UNIVERSITY of HOUSTON

DIVISION OF RESEARCH

Institutional Review Boards

Faculty Sponsor Manual

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Table of Contents

What is the purpose of this manual?

This Faculty Sponsor Manual is designed to guide faculty members and their students through policies and standard operating procedures related to the conduct of human subjects research at the University of Houston.

General information regarding human research protections and relevant federal regulations and guidance is incorporated into the required human protections training. For additional information see below: "What training do my students and I need when conducting human subjects research?"

What is Research?

RESEARCH is defined as "a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge[1]." Student theses and dissertations, by default, are designed to contribute to generalizable knowledge. Individual projects in research methods courses may or may not fall under the definition of "Research," based on the ultimate intent of disseminating results, however such activity does require notification to the IRB office if the project involves typical research-related activities (including but not limited to: informed consent, interviews, focus groups, surveys) involving human subjects. See the IRB handbook for more details.

What is a Human Subject?

HUMAN SUBJECT means a living individual about whom an investigator (whether professional or student) conducting research (i) obtains information or biospecimens through intervention or interaction with the individual, and uses studies, or analyzes the information or biospecimens; or (ii) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens[2].

You and your student are responsible for ensuring that IRB approval (or an organizational review and approval of exempt Human Research) is obtained before conducting human subjects research. If you have questions about whether a thesis or dissertation meets the definition of human subjects research, the IRB Office is available for guidance. You may contact the IRB office any time at CPHS@central.uh.edu.

Who must have a Faculty Sponsor?

Student or Post Doctoral research projects are reviewed using the same guidelines and regulatory requirements followed by the IRB for the protection of human subjects in general. ***All student-initiated and student-conducted human subjects research (including post-doctoral fellows) must be reviewed and approved by the IRB before initiation.*** All research projects for which a student serves as Principal

[1] 45 CFR 46.103(d)
[2] 45 CFR 46.102(f)

Investigator (PI) require that a full-time faculty member (typically the thesis/dissertation committee chair/faculty advisor), be designated as the faculty sponsor on the IRB Application[3]. Other thesis or dissertation committee members who will be engaged in the research (recruitment, consent, study procedures, or review of identifiable data) should be listed as study team members. Post Doctoral Fellows cannot serve as Faculty Sponsor on student-led research.

If allowed by the college/department, as an alternative to submitting their own protocol, students obtaining data from a larger project under a faculty PI may be listed as study personnel on the faculty member's protocol as long as the thesis/dissertation aims or hypotheses generally fall under that of the parent project. In this case, the faculty PI must ensure that 1) the student is added to the protocol as part of the study team, and 2) the thesis/dissertation's aims and 3) any additional study procedures/documents (if applicable) are added to the protocol using the "modification"activity. These items must be approved prior to the student's engagement in the human research.

What is the Faculty Sponsor's Role?

Faculty sponsors are responsible for guiding investigators through each phase of the IRB process. They must be familiar with research methods specific to the field of study and stay informed regarding the rules and regulations governing research at this institution. The faculty sponsor should be the primary resource when student investigators have questions or need assistance with their projects. IRB personnel may also serve as a resource.Sspecific office hours and appointments are available to both students and faculty sponsors for this purpose[4].

Faculty sponsors are responsible for:

1. Evaluating whether the student investigator has sufficient knowledge and experience to conduct the proposed research, including the completion of required online human subjects protection training (CITI) and any other relevant and protocol-specific research-related training.
2. Before IRB submission and using the "Ancillary Reviewer" function in ICON, reviewing all documentation compiled by the student to:
    - Verify scientific merit and appropriate study design for relevant field
    - Ensure the project meets criteria for degree satisfaction
    - Ensure field-specific codes of conduct are adhered to
3. Ensuring that the proposed research is not initiated (including advertisement/recruitment) until final written approval from the IRB has been obtained.

[3] Full-time faculty and staff ordinarily do not need a faculty sponsor unless conducting research for the purpose of their doctoral dissertation or masters thesis.
[4] See https://www.uh.edu/research/compliance/irb/irb-cmte-3/ for further detail.

4. Providing ongoing supervision of the submission and conduct of the study, including advising the student on clarifications/changes requested by the IRB, monitoring the progress of the project and ensuring continued adherence to the protocol and regulatory requirements (e.g. timely submission of unanticipated problems, reporting issues of noncompliance, using approved documents/tools, and avoiding over enrollment of subjects).
5. Keeping abreast of the policies and procedures of the University of Houston IRB, the published guidelines for the ethical conduct of research relevant to the field of inquiry, and state and federal regulations; providing the student with guidance on the protection of human subjects as necessary.

What is the Student PI's role?

Students serving as Principal Investigators are responsible for:

1. Ensuring the research is not initiated until final approval is received
2. The overall design and conduct of the study, and ensuring compliance with the IRB-approved protocol throughout the duration of the research.
3. Contacting the faculty sponsor and the IRB for any questions related to the IRB submission process or the conduct of the research;
4. The conduct of the research team, including the assurance that all team members read and understand the protocol and are trained on applicable study procedures;
5. Ensuring the protection of the rights and welfare of human subjects including obtaining informed consent, maintaining privacy during interaction with subjects, and confidentiality of data as outlined in the protocol
6. Submission of a modification within ICON and awaiting IRB approval before implementing changes to the study
7. Reporting any unanticipated problems or issues of noncompliance identified by study team members to the IRB, using the "Reportable New Information" function in ICON
8. Consultation with the Faculty Sponsor and identification of protocol modifications warranted by unexpected events and circumstances

What training do my students and I need when conducting Human Research?

All study team members, *including faculty sponsors,* must complete required human subjects training before the conduct or supervision of student research. Please visit www.citiprogram.org to complete one of the following modules:

- Group 1: Biomedical and Physical Science Research Investigators and Graduate Students, or
- Group 2: Social and Behavioral Research Investigators and Graduate Students,

Additional CITI training modules are required for anyone working with Protected Health Information (PHI) or student/educational records under FERPA. Human subjects training completion is pulled into the ICON online system from CITI. If the training does not populate into the "training" tab in ICON, please check the team member's CITI account to verify that their profile matches the ICON account profile exactly (name and @UH email address). Accounts linked to email addresses other than .UH.edu will not link to the online system. If the name and email address do not match, please update the CITI profile to reflect the correct information appears in ICON. Training must be completed before IRB approval.

If CITI training was completed at another institution, access the existing CITI account and choose "Affiliate with Another Institution." Add the University of Houston and complete the registration process. Note that there may be additional modules to complete to fulfill the UH training requirements.

Training is valid for a three-year period, after which time a refresher course must be taken.

All study team members should be provided with a copy of the approved protocol and be trained specifically to approved protocol requirements and processes.

What activities require IRB Review?

Any activity meeting both the definitions of "research" and "human subjects" as outlined above must be submitted for review. WORKSHEET HRP-310 (Human Research) outlines the steps to make this determination. Once determined to be human subjects research, any non-exempt protocol is reviewed by the IRB (or designated IRB reviewer) using the criteria found in "WORKSHEET: Criteria for Approval (HRP-314)."

While some low-risk human research activities fall under an exempt review category ("WORKSHEET: Exemption Determination (HRP-312))", a protocol is still required and is reviewed by administrative staff in the IRB office using similar criteria.

All checklists and worksheets can be found in the ICON library. Your students are encouraged to use the checklists to write their Investigator Protocol in a way that addresses the criteria for approval. If you are still unsure, please contact our office for guidance. If you think your student will need a formal determination letter of "not human subjects research[5]," they will need to complete an IRB application in ICON. Be sure any supporting documents that may help with the determination are uploaded, in case a full review is determined to be required. Remember, students may not begin any research

[5] Some journals may require this determination for publication; check journal requirements and if needed, obtain this determination prior to initiation of the research.

activity involving human subjects until the IRB has issued approval correspondence specific to that activity.

How does my student submit new Human Subjects Research to the IRB?

Click "Create New Study" to open the electronic SmartForm in the IRB module of the ICON system and attach all supplemental documentation applicable to the proposed study (protocol, consent forms, letters of cooperation, study instruments, etc.). It is important to note that the protocol should be fully developed on the HRP-503 template, located under the "Templates" tab of the IRB Library in ICON, before beginning the submission process as the SmartForm will not advance past the first page until the protocol document is attached. Consent form templates are also located under this tab.

Before submitting a research protocol to the IRB, applicable ancillary reviewers must be assigned as follows:

- For student-led protocols, both the Department Chair and a Dean level ancillary reviewer must be assigned. Please review the "Designated Ancillary Reviewers" document in the ICON Library under the "General" tab. Only ONE of these reviews must be completed before submitting to the IRB[6]. In addition to the Chair/Dean ancillary reviewers, the faculty sponsor must also be added as an ancillary reviewer and must complete a review before submission (see "What is the Faculty Sponsor's Role," above).
- Biosafety must be added as an ancillary review if the project intends to collect or use human biological specimens (saliva, blood or urine) or recombinant materials, as additional training and review are required by Environmental Health and Safety (EHS).
- Your college may require other ancillary reviewers. Please check with the applicable Associate Dean for Research.

Once all ancillary reviews have been obtained, the PI may submit the SmartForm by clicking the "Submit" activity in ICON.

Can my student request reliance on another IRB?

Reliance agreements are arrangements between institutions allowing the IRB of one institution to rely on the IRB of another institution for review of collaborative or multi-site human subjects research. Sometimes a student chooses to conduct research or gather research data at an institution where he/she works for his/her UH thesis or dissertation. If this is the case, as the research is being conducted to fulfill a UH degree requirement,

[6] All individuals listed for the Department/College on the "Designated Ancillary Reviewers" document must be added as ancillary reviewers. Each unit has its own system for which of these individuals will routinely sign off on the protocol (and who may serve as backup during his/her absence), however the other reviewers listed will use the notification to be informed of/track human subjects research activities taking place in the unit.

UH oversight is still required, but may be able to be fulfilled through reliance on the other institution's IRB. If you have a student in this situation, please contact the IRB office for guidance. Additional information may also be found on the UH IRB reliance webpage: https://www.uh.edu/research/compliance/irb/irb-reliance/.

How does my student write an Investigator Protocol?

Use the "Template Protocol (HRP-503)," found in the ICON library as a starting point for drafting a new Investigator Protocol. Here are some key points to remember when developing an Investigator Protocol:

- The italicized bullet points in the "Template Protocol (HRP-503)" serve as guidance to investigators when developing an Investigator Protocol for submission to the IRB. These are items the IRB must consider when reviewing research, and the protocol review may be delayed if these points are not addressed.
- When writing an Investigator Protocol, always keep an electronic copy. This document may require modification when responding to the IRB's feedback and making future changes to the Investigator Protocol.
- Depending on the nature of the research, certain sections of the template may not apply to the research design. Do not delete these sections. Simply state "N/A" as appropriate.
- Individuals who are members of the following vulnerable populations may not be specifically targeted for recruitment as research subjects unless expressly stated within the inclusion criteria:
    - Adults unable to provide legally effective consent
    - Individuals who are not yet adults (infants, children, teenagers)
    - Pregnant women
    - Prisoners
    - Economically or educationally disadvantaged persons

  While these groups may be considered for inclusion in research, the IRB is required to review for additional regulatory criteria/protections. Ensure that all questions related to vulnerable populations are addressed within the protocol template. The IRB office is available for guidance regarding these additional criteria/protections. Checklists utilized by the IRB to review such research are also available to you in the ICON Library.
- If UH students will be recruited as research participants, this must be identified in the protocol. In most cases, an individual with access to or influence on the student's grades may not be involved in recruitment or informed consent, or in the review of identifiable data for the study. This policy addresses the IRB

requirement to avoid undue influence in subject selection. If extra credit will be offered as an incentive for participation, it may not be the only method by which extra credit may be earned in the course.

How does my student create an informed consent document?

Use the applicable "Template Consent Document (HRP-502a-e)" located in the ICON Library to create consent/parental permission/ documents, and the "Template Child Assent" to formulate assent documents and scripts. Written parental permission and child assent are required for research involving subjects under the age of eighteen.

Note that all consent documents must contain the required elements of informed consent as well as all additional appropriate elements defined by federal regulations. The templates provided contain these elements.

Review the "Long Form of Consent Documentation" section in the IRB's "WORKSHEET: Criteria for Approval (HRP-314)" to ensure that these elements are addressed. When using short form consent documentation, the appropriate signature block from "Template Consent Document (HRP-502)" should be used on the short form.

Some studies may qualify for a waiver of documented consent (for example, low-risk survey research conducted online). In these cases, all elements of informed consent must still be provided, although physical signature is waived. In other cases (such as review of archival data), the consent process may be waived altogether. Both of these options require that specific regulatory criteria are met; please review "CHECKLIST: Waiver or Alteration of the Consent Process (HRP-410)" and "CHECKLIST: Waiver of Written Documentation of Consent (HRP-411)" if you believe one of these options may apply, and provide the requested justifications in the protocol.

Once approved, consent documents will be watermarked with an approval and expiration date. Please utilize only the watermarked version to obtain subject consent. This ensures that only the current IRB-approved version is used and helps to avoid noncompliance.

What are the different regulatory classifications of review for research activities?

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

- Not Research: Activities must meet the definition of "Research" to fall under IRB oversight. If a project does not meet the definition of research provided above (for example, it is not intended to generate generalizable information), a submission to the IRB is not required. Contact the IRB Office in cases where it is unclear whether an activity is Human Research. All theses and dissertations meet the "generalizable information" threshold.
- Not Human Subjects: Activities must involve "Human Subjects" to fall under IRB oversight. Activities that do not meet the definition above are not subject to IRB

oversight or review. Review the "WORKSHEET: Human Research (HRP-310)," located under the "Worksheets" tab of the ICON library for reference. Contact the IRB Office in cases where it is unclear whether an activity is Human Research.

- Exempt Review: Certain categories of Human Research may be exempt from regulation but still require IRB office/institutional review. It is the responsibility of the institution, not the investigator, to determine whether Human Research is exempt from IRB review. Therefore a protocol must be submitted in ICON. Review the "WORKSHEET: Exemption Determination (HRP-312)," located under the "Worksheets" tab of the ICON library for reference on the categories of research that may be exempt.
- Expedited Review: Certain categories of non-exempt Human Research defined by the regulations may qualify for review using an expedited procedure. This means that the project may be reviewed by a single designated IRB member, rather than a fully convened board. Review the "WORKSHEET: Expedited Review (HRP-313)," located under the "Worksheets" tab of the ICON library, for reference on the categories of research that may be reviewed using the expedited procedure.
- Review by the Convened IRB: Non-Exempt Human Research that does not qualify for expedited review must be reviewed by the convened IRB. All student research that is not regulated by FDA (drugs/devices/biologics) is reviewed by IRB 3. The fully convened IRB meets monthly; submission deadlines and meeting dates can be found on the IRB 3 website.

What are the turnaround times for submission?

When developing a research protocol and study materials, be sure to plan ahead! The process may take additional time depending on the nature of the research and the quality of the protocol submitted. Think through all details of the research with the IRB protocol template in mind.

- The student and faculty sponsor should work together to discuss the protocol and research methodology before IRB submission; the faculty sponsor should review the submission in full to ensure 1) scientific validity, 2) that the project meets degree requirements, and 3) that the submission is complete.
- Factor in time for Departmental/Ancillary reviewers to conduct their reviews and request revisions as necessary.
- Once the protocol has been submitted in ICON, a Pre-Review is conducted by IRB staff within 7-10 business days to verify general completeness of the application, verify training status of all research team members, ensure that study tools and consent documents are attached, and to determine review category. The IRB staff member will request modifications to areas that are incomplete

before moving the protocol forward for detailed review. If a protocol is incomplete, there may be significant delays in the review process.

- If the protocol meets exempt or expedited review criteria, it is reviewed on a rolling basis in the order received (i.e., it does not get assigned to a convened meeting). This review typically takes 7-10 business days once pre-review modifications are addressed. Turnaround times may be slightly longer at peak times for student submissions. Again, please plan and submit early if possible.
- If an application meets full board review criteria, the convened IRB meets once each month. Please see the IRB website for meeting dates if you think the application will require a convened IRB review. As these protocols are more complex or may carry a higher degree of risk, it is important to plan the timing of the submission appropriately and understand that the total turnaround time may be longer. Feedback from convened IRB meetings will be provided 7-10 business days following the meeting.
- Almost all protocols require at least minor revisions following review, many of which can be reviewed within the IRB office (see "Modifications Required to Secure Approval" below). Time should be factored in to consider and respond to these revisions, and for the IRB office to review them and provide final approval. Please respond to all requested revisions as thoroughly as possible to avoid additional delays.

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

The IRB may approve research, require modifications to the research to secure approval, defer research, or disapprove research.

- **Approve**: This determination is made when all criteria for approval are met. See "How does the IRB decide whether to approve Human Research?" below.
- **Modifications Required to Secure Approval**: This determination is made when the IRB or designated reviewer requires specific, clear-cut modifications to the research before approval can be granted. This means that all regulatory review criteria have been met; however additional modifications or documents must be provided for the protocol to be considered complete (for example, minor modifications to consent forms, revision of a flyer, or completion of training). Modifications may be reviewed by the IRB office staff.
- **Deferred**: This determination is made when the convened IRB determines that regulatory review criteria either have not been met, or that not enough information is provided to determine if these criteria have been met (for example, risks to subjects are unclear or not minimized, subject selection is not equitable, the consent process described is not approvable). When making this motion, the IRB describes its reasons for this decision, offers suggestions for revisions to

address these concerns, and provides the investigator an opportunity to respond by providing additional information or justification to the IRB. Responses to a deferred protocol require review by the full committee at a convened IRB meeting.

- **Disapprove**: This determination is made when the IRB determines that it is unable to approve research because the protocol does not meet regulatory approval criteria and the IRB also cannot describe modifications that might make the research approvable in its current state or design. When making this motion, the IRB describes its reasons for this decision and gives the investigator an opportunity to re-write and resubmit the protocol. The investigator may request to be alotted time in a convened meeting to discuss the issues with the board. The research may also be disapproved at an institutional level if it involves subject areas or procedures unacceptable to the university's vision or mission. The Institutional Official may not approve a study if the IRB has disapproved it. Protocols that are disapproved require a full re-design and a new submission to be reconsidered by the IRB/institution.

How does the IRB decide whether to approve Human Research?

Applications are reviewed based upon "WORKSHEET: Criteria for Approval (HRP-314)." The IRB must ensure the following in order to approve research involving human subjects:

(1) Risks to subjects are minimized:

(i) By using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk, and

(ii) Whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

(2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (*e.g.,* the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

(3) Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted. The IRB should be particularly cognizant of the special problems of research that involves a category of subjects who are vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons.

(4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by 45 CFR 46.116.

(5) Informed consent will be appropriately documented or appropriately waived in accordance with 45 CFR 46.117.

(6) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

(7) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

More detail regarding approval criteria can be found in "WORKSHEET: Criteria for Approval (HRP-314)." This worksheet also contains all applicable elements and considerations for informed consent, and references other checklists that might be relevant. All checklists and worksheets can be found in the ICON library.

These checklists are used for initial review, continuing review, and review of modifications to previously approved Human Research. You are encouraged to use the checklists to write your Investigator Protocol in a way that addresses the criteria for approval.

What will happen after IRB review?

The IRB will provide the student with a written decision indicating one of the determinations above.

- If the IRB **approves** the research: The research may commence once all other organizational approvals have been met (for example, biosafety approval may be required, applicable conflict of interest disclosures must be up to date). IRB approval for full board protocols is typically granted for one year; the expiration date is noted in the approval letter. Approval of the research expires on the expiration date with no exceptions; a continuing review submission must be made prior to expiration and approved by the IRB or IRB office to continue active approval. Research conducted without active IRB approval is noncompliant with federal regulations and institutional requirements and may have significant consequences. Research approved under exempt and expedited review procedures typically has no expiration; however, follow-on submissions such as modifications and reportable information must be submitted for all protocols, regardless of review mechanism, to maintain compliance.
- If the IRB **requires modifications to secure approval**: Make the requested modifications to the protocol and relevant documents and submit them to the IRB office through ICON. Please use track changes to revise any documents. If all requested modifications are made and addressed adequately, the IRB will issue a final approval letter. Research may not commence until this final approval letter is received. If the PI does not agree with the requested modifications, detailed

response and appropriate justification should be returned. The IRB will consider this information and respond to the investigator.

- If the IRB **defers** the research: The IRB will provide a statement of the reasons for deferral and suggestions to make the study approvable, and provide an opportunity to respond in writing. Once returned to the IRB, the protocol will need to be re-reviewed by the full committee. Please use track changes to revise any documents. If the IRB's reasons for the deferral are addressed in a resubmission and all approval criteria are met, the research can be approved. Any minor issues remaining may be determined to constitute "modifications needed to secure approval (see above).
- If the IRB **disapproves** the research: The IRB will provide a statement of the reasons for disapproval and give the PI an opportunity to respond in writing. The application must be submitted as a new protocol after substantial changes have been made to the proposed study. The investigator cannot conduct any research activities that have been disapproved by the IRB.

In all cases, you and your student have the right to work directly with the IRB and IRB office to address required corrections and their concerns regarding IRB review.

What are my student's obligations after IRB approval?

1) Human Research activities, including advertisement and recruitment, may not commence until the student has received the final IRB approval letter.
2) Human Research activities may not begin until all other required institutional approvals have been obtained. (For example, some departments or divisions may require approval for research that involves their resources before commencement).
3) Ensure that there are adequate resources to carry out the research safely. This includes, but is not limited to, sufficient investigator time, appropriately qualified research team members, equipment, and space.
4) Ensure that Research Team members remain qualified (e.g., including but not limited to appropriate training, education, expertise, credentials, protocol requirements and, when relevant, privileges) to perform procedures and duties assigned to them during the study.
5) Personally conduct (and supervise, if additional team members are involved) the Human Research.
   a) Conduct the Human Research based on the relevant current protocol as approved by the IRB.
   b) Ensure that consent or permission is obtained according to the relevant current approved protocol.
   c) Do not initiate modifications to research without prior IRB review and approval unless necessary to eliminate apparent immediate hazards to subjects (such changes must be reported to the IRB as soon as possible with adequate justification).
   d) Protect the rights, safety, and welfare of all subjects involved in the research.

6) Submit to the IRB:
   a) Any proposed modifications as described in this manual, including changes to study personnel. (See “How do we submit a modification?”)
   b) A continuing review application annually or otherwise as requested in the approval letter. (See “How do we submit continuing review?”)
   c) A continuing review application when the Human Research protocol is to be closed. (See “How Do we Close Out a Study?”)
7) Report required information to the IRB within five business days:
   a) Information that indicates a new or increased risk, or a new safety issue. For example:
      i) New information (e.g., an interim analysis, safety monitoring report, publication in the literature, sponsor report, or investigator finding) that indicates an increase in the frequency or magnitude of a previously known risk, or uncovers a new risk
      ii) Protocol violation that harmed subjects or others or that indicates subjects or others might be at increased risk of harm
      iii) Complaint of a subject that indicates subjects or others might be at increased risk of harm or risk of a new harm
      iv) Any changes significantly affecting the conduct of the research
   b) Harm experienced by a subject or other individual, which in the opinion of the investigator are **unexpected** and **probably related** to the research procedures.
      (1) Harm is “**unexpected**” when its specificity or severity are inconsistent with risk information previously reviewed and approved by the IRB regarding nature, severity, frequency, and characteristics of the study population.
      (2) Harm is “**probably related**” to the research procedures if in the opinion of the investigator, the research procedures more likely than not caused the harm.
   c) Non-compliance with the federal regulations governing human research or with the requirements or determinations of the IRB, or an allegation of such non-compliance. Please note that instances of noncompliance, such as over-enrollment of subjects or conducting research before approval or following the expiration of the protocol (i.e., without IRB approval) may result in corrective action, including not using the noncompliant data for research purposes.
   d) Audit, inspection, or inquiry by a federal agency and any resulting reports.
   e) Written reports of study monitors.
   f) Failure to follow the protocol due to the action or inaction of the investigator or research staff
   g) Breach of confidentiality, including but not limited to loss or theft of identifiable research data.
   h) Change to the protocol taken without prior IRB review to eliminate an apparent immediate hazard to a subject
   i) Incarceration of a subject in a study not approved by the IRB to involve prisoners, if you wish for that subject to continue participation while incarcerated.
   j) Complaint from a subject that cannot be resolved by the research team.

k) Premature suspension or termination of the protocol by the sponsor, investigator, or institution.

8) Ensure team members follow the UH Conflict of Interest policy in disclosing financial interests that relate to the research within 30 days of acquiring the interest.
9) Follow additional requirements of federal agencies that fund and/or oversee the research (such as the FDA or Department of Education) detailed in the appendices to this document and in "WORKSHEET: ADDITIONAL FEDERAL AGENCY CRITERIA (HRP-318)". These represent additional requirements and do not override the baseline requirements of this section.

How do we document consent?

Use the signature block approved by the IRB. Complete all items in the signature block, including dates. Please keep in mind that consent is a process and not simply a document and should represent an ongoing dialogue between the study team and the subject in most cases.

The following are the requirements for long-form consent documents:

- The subject or representative signs and dates the consent document.
- The individual obtaining consent signs and dates the consent document.
- Whenever the IRB or the sponsor require a witness or for subjects who cannot read and whenever required by the IRB or the sponsor, a witness to the oral presentation signs and dates the consent document. The subject can indicate their consent by "making their mark" on the consent document.
- A copy of the signed and dated consent document is to be provided to the subject. A signed and dated copy must also be maintained in the research record, and maintained separately from coded or identifiable data.

The following are the requirements for Waiver of documentation of Consent:

- This waiver is typically used when the research participants are not physically present to sign a consent form and the study is minimal risk.
- Use of the HRP-502e Template Cover Letter is required, and the participant is given the opportunity to read the cover letter before deciding on participation in the research (see SOP HRP-090).
- Please see "CHECKLIST: Waiver or Alteration of the Consent Process (HRP-410)" and "CHECKLIST: Waiver of Written Documentation of Consent (HRP-411)" for the requirements to qualify for the waiver.

How do we submit a modification?

The student should access the study and click the "Create Modification/CR" activity. Complete the Modification SmartForm in the ICON system and attach all requested supplementary documentation. Submit the SmartForm by clicking the "Submit" activity. Maintain electronic copies of all information submitted to the IRB in case revisions are required. Please note that research must continue to be conducted as approved without

the inclusion of the proposed changes until written IRB approval is received. Updates to the list of study personnel will be approved administratively by office staff unless the update represents an additional modification to the research, the change is to appoint a new PI, or potential conflict of interest requires further review. New personnel will not be approved until they have completed the CITI training requirement.

How do we submit continuing review?

The student should access the study and click the “Create Modification/CR” activity. Complete the Continuing Review SmartForm in the ICON system and attach any applicable supplementary documentation. Submit the SmartForm by clicking the “Submit” activity. Maintain electronic copies of all information submitted to the IRB in case revisions are required. Before submitting the research for continuing review, the student must again:

- Ascertain whether any member of the research staff has a financial interest related to the research. A “yes” or “no” answer is sufficient. There is no need to obtain additional financial details from a study team member; a “yes” answer will be referred to the conflict of interest office for follow-up and review.
- Obtain the verbal or written agreement of each member of the research staff to his/her role in the research.

If the continuing review involves modifications to previously approved research, an option is available to submit a “continuing review with modifications.” However, if the modification is complex, or the study is close to its IRB expiration date, it is strongly recommended to submit those modifications as a separate request using the Modification SmartForm the electronic system to avoid a lapse in approval.

If the continuing review application is not received by the date requested in the approval letter, they may be restricted from submitting new Human Research until the completed application has been received.

What Happens if IRB Approval Expires?

If IRB approval of a human subjects research protocol expires, all research procedures related to the protocol must cease, including recruitment, advertisement, screening, enrollment, consent, interventions, interactions, and collection or analysis of private identifiable information.

Continuing research during a lapse in protocol approval is a violation of both federal and organizational policy. If current subjects may be harmed by stopping research procedures that are not available outside the research context, contact the IRB coordinator or Chair immediately and provide written justification stating how subjects can be harmed by stopping Human Research procedures and provide a list of the currently enrolled subjects this applies to. The IRB will provide further direction.

If a student anticipates leaving the institution and the research will continue, the student should consult with the faculty advisor and submit a modification to change the PI prior to graduation.

How do we close out a study?

Once research is complete (including analysis of identifiable data), all studies should be formally closed. Click “Create Modification/CR” in ICON and select “Continuing Review.” If the first four boxes are checked within the continuing review submission, the study will be automatically closed. Please ensure this process takes place prior to the student leaving the university.

How long do we keep records?

All records related to IRB-approved human subjects research, including signed and dated consent documents, must be securely maintained **on the UH campus or on the UH server** for at least three years following completion of the research. Maintain signed and dated HIPAA authorizations and consent documents that include HIPAA authorizations for at least six years following completion of the research. Students should state within the protocol document that their faculty sponsor (or other individual specifically designated by the college or department) will maintain the records on campus and list the faculty sponsor’s building and room number. Electronic records stored on a secure university server is also a sufficient means of storage. If the department has a designated location for long-term storage, this location and the individual responsible for long-term storage may be listed as well.

If the student’s research project is sponsored and/or under the oversight of additional federal agencies (for example, NIH-funded research), additional maintenance requirements may apply. Carefully review the requirements of the sponsor and/or agency prior to disposing of research records.

What are additional services provided to students and faculty sponsors?

If you or your students have specific questions about preparing a student protocol and/or other research-related documents, office hours are listed on the IRB website on the IRB 3 page. If these hours conflict with your/the student’s schedule, you may also schedule an appointment to meet with the IRB 3 specialist. Student IRB services available include:

- The opportunity to ask questions about the IRB submission and review process, including whether the study qualifies as human subjects research and what application materials are required
- Discussion of human subjects issues as related to the student’s specific project
- Guidance to students on the drafting of his/her protocol prior to submitting it to the IRB (pre-review)

- Hands-on assistance with the IRB module of the ICON online system

IRB staff are also available to provide human subjects training sessions (ethical principles, ICON instruction, case studies as applicable) as a guest lecture in research methods courses or lab meetings. Contact CPHS@central.uh.edu to schedule.

How do we get additional information and answers to questions?

This document and the policies and procedures for the Human Research Protection Program are available in the ICON library; selected items are also available on the IRB Web Site at http://www.uh.edu/research/compliance/irb/policies/

If you have any questions or concerns about the Human Research Protection Program, contact the IRB Office at:

Research Integrity and Oversight (RIO)
316 E. Cullen Building, 4th floor
Houston, TX 77204-2015
Email: cphs@central.uh.edu
Main IRB office number: (713) 743-9204
IRB email: CPHS@central.uh.edu

The IRB has the responsibility to investigate allegations of non-compliance and require corrective actions as needed. The IRB may also suspend the conduct of a study to protect human subjects pending an investigation of noncompliance or if the risk assessment must be updated and reconsidered based on new information.

Questions, concerns, complaints, allegations of undue influence or non-compliance, or input regarding the Human Research Protection Program (HRPP) may be reported orally or in writing. Concerns may be reported to the IRB Chair, IRB Office, or Associate Vice President for Research and Technology Transfer.

Faculty, staff, and students are also permitted to report concerns on an anonymous basis using the UH Fraud and Noncompliance hotline.

Employees who report in good faith possible compliance issues may not be subjected to retaliation or harassment as a result of the reporting. Concerns about possible retaliation should be immediately reported to the Associate Vice President for Research and Technology Transfer.

Additional IRB Contacts:

Dr. Danielle Griffin
Associate Director, Research Integrity and Oversight (RIO)
Email: dgriffi5@central.uh.edu
(713) 743-4057

Ms. Kirstin M. Holzschuh
Executive Director, Research Integrity and Oversight (RIO)
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Dr. Claudia Neuhauser
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