and any modified documents in tracked changes (if requesting changes as part of the continuing review) such as the consent forms.
- ✓ Other documents that may be submitted include an Adverse Events log (must be signed by the PI) Protocol Deviation Tracking Log, Sponsor reports or notifications, DSMB report or independent medical monitor report, Form X Conflict of Interest form (if there are changes in COI for any research personnel), publications or meeting proceedings.

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How does UTHSCSA define an enrolled subject?

- ✓ The IRB considers a subject enrolled in a study when the subject signs a consent document. Any screening or testing done for research purposes to determine subject eligibility should not be conducted prior to the subject agreeing and documenting their consent to participate in the research (except where waiver approved).
- ✓ In cases where the IRB approves a waiver from the requirement for obtaining informed consent and/or a waiver from the requirement for documentation of informed consent, any individual on whom data has been collected should be counted as an enrolled subject.

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Adverse Events

What is the IRB's policy regarding reporting adverse events?

- ✓ Events or problems that do not meet criteria are recognized by OHRP and the FDA to not yield information useful to IRBs - often lacking context and detail - often incomplete and unanalyzed - and as such inhibit an IRB's ability to assure the protection of human subjects. The IRB Chair or designated reviewer will return a report to the investigator without being reviewed by the IRB if that report does not meet criteria. In order to meet criteria for prompt reporting, before any other consideration, events or problems must first be analyzed by the local investigator considering the need for substantive action (implementing actions if necessary to eliminate immediate hazard). The first criteria in this analysis must be whether the event or problem is unanticipated (e.g., protocol documentation / not within the frequency and severity expected for population's underlying condition (only protocol documentation for UADE's)). See the policy for remaining criteria and further clarification. If anticipated, reporting is still required but may be in the form of a summary as part of the next progress report sent to the IRB for continuing review.

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Protocol Deviations

What do I do with my protocol deviation tracking log?

- ✓ Minor Administrative Protocol Deviations
  - ➢ Minor or administrative protocol deviations are defined as those which do not affect the scientific soundness of the research or adversely affect the rights, safety, or welfare of human subjects. A minor or administrative protocol deviation is limited to minor departures from the protocol for a single subject. Examples include: follow up visits that occurred outside the protocol required timeline or blood samples obtained at times close to but not precisely at the time points specified in the protocol. Provide a summary in next year's progress report.
- ✓ Emergency Deviations
  - ➢ When a deviation occurs in an emergency situation, such as when a departure from the protocol is required to eliminate apparent immediate hazard to the subject. Examples include: withholding study drug in response to a serious adverse event (actual harm) or to avoid a serious harm (risk of harm) Emergency deviations are always considered Unanticipated Problems Involving Risks to Subjects or Others (UPIRSOs). Submit a Prompt Report and summarize event in next year's progress report.
- ✓ Major, Non Emergent Deviations
  - ➢ A planned, major, non-emergent change in the protocol may not be initiated without IRB review and approval. Examples include: any changes to the study design or procedures or changes to study staff or sites). Submit an Amendment request to the IRB before change is made.

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Study personnel

Who needs to be listed as study staff?

- ✓ Research team members who will be performing research activities and/or research procedures listed in the protocol
- ✓ Clinical (or commercial) services that involve administering the study interventions being tested or evaluated under the protocol

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Informed Consent

Do I need to use a consent form that has a stamp on it?

- ✓ Yes. You must use the most recently IRB approved consent form when enrolling patients. Using the consent document with the IRB stamp allows anyone looking at your records to know you used the most current (accurate) consent form.

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I am only enrolling non-English Speaking subjects into my study. Do I have to submit an English consent document for IRB approval?

- ✓ Yes. However you have two options regarding the method of approval:
  - Submit the translated consent as an amendment - You may submit an English consent form at initial submission and receive final approval. Then, after the consent form has been translated, you should submit: the English (stamped) consent document, the translated consent document Form H-1 (translation certification), a completed Amendment form and Form A-1 (signature assurance sheet). In this scenario, you will have two approved (stamped) consent documents for your study (one English and one non-English).
  - Receive approval of the translated consent at initial approval – You should submit the English consent form during initial review and the reviewer will provide you with a PDF version of the English consent with the words "IRB Approved for Translation on MM/DD/YY" in the background of the document. Once the consent form has been translated, submit the English approved (PDF) consent, the translated consent and Form H-1 to the reviewer to receive final approval. The date on the English PDF consent will be the date used on the Form H-1. You will then only receive one officially stamped consent document for your study (one non-English). (This process is only available for use on Expedited submissions).

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Does the new Clinical Trial (ClinicalTrials.gov) statement in the informed consent document apply to my research study?

- ✓ Yes if your study is a controlled interventional study of drugs, biological products, or devices subject to FDA regulation **and** the study was initiated after March 7, 2012
- ✓ No if your study is a small feasibility device trial measuring feasibility of the device or a Phase I Clinical Trial.

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Recruitment material

Does the IRB need to review recruitment material for my study?

- ✓ Recruitment materials will not be stamped by the IRB unless required by the sponsor or institution where it will be posted.

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IRB Authority

Does my study/project need IRB Review?

- ✓ All projects that meet the definition of research involving human subjects (as defined by federal regulations) require IRB review. Please review the worksheet to determine whether an activity is human research to determine whether your project requires IRB review.
- ✓ Regulatory and ethical obligations to protect research participants apply, for example, to research that uses:
  - ➢ Data from varied research methods including surveys, interviews, and observation
  - ➢ Private information, such as medical, family, or employment information, or residual administrative records including earnings, and treatment histories that can be readily identified with individuals, even if the information was not specifically collected for the study in question;
  - ➢ Tissue specimens, obtained for routine medical care that would have been discarded if not used for research, or DNA samples, where samples or specimens can be linked to a living individual.

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What is the difference between convened IRB, expedited and exempt review?

- ✓ Convened IRB – Submissions are reviewed by a convened board. Committee members meet to discuss the proposal. The board can recommend approval, approval with changes, disapprove, or table the study. Studies reviewed by the convened IRB are generally are greater than minimal risk.
- ✓ Expedited – submissions are reviewed by the IRB Chair or other qualified IRB member. The reviewer evaluates the study for approval. This type of review can be carried out on a study that involves minimal risk and fits into one of 7 expedited categories. The reviewer may exercise all the rights of the convened IRB however, may not disapprove a submission. If the reviewer is unable to make a determination the study will be considered at a convened IRB meeting.
- ✓ Exempt – Submissions are reviewed by an OIRB staff member, IRB Chair or other qualified IRB member. The reviewer evaluates the studies for approval. The submissions must fit into one of the categories listed in 45 CFR 46.101(b). The investigator makes the initial decision as to which category the research falls under. The IRB may approve the submission under the requested category. If the study does not meet the requirements of exempt review in the opinion of the IRB, a study must be submitted for a different level of review.

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Why does the IRB need to review my grant?

- ✓ In the past, numerous instances have been identified in which human subject research described in a grant application differed significantly from how it was described in an IRB application. The grant included important elements (e.g., targeting of vulnerable subjects, additional arms, different doses, etc.) that were ultimately implemented without IRB review and approval. US Department of Health and Human Services (DHHS) regulations at 45 CFR 46.103(f) require that each grant application or proposal for DHHS-supported human subject research be reviewed and approved by the IRB.

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When are IRB meetings and submission deadlines?

- ✓ There is an IRB meeting once every two weeks. The schedule is at http://research.uthscsa.edu/irb/dates.shtml

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CITI Training

Who needs to have completed CITI Training?

- ✓ All investigators and research staff engaged in exempt and non-exempt human research must complete appropriate education in research ethics, human research protections and regulatory policy.

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How often do I need to re-take the CITI Training?

- ✓ If engaged in research at UTHSCSA, appropriate learner module must be renewed every three years.
- ✓ If engaged in research at the VA, the VA Human Subjects Protection and Good Clinical Practices Course must be renewed every three years.

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What if I have another type of Human Subjects Protection Training from another program?

- ✓ The other training may only be accepted if the Research Protection Programs Director or IRB Associate Director approves the substitution for all non-Exempt research. For Exempt research, the OIRB may accept other research ethics training in lieu of CITI training. Documentation must be obtained, maintained and submitted by the trained individual as necessary to indicate that training was completed (or for refresher training was completed every three years) indicating that the Director or Associate Director determined the education to be appropriate education in research ethics, human research protections and regulatory policy.

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IRB Fees

Does the IRB charge a fee for the review of research?

- ✓ Yes. The fee structure is different for UTHSCA and non-UTHSCSA based research:
- ✓ The IRB charges a fee for **UTHSCSA** industry-sponsored research (pharmaceutical or device firms and other for-profit entities). The IRB does not charge for UTHSCSA studies with federal, state, institutional or other grant funding or for unfunded studies.
- ✓ The IRB charges a fee for **non-UTHSCSA** research regardless of the funding according to the MOU between UTHSCSA and the other institution.

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Whose responsibility is it to pay the IRB fee?

- ✓ The fee is the responsibility of the investigator. It is the investigator's responsibility to ensure the contract makes allowance for the IRB fee.

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Will I be charged if the Sponsor withdraws the study after IRB approval but before enrollment begins?

- ✓ Yes. If the study is reviewed by the IRB a fee is charged.

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My study was tabled by the IRB and the sponsor withdrew the study. Why am I being charged an IRB fee?

- ✓ Review by the IRB is a service, and if the study is reviewed, a fee is charged regardless of the outcome.

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Who do I contact regarding payment of an IRB fee?

- ✓ Please contact the OIRB office at 210-567-8250.

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Does the IRB charge for each new study, amendment, and progress report?

- ✓ Yes. See the IRB Review Fees Memorandum for details.

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How much is the IRB fee?

- ✓ See the IRB Review Fees Memorandum for details.

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What method of payment is accepted?

- ✓ Invoices may be paid by check or Inter-Departmental Transfers (IDTs).

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eProtocol

How do I inquire about a study reviewed under eProtocol?

eProtocol was discontinued in August 2012. UTHSCSA staff no longer have access to the IRB section of eProtocol. OIRB retrieved all files from the system and have stored them electronically by eProtocol tracking number and PI name. If you have questions for OIRB about your submission, please do the following

- ✓ Locate your approval letter from eProtocol and reference the eProtocol tracking number when contacting the IRB office.
- ✓ If you do not have your approval letter, locate any communication you have received and reference the eProtocol tracking number with your question to the IRB office.
- ✓ If you cannot locate either of the above items, reference the PI name and title of the study when contacting the IRB office.

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Why can't I login to eProtocol?

eProtocol was discontinued in August 2012. UTHSCSA staff no longer have access to the IRB section of eProtocol.

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PI Self-Assessment Program

What is the PI Self-Assessment Program?

- ✓ The PI Self-Assessment Program is part of the IRB's quality improvement activities. The PI self-assessment provides an opportunity to educate investigators and research staff on federal, state, and HSC policies and procedures; assist researchers in assessing their own programs, and assist in identifying areas on which additional education programs may need focus.

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Who will need to complete an assessment and how often?

- ✓ All investigators will eventually need to complete a survey. Each investigator will need to complete an assessment once every three years.

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How will Investigators be notified that they need to complete an assessment?

- ✓ Investigators are notified two ways. The first notification will be in the initial notice to investigators that a progress report is due from the OIRB. The second notice will come from the Department of Epidemiology and Biostatistics (DEB) providing the investigator with the information necessary access the assessment in the Informatics Data Exchange and Acquisition System (IDEAS).

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Will the assessment remain anonymous and how will the Investigator receive feedback from the IRB?

- ✓ To ensure the integrity of the data obtained from the investigators, the Office of the IRB will have an independent third party, the DEB, send username and password along with a link to IDEAS for each investigator. If the PI already has an IDEAS username and password set up, the investigator will be asked to use that information to access the assessment. Each assessment will be assigned an identification number. Completed assessments will be stored in IDEAS with the identification number. The assumption is that the PIs may be more comfortable completing an anonymous assessment and more likely to be forthcoming with the requested information.

  Based upon assessment responses, the OIRB staff will create individualized feedback for each completed assessment. This is aimed to assist the investigator with making the necessary improvements and/or corrections. Feedback reports are stored in IDEAS. The investigator will receive notification when a feedback report is available for review.

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How long will the investigator have to complete the assessment?

- ✓ Investigators are expected to complete the assessment within two weeks of notification.

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What if an investigator does not complete an assessment?

- ✓ The OIRB will run a report in IDEAS to determine names of investigators who have not completed the assessment. OIRB Staff will contact to those investigators and plan for completion of the assessment.

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Where may I find a sample of the assessment?

- ✓ You may find a sample of the assessment on the IRB's website: http://research.uthscsa.edu/irb/miscforms.shtml

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When did the PI-Self Assessment Program begin?

- ✓ April 2, 2012

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Where to see more information or who to contact with questions regarding the PI Self-Assessment Program?

- ✓ PI Self Assessment Program Policy and Procedure:
  - ✓ http://research.uthscsa.edu/irb/sop.shtml#self_assess
- ✓ OIRB office 210-567-8250

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Miscellaneous

Where may I find the IRB's e-signature policy in accordance with 21 CFR 11 Electronic Records; Electronic Signatures?

- ✓ The UTHSCSA IRB's use of electronic signature is not subject to part 11 because the electronic signatures we use meet the FDA's definition of **a flattened digital signature**. As a result, our use of these signatures falls into the realm of "use of computers to generate paper printouts of electronic records, and those paper records meet all the requirements of the applicable predicate rules and persons rely on the paper records to perform their regulated activities." Thus, our limited use of digital signatures on our documents that can be printed is not generally considered to be "using electronic records in lieu of paper records" under §§ 11.2(a) and 11.2(b). In these instances, the use of computer systems in the generation of paper records would not trigger part 11" by the FDA. For more information: http://www.fda.gov/RegulatoryInformation/Guidances/ucm125067.htm

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