

UTHSC IRB

THINGS TO REMEMBER WHEN CONDUCTING HUMAN SUBJECTS RESEARCH

This is only a quick-reference sheet for common questions or problem areas, and policies are subject to change. You should always consult *all* of the IRB's current policies, *in full*, at <https://uthsc.edu/research/regulatory-support/irb/index.php>

If you have any questions, please call 901.448.824.

Rule #1: If you are UTHSC faculty, staff, student, resident, or fellow, you and are conducting a human subjects research project as an employee or agent of UTHSC, you must have approval from the IRB before you may begin any part of your human subjects research project.

Informed Consent:

- You must either obtain full informed consent with a signed consent form, or obtain IRB approval for an alteration or waiver of informed consent.
- You must use the full UTHSC IRB consent form templates, located at <https://uthsc.edu/research/regulatory-support/irb/researchers/consent-forms.php> unless you have an alteration or waiver of informed consent approved by the IRB.
- You must obtain consent BEFORE any procedures (screening or otherwise) have been done, unless a waiver of consent has been approved by the IRB.
- You may only use the unexpired, IRB-stamped-approved consent form(s)/consent statement with which to obtain consent.
- Only key study personnel listed in your application can obtain consent and must be designated as “will obtain consent.”
- One of the investigators must sign the consent form within 72 hours of the subject and person obtaining consent.
- You must keep the original copy of the signed consent form in the study files.
- Child *assent* applies to two different age groups (8-13 and 14-17), and the documentation processes are different. Consult our policy entitled “Additional Protections: Children.”
- Only a parent or a court-appointed legal guardian can provide permission for a child to participate in research. Consult our policy, “Additional Protections: Children.”
- Adult *assent* may be required for some studies that include adults who do not have the capacity to consent, and documentation of their assent is required. Consult our policy entitled “Informed Consent.”
- Identification of an appropriate surrogate or legally authorized representative (LAR) for an adult subject is described in state law. Consult our policy entitled “Informed Consent.”

- There are special procedures for consenting subjects who are illiterate, or who do not speak English. Consult our policy entitled “Informed Consent of Subjects Who Do Not Speak English, Illiterate English-Speaking Subjects, and Visually/Hearing-Impaired English-Speaking Subjects.”
- Someone is considered enrolled when he/she signs a consent form (even a screening consent form), OR if a waiver or alteration of consent was granted, when he/she begins any study procedures, he/she is considered enrolled.

HIPAA:

- If the potential subjects are patients of any of the investigators AND the study will offer a treatment for the potential subject’s condition, you do not need to request a HIPAA waiver in your IRB application in order to identify potential subjects for recruitment or to contact potential subjects regarding participation. In all other cases, a HIPAA waiver approved by the IRB is necessary to identify potential subjects for recruitment or to contact potential subjects regarding study participation.
- Regardless of whether potential subjects are patients of any of the investigators or whether the study will offer a treatment for the potential subject’s condition, you will need a HIPAA waiver approved by the IRB to collect data for the conduct of the study; for example, when a retrospective chart review will be conducted.
- Remember you are viewing/using protected health information (PHI) if you or one of your research team members listed in the application will remove any of the 18 HIPAA identifiers from the data.
- The use of limited data sets (absence of 16 of the 18 identifiers) or de-identified data (absence of all 18 identifiers) apply only to data which has already been stripped before your study team sees it.

Revisions:

- Any and every change you wish to make to your project must be submitted to the IRB via a *Form 2: Change Request and Amendment* and approved before you may implement the change.
- Submission of multiple *Form 2: Change Request and Amendments* at one time for one project is *not* allowed. You must wait until you receive the final approval letter for one *Form 2: change Request and Amendment* before you can submit another one. If more than one *Form 2: change Request and Amendment* is submitted for a project, you will be asked to retract the extra form(s).
- If you add an investigator to your project through a Form 2, you must add that investigator to the routing form’s signature routing assignment list so he/she can sign off confirming his/her participation in the study.
- Minor changes in the consent form, such as changing an investigator/address, do not require the re-consenting of subjects. When changes could impact a subject’s decision regarding whether to continue participating, such as a new procedure, a new risk, or a reduction in payment, then subjects should be re-consented.

Continuations:

➤ Exempt projects do not have annual continuations. Expedited (XP) and Full Board (FB) projects reviewed BEFORE January 21, 2019 (under the previous Common Rule) and receiving initial approval (or approval pending a satisfactory response to administrative provisos), must be approved to continue for another year, each year, via a Form 3 until the study is closed with the IRB.

If your study qualifies for expedited status and is approved (or approved pending a satisfactory response to administrative provisos) ON or AFTER January 21st, 2019 (the effective date of the revised Common Rule), you will NOT receive an expiration date at the time of initial approval. Rather, you will receive an annual “check-in” date and will be asked to complete a short check-in form regarding the status of your study on or before this check-in date each year. You must continue to do this until the study is closed with the IRB. This does NOT apply to FDA-regulated studies. If your study is FDA-regulated and is approved (or approved pending a satisfactory response to administrative provisos) ON or AFTER January 21st, 2019, you will still be required to submit a *Form 3: Continuing Review* for review and approval prior to the assigned expiration date until the study is closed with the UTHSC IRB. If your Full Board DHHS-regulated project has progressed to the point that it only involves one or both of the following then the IRB will not require further review. However, you still must submit a final Form 3: Continuing Review to the IRB as a notification of your study status:

1. Remaining study activities are limited to data analysis, including analysis of identifiable private information or identifiable biospecimens, or
 2. Remaining study activities only involve accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.
- As courtesy, iMedRIS sends automatic reminders, but it is the Principal Investigator’s (PI’s) responsibility to obtain approval for continuation each year before the study expires.
- For studies requiring review by the Full Board (FB), you must submit the *Form 3: Continuing Review* at least 3 weeks BEFORE the last Board meeting that will occur before your expiration date; consult the full board meeting schedule including submission deadlines at <https://uthsc.edu/research/regulatory-support/irb/researchers/meeting-schedule.php>
- For Expedited (XP) studies, you should submit the *Form 3: Continuing Review* at least 2 weeks before your expiration date to provide time for IRB review, for you to answer any provisos and send your response back in, and for the IRB to review your response to ensure it is sufficient.
- If you let IRB approval for your study expire, you must cease all study activities on the expiration date. You may not enroll any new subjects, and you may not obtain any data on current subjects until your study has been approved (again) by the IRB to continue for another year. If you think that ceasing study activities, such as distributing medication to

subjects, may cause subjects harm, you must contact the IRB immediately in order to get any such activity temporarily approved for one or all subjects.

Unanticipated Problem/ Adverse Event Reporting:

- Under federal guidelines, unanticipated problems including adverse events (AEs), must be reported to the IRB if they meet all three criteria below:
 - ✓ Unexpected,
 - ✓ Good/clear evidence of being related to study procedures, and
 - ✓ Serious (significant enough to suggest that the research may place subjects or others at a greater risk of harm than was previously known or recognized; or for adverse events, required hospitalization, prolonged hospitalization, etc.).
- In order to assess whether the unanticipated problem/adverse event meets all three criteria, you should determine whether “the event suggests that changes may be necessary in the research procedures, informed consent/information/process and/or other aspects of the study.”
- Very serious internal (at our local sites), reportable AEs, such as a death, must be reported to the IRB within 24 hours.
 - Internal (at our local sites) reportable AEs must be reported within 5 days.
 - External (at other sites in a multi-center study) reportable AEs must be reported within 10 days.

Protocol Waivers and Deviations:

- Protocol waivers must be submitted to the IRB and approved before they are implemented.
- Only major protocol deviations must be reported to the IRB within 5 days.
- A major deviation:
 - (a) has harmed or has posed a significant risk of substantive harm to the individual research subject, or
 - (b) has compromised the scientific integrity of the data collected for the study, or
 - (c) appears to result from the willing or knowing misconduct on the part of an investigator or study staff, or
 - (d) appears to involve some other serious or continuing noncompliance with federal, state, or local research regulations.

Advertisements:

- All advertisements must be submitted to the IRB and approved before they are used.
- The IRB must review all types of recruitment materials including, web, email, flyer, mail, social media, TV, radio, etc..
- The payment method must not stand out (i.e., place in a bigger font, bold, underline, etc.).

- If radio/newspaper/TV wants to interview an investigator, only submit this script to the IRB for prior approval if you are going to mention recruitment information (contact #, inclusion criteria, etc.).
- If you are using QR codes in your advertisements, you must submit the information found “behind” the QR code.

Pregnant women and fetuses:

- Both pregnant women and fetuses are considered subjects when you are obtaining information about both; thus, you should double the number of subjects you request to enroll in your application (versus considering them one *subject pair*).
- If a pregnant subject is under 18, you (as the investigator) have the choice regarding obtaining consent from her (treating her as an adult), OR obtaining assent from her and permission from her parent/legal guardian. All minor pregnant subjects in your study should be treated the same once you make this decision. Further, if you are obtaining information about the fetus, you must get permission to do so from the minor pregnant subject (the fetus’ mother).

Prisoners:

- Consult the definition of prisoner at <https://uthsc.edu/research/regulatory-support/irb/researchers/standard-operating-procedures.php> .
- Research where prisoners will be, or most likely could be, subjects must be reviewed by the full, convened Board. Prisoner research may not be exempt or expedited.
- If you are conducting an IRB-approved study and one of your subjects becomes a prisoner, you must submit a revision and have that revision approved by the full Board before the prisoner may continue participating in your study.
- If you are conducting an IRB-approved study and you have a new, potential subject who is a prisoner, you must submit a revision to include prisoners in your study and have that revision approved by the full Board before you may enroll the prisoner in your study.

Record Retention:

- All research records must be maintained for 5 years after study has been completed, per UTHSC policy.
- All consent forms containing the HIPAA authorization must be maintained for 6 years from the date it was signed or the date when it was last in effect, whichever is later.
- FDA drug studies with an IND: All records must be maintained for 2 years after the marketing application is approved for the drug, for the indication being investigated (consult the full policy at <https://uthsc.edu/research/regulatory-support/irb/researchers/documents/study-closure-and-record-retention.pdf>).
- FDA device studies: All records must be maintained for 2 years after the date on which the device investigation is terminated/completed, or 2 years after records are no longer

required to support the device PMA (premarket approval) application, whichever is later (consult the full policy at <https://uthsc.edu/research/regulatory-support/irb/researchers/documents/study-closure-and-record-retention.pdf>).

Investigators Responsibilities:

- Consult the policy at <https://uthsc.edu/research/regulatory-support/irb/researchers/documents/investigator-responsibilities.pdf> so that you are educated regarding all of your responsibilities.