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Scope

Throughout this document “Institution” refers to The University of Texas M. D. Anderson Cancer Center (MD Anderson).

What is the purpose of this manual?

This document, HRP-103 - INVESTIGATOR MANUAL, is designed to guide you through policies and procedures related to the conduct of Human Research that are specific to MD Anderson.

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 does my staff and I need in order to conduct Human Research?”

What is Human Research?

HRP-101 - HUMAN RESEARCH PROTECTION PROGRAM PLAN defines the activities that this Institution considers to be “Human Research.” An algorithm for determining whether an activity is Human Research can be found in HRP-310 - WORKSHEET - Human Research Determination, located in the ePCRTL IRB Library. Use this document for guidance as to whether an activity meets either the DHHS or FDA definition of Human Research, keeping in mind that the IRB makes the ultimate determination in questionable cases as to whether an activity constitutes Human Research subject to IRB oversight.

You are responsible not to conduct Human Research without prior IRB review and approval (or determination of exempt Human Research). If you are unsure if an activity is Human Research, submit a request for review of the activity in ePRTC (the electronic IRB submission and review system).

What is the Human Research Protection Program?

HRP-101 - HUMAN RESEARCH PROTECTION PROGRAM PLAN describes this Institution’s overall plan to protect participants in Human Research.

- The mission of the Human Research Protection Program.
- The ethical principles that the Institution follows governing the conduct of Human Research.
- The applicable laws that govern Human Research.
- When the Institution becomes “engaged in Human Research” and when someone is acting as an agent of the Institution conducting Human Research.
- The types of Human Research that may not be conducted.
- The roles and responsibilities of individuals within the Institution.
**What training does my staff and I need to conduct Human Research?**

MD Anderson has training requirements for individuals who conduct Human Research. You may also have additional training imposed by other federal, state, or institutional policies. Please refer to the Office of Protocol Support and Management at for specific training requirements: [https://mdandersonorg.sharepoint.com/sites/protocol-support-management/SitePages/research-education.aspx](https://mdandersonorg.sharepoint.com/sites/protocol-support-management/SitePages/research-education.aspx)

**What financial interests do my staff and I need to disclose to conduct Human Research?**

Individuals involved in the design, conduct, or reporting of research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards, are considered to have an institution responsibility.

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

- On submission of an initial review.
- At least annually as part of continuing review (when applicable).
- Within 30 days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new financial interest.

Individuals with reimbursed or sponsored travel by an entity other than a federal, state, or local government agency, higher education institution or affiliated research institute, academic teaching hospital, or medical center are required to disclose the purpose of the trip, the identity of the sponsor or organizer, the destination, and the duration of the travel.

Identification of any financial interests related to a particular research study is in addition to the MD Anderson annual conflict of interest reporting requirements.

Additional details can be found at [https://mdandersonorg.sharepoint.com/sites/compliance/SitePages/Conflicts-of-Interest.aspx](https://mdandersonorg.sharepoint.com/sites/compliance/SitePages/Conflicts-of-Interest.aspx) for the following MD Anderson policies:

- “Institutional Conflict of Interest Policy for the University of Texas Cancer Center and its Institutional Decision Makers (ADM1273)”;
- “Conflicts of Interest and Conflicts of Commitment Policy for Faculty Members, Investigators, Institutional Decision Makers, and Trainees (ACA0001)”;
- “Conflict of Interest and Conflict of Commitment Policy (ADM0255)”.

**How do I submit new Human Research to the IRB?**

Complete the New Study SmartForm in ePRTCL and attach all requested supplements, have the SmartForm submitted by the PI 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 initial review, you must:
• Obtain the financial interest status (“yes” or “no”) of each research staff.
• Obtain the agreement of research staff to his/her role in the research.

**What if I will be doing a quality improvement project? Do I need to submit to the IRB?**

The Quality Improvement Assessment Board (QIAB) is established by Institutional Policy, Quality Assessment Improvement Board Policy (ADM1080) and reviews all MDACC Quality Improvement (QI) projects to: assure patient safety; optimize the potential benefits being sought; and discern which projects may be more appropriately designed or categorized as research studies IRB oversight. Please refer to the QIAB for additional information: https://mdanderson.org.sharepoint.com/sites/quality-education/SitePages/Quality-Improvement-Assessment-Board.aspx

**Can I hold the Investigational New Drug (IND) or Investigational Device Exemption (IDE) for an investigational drug or device study?**

The University of Texas MD Anderson Cancer Center has worked to initiate an institutional program to provide investigators with support, while at the same time ensuring compliance with sponsor federal regulatory requirements. As a result, MD Anderson takes the obligations of IND and IDE sponsorship off the investigator and assumes this responsibility at a centralized level.

MD Anderson is the sponsor of record for all investigator-initiated studies that are conducted under an IND or IDE and are not sponsored by another entity. The Vice President for Clinical Research is the Official Sponsor representative, and the IND Office serves to represent the sponsor on a day-to-day basis. For additional information, please contact the IND office at: IND_PM@mdanderson.org

**How do I submit a request to use a Humanitarian Use Device (HUD) for clinical use?**

MD Anderson utilizes the IRB to review and approve the use of a HUD before it can be used at a facility for clinical care. You can refer to HRP-323 - WORKSHEET - Criteria for Approval HUD for additional information regarding the criteria that the IRB uses to review and approve HUD uses. The clinical use of a HUD is not considered Human Research but must still be submitted for review and approval by the IRB prior to clinical use (with the exception of emergency use). An informed consent form is not required by the IRB for HUD use as the IRB expects that the HUD patient brochure will be used to inform the patient about the HUD and expected use.

Complete the New Study SmartForm in ePRTCL and attach all requested supplements. Attach the Patient Information Brochure (or equivalent) in lieu of an informed consent form. Have the SmartForm submitted by the PI 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 initial review, you must:

• Obtain the financial interest status (“yes” or “no”) of each staff member.
• Obtain the agreement of staff to his/her role in the HUD use.

**How do I request to rely on an external IRB?**

Please refer to HRP-832 - WORKSHEET - Considerations for Ceding IRB Review for the criteria that are used to determine if MD Anderson can rely on an External IRB for review. Complete the New Study SmartForm in ePRTCL, indicate that an External IRB will serve as the IRB of Record and attach all requested supplements. When choosing the External IRB, if the IRB is not in the list, please contact the OHSP. The OHSP will then work with you to make sure that reliance criteria are met and that an appropriate reliance agreement in in place with the External IRB.

Have the SmartForm submitted by the PI by clicking the “Submit” activity. Maintain electronic copies of all information submitted to the IRB in case revisions are required.

**How do I request that the MD Anderson IRB serve as the IRB of record (sIRB) for my collaborative or multi-site research study?**

Please refer to HRP-833 - WORKSHEET - Considerations for Serving as the sIRB for the criteria that are used to determine if MD Anderson can serve as the sIRB. On the New Study SmartForm in ePRTCL, indicate that the study is a multi-site or collaborative research study, then select “Yes” to the question “Will your IRB act as the single IRB of record for other participating sites?” Complete the rest of the New Study SmartForm and attach all available supplements.

Participating sites (pSites) can be added by clicking the “Add Participating Site” activity. You can utilize HRP-811 - FORM - Basic Site Information to collect information about each pSite to then enter that information into ePRTCL. You can either choose to submit just the study and MD Anderson PI first for review by the IRB and then submit pSites after the study has been approved, OR you can submit the study and MD Anderson PI along with any known pSites for review by the IRB at the same time. Have the SmartForm submitted by the MD Anderson PI by clicking the “Submit” activity.

**What if I’m a student conducting Human Research?**

Students may only participate in a research project where an MD Anderson faculty member or employee is serving as the student’s Mentor. When serving as a Mentor, the MD Anderson faculty or employee is responsible for providing supervision and guidance to the student by:

- Serving as the PI for the protocol;
- Overseeing the design and conduct of the protocol;
- Ensuring that the student assuming research duties is well-trained and competent;
- Ensuring that the student has taken the required institutional human subjects and privacy training courses;
- Protection of the rights and welfare of participants, including obtaining informed consent and maintaining privacy and confidentiality of data;
- Reviewing the New Study application in ePRTCL prior to submission to the IRB;
**What do I need to submit to the IRB if I have a sponsor/multi-site protocol that I’m using?**

If you will be using a sponsor/multi-site protocol for the conduct of a study, attach that protocol in ePRTCL. You will also need to complete HRP-508 - TEMPLATE SITE SUPPLEMENT TO SPONSOR PROTOCOL to capture MD Anderson specific items related to the conduct of the protocol. Also attach the Site Supplement in ePRTCL along with the sponsor protocol.

**Does the IRB need to review advertisements that I will use for the study?**

Yes, advertising or soliciting for study participants is the start of the informed consent process and participant selection process. Advertisements must be reviewed and approved by the IRB during the initial review of the study. Following initial review, if you decide to advertise for participants or change the advertisement, a study modification should be submitted for IRB approval. Refer to HRP-315 - WORKSHEET – Advertisements for guidelines.

IRB review and approval is generally not required for the following:

1. Communications intended to be seen or heard by health professionals, such as “dear doctor” letters and doctor-to-doctor letters.
2. News stories without recruitment material.
3. Publicity intended for other audiences, such as financial page advertisements directed toward prospective investors.
4. Clinical trial listing services as outlined below:
   a. National Cancer Institute’s Cancer Clinical Trial Listing (PDQ)
   b. AIDS Clinical Trials Information Service (ACTIS)
   c. National Institutes of Health clinicaltrials.gov
   d. MD Anderson Cancer Center clinicaltrials.org

These sites only contain basic necessary information about a clinical study (e.g. title, purpose, study summary, eligibility, study sites, contact information) and therefore IRB review of listings on these sites is not required.

**What do I need to take into consideration when initiating contact for the first time with potential participants?**

If you do not have a pre-existing relationship with the potential participant (e.g. s/he is your patient), care should be taken to ensure that the potential participant understands how you acquired private information about them and that it was obtained in a legitimate manner. For
example, if the potential participant was referred to you by the person’s physician or other treating health care professional, you can cite that reason for the contact.

If you identify potential participants through chart reviews, an initial “cold contact” to a potential participant may cause concern regarding how you accessed personal information and could lead a complaint to the Privacy Office if misconstrued as illegal use of PHI. You may want to consider first sending a letter to potential participants and providing a telephone number or other means that the potential participant can use to verify that the study is MD Anderson research.

**What guidelines should I follow if I want to pay participants in my study?**

You can refer to HRP-316 - WORKSHEET – Payments for information regarding the criteria that the IRB uses to review and approve payment to participants. The amount of payment should be based on the incremental time, inconvenience and discomfort associated with participation in the research (compared with not participating) or the actual out-of-pocket expenses. It is appropriate to provide participants with higher payments for larger amounts of time, more inconvenience (e.g., strategies that require participant responses throughout the day, or requiring travel to distant study sites), and more discomfort (e.g., blood draw vs. bronchoscopy).

Payment to physicians or staff in exchange for referral of potential participants and payment tied to the rate or timing of enrollment (e.g., a bonus payment) is prohibited.

Based on the principle of equity, lotteries or drawings are discouraged. It is preferred that a payment be distributed evenly among all participants. In the case where a lottery is critical to the success of the study, the plan must comply with applicable state laws.

Distribution of payments must be documented in the permanent study records. Procedures for distribution and documentation of payments must be clearly described in the protocol or appendices.

**Can I enroll pediatric patients in Phase 1 adult studies?**

Yes, pediatric patients under the age of 18 can be enrolled in Phase 1 studies if permitted in the inclusion/exclusion criteria of the study. Please refer to HRP-416 - CHECKLIST - Children for additional requirements.

**Does my study need a Certificate of Confidentiality?**

A Certificate of Confidentiality (CoC) protects the privacy of research participants by prohibiting disclosure of identifiable, sensitive research information to anyone not connected to the research except when the participant consents or in a few other specific situations. Please refer to HRP-333 - WORKSHEET - Certificate of Confidentiality for the criteria that are used to determine if you need/are automatically issued a Certificate of Confidentiality for your study.
**How do I involve the community in the design and conduct of my Human Research?**

The Community Scientist Program is designed to provide researchers with rapid feedback from trained community members to ensure their research projects are culturally appropriate and relevant to the community. Our Community Scientists are a diverse group of community members who provide valuable insights to researchers by sharing lived experiences with cancer or a chronic illness.

This free program allows researchers to use Community Scientists as consultants on aspects of their proposals or active studies. As community/patient engagement increasingly becomes a requirement among funding agencies like the NIH and FDA, feedback sessions with the program can help with overall research outcomes.

Community Scientists:

- Serve as a sounding board to ensure research addresses local patient and community member interests;
- Provide advice on the development of culturally appropriate studies and recruitment strategies; and
- Provide input on research questions, study designs, and recruitment and retention barriers.
- For additional information contact: CommunityScientistProgram@mdanderson.org

**How do I create a consent document?**

Please contact the consent editor team at consenteditors@mdanderson.org if you need help with creating an informed consent document (ICD). There are multiple consent templates available which can be found in the ePRTCL IRB Library.

You should use the biomedical ICD template whenever the study involves an investigational agent (e.g. drug, device); the study is FDA regulated; or the study involves any medical procedures (e.g. blood draws, scans).

You should use the psychosocial ICD template whenever the study primarily involves procedures such as questionnaires, surveys, diaries or focus groups to evaluate the primary objective; quality of life studies; or studies that primarily involve behavioral interventions (e.g. therapy).

Note that all ICDs (and study summaries when using the short form VTPS process) must contain all of the required and all additional appropriate elements of informed consent disclosure. Review the “Long Form of Consent Documentation” section in HRP-314 - WORKSHEET - Criteria for Approval, to ensure that these elements are addressed.

If your research study meets the requirements for an exemption and there are interactions with participants, you may use an abbreviated process for obtaining consent. Consent can be verbal,
but you must provide the following information to participants through an information sheet or written script:

- The participant is being asked to participate in a research study;
- A description of the procedure(s) the participant will be asked to complete;
- Participation is voluntary; and
- The investigator’s name and contact information.

We recommend that you date the revisions of your consent documents to ensure that you use the most recent version approved by the IRB.

**Do I need to obtain informed consent in order to screen, recruit, or determine the eligibility of prospective participants?**

The IRB may approve a research proposal in which an investigator will obtain information or biospecimens for the purpose of screening, recruiting, or determining the eligibility of prospective participants without the informed consent of the prospective participant or the participant’s legally authorized representative, if either of the following conditions are met:

1. The investigator will obtain information through oral or written communication with the prospective participant or legally authorized representative, OR
2. The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.

The research protocol should include information about how potential participants will be identified and recruited in order for the IRB to be able to determine whether informed consent for these activities is required.

**What if I expect to enroll non-English speaking participants in my study?**

You should identify in the protocol or HRP-508 - TEMPLATE SITE SUPPLEMENT TO SPONSOR PROTOCOL that non-English speakers can be enrolled in the study. If you know the language(s) of potential participants, the consent form must be translated into the language understandable to the non-English speaking participants expected to enroll in your study. You may use the services of MD Anderson Language Assistance department or another certified translation service to prepare the requisite translation of the English consent form. When the translation is not provided by the MD Anderson Language Assistance department, you must upload into ePRTCL (under “Other Attachments”) the documentation to show that the translated consent form has been certified as an accurate and complete translation of the English ICD.

If your study allows for non-English speakers to be enrolled in the study, but are unexpectedly encountered, you may provide the participant a Verbal Translation Preparative Sheet (VTPS) (also known as the consent short form) in the primary language of the participant. The VTPS informs the participant of the type of information they should receive during the informed consent process with the interpreter. An unexpected encounter using the VTPS should only
occur twice for a single protocol. Following the second occurrence, you should have the consent document translated into that language if there are at least 5 accrual spots at MD Anderson remaining.

**What are the different regulatory classifications that research activities may fall under?**

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

- **Not “Human Research”:** Activities must meet the institutional definition of “Human Research” to fall under IRB oversight. Activities that do not meet this definition of are not subject to IRB oversight or review. Review the OHSP’s HRP-310 - WORKSHEET - Human Research Determination for reference. Contact the OHSP in cases where it is unclear whether an activity is Human Research.

- **Exempt:** Certain categories of Human Research may be exempt from regulation but require IRB review. It is the responsibility of the Institution, not the investigator, to determine whether Human Research is exempt from IRB review. Review the OHSP’s HRP-312 - WORKSHEET - Exemption Determination for reference on the categories of research that may be exempt.

- **Review Using the Expedited Procedure:** Certain categories of non-exempt Human Research may qualify for review using the expedited procedure, meaning that the project may be approved by a single designated IRB reviewer, rather than the convened board. Review the OHSP’s HRP-313 - WORKSHEET - Expedited Review 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 review using the expedited procedure must be reviewed by the convened IRB.

**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, table research, defer research or disapprove research:

- **Approval:** 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:** Made when IRB members require specific modifications to the research before approval can be finalized.

- **Tabled:** Made when the IRB cannot approve the research at a meeting for reasons unrelated to the research, such as loss of quorum. When taking this action, the IRB automatically schedules the research for review at the next meeting.

- **Deferred:** Made when the IRB determines that the board is unable to approve research and the IRB suggests modifications that might make the research approvable. When making this motion, the IRB describes its reasons for this decision, describes
modifications that might make the research approvable, and gives the investigator an opportunity to respond to the IRB in person or in writing.

- **Disapproval:** Made when the IRB determines that it is unable to approve research and the IRB cannot describe modifications that might make the research approvable. When making this motion, the IRB describes its reasons for this decision and gives the investigator an opportunity to respond to the IRB in person or in writing.

**How does the IRB decide whether to approve Human Research?**

The criteria for IRB approval can be found in HRP-312 - WORKSHEET - Exemption Determination for exempt Human Research and HRP-314 - WORKSHEET - Criteria for Approval for non-exempt Human Research. The latter worksheet references other checklists that might be relevant. All checklists and worksheets can be found in the ePCRTL IRB Library.

These worksheets and checklists are used for initial review, continuing review, and review of modifications to previously approved Human Research.

**What other reviews do I need besides IRB review?**

Depending on the type of research being conducted you may need other reviews either before you submit to the IRB or before you can start your study. Please refer to HRP-309 - WORKSHEET - Ancillary Review Matrix to see what other reviews your study may need.

**What will happen after IRB review?**

The IRB will provide you with a written decision in ePRTCL indicating that the IRB has approved the Human Research, requires modifications to secure approval, or has disapproved the Human Research.

- **If the IRB has approved the Human Research:** The Human Research may commence once all other institutional approvals have been met. IRB approval is usually good for a limited period of time which is noted in the approval letter.

- **If the IRB requires modifications to secure approval and you accept the modifications:** Make the requested modifications and submit them to the IRB. If all requested modifications are made, the IRB will issue a final approval. Research cannot commence until this final approval is received. If you do not accept the modifications, write up your response and submit it to the IRB.

- **If the IRB defers the Human Research:** The IRB will provide a statement of the reasons for deferral and suggestions to make the study approvable and give you an opportunity to respond in writing. In most cases if the IRB’s reasons for the deferral are addressed in a modification, the Human Research can be approved.

- **If the IRB disapproves the Human Research:** The IRB will provide a statement of the reasons for disapproval and give you an opportunity to respond in writing.

In all cases, you have the right to address your concerns to the IRB directly at an IRB meeting.
What are my obligations after IRB approval?

1) Do not start Human Research activities until:
   a) You have obtained all required institutional approvals, including approvals of departments or divisions that require approval prior to commencing research that involves their resources.
   b) You have the final IRB approval letter and activation memo.
   c) The study record in ePRTCL has the word “Active” in red along with a date to indicate that you can start the research.

2) 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.

3) Ensure that Research Staff are 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.

4) Update the OHSP with any changes to the list of study personnel.

5) Personally conduct or supervise the Human Research. Recognize that the investigator is accountable for the failures of any study team member.
   a) Conduct the Human Research in accordance with the relevant current protocol as approved by the IRB, and in accordance with applicable federal regulations and local laws.
   b) When required by the IRB, ensure that consent or permission is obtained in accordance with the relevant current protocol as approved by the IRB.
   c) Do not modify the Human Research without prior IRB review and approval unless necessary to eliminate apparent immediate hazards to subjects.
   d) Protect the rights, safety, and welfare of subjects involved in the research.

6) Submit to the IRB:
   a) Proposed modifications as described in this manual. (See “How do I submit a modification?”)
   b) A continuing review application if requested in the approval letter. (See “How do I submit continuing review?”)
   c) A continuing review application when the Human Research is closed. (See “How Do I Close Out a Study?”)

7) Complete the Report New Information SmartForm in ePRTCL within five business days for any of the following information items:
   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) indicates an increase in the frequency or magnitude of a previously known risk, or uncovers a new risk.
      ii) An investigator brochure, package insert, or device labeling is revised to indicate an increase in the frequency or magnitude of a previously known risk, or describe a new risk.
      iii) Withdrawal, restriction, or modification of a marketed approval of a drug, device, or biologic used in a research protocol.
iv) Protocol violation that harmed subjects or others or that indicates subjects or others might be at increased risk of harm

v) Complaint of a subject that indicates subjects or others might be at increased risk of harm or at risk of a new harm

vi) 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.

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

ii) A 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.

d) Audit, inspection, or inquiry by a federal agency and any resulting reports (e.g. FDA Form 483.)

e) Written reports of study monitors.

f) Failure to follow the protocol due to the action or inaction of the investigator or research staff that potentially impacts subject safety or integrity of the study.

g) Breach of confidentiality.

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.

j) Complaint of a subject that cannot be resolved by the research team.

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

l) Unanticipated adverse device effect (any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects).

m) Emergency use of a test article

8) Submit an updated disclosure of financial interests to the Conflict of Interest (COI) Office within thirty days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new financial interest.

9) Do not accept or provide payments to professionals in exchange for referrals of potential participants (“finder’s fees.”)

10) Do not accept payments designed to accelerate recruitment that were tied to the rate or timing of enrollment (“bonus payments.”)

11) See additional requirements of various federal agencies in Appendix A. These represent additional requirements and do no override the baseline requirements of this section.

12) If the study is a clinical trial and supported by a Common Rule agency, one IRB-approved version of a consent form that has been used to enroll participants must be posted on a public federal website designated for posting such consent forms. The form must be posted after
recruitment closes, and no later than 60 days after the last study visit. Please contact the study sponsor with any questions.

a) If certain information should not be made publicly available on a Federal website (e.g. confidential commercial information), the supporting Federal department or agency may permit or require redactions to the information posted. Contact the Federal department or agency supporting the clinical trial for a formal determination.

b) Contact the supporting Federal department or agency sponsor with any other questions regarding consent form posting obligations.

13) Keep data confidential. MD Anderson has guidelines for best practices for maintaining confidentiality found at: https://mdanderson.org.sharepoint.com/sites/compliance/SitePages/Privacy-and-Information-Security.aspx

**What are my obligations as the overall study PI for an sIRB study?**

1) Coordinate with OHSP to determine whether this Institution’s IRB can act as the single IRB for all or some institutions participating in the study or if an external IRB will assume oversight.

2) Identify all sites that will be engaged in the human research and requiring oversight by the IRB.

3) Ensure that all sites receive a request to rely on the reviewing IRB and that all institutional requirements are satisfied before a study is activated at a relying site.

4) Collaborate with the reviewing IRB to document roles and responsibilities for communicating and coordinating key information from study teams and the IRB or HRPP at relying sites.

5) Respond to questions or information requests from study teams or the IRB or HRPP staff at relying sites.

6) Provide relying site investigators with the policies of the reviewing IRB.

7) Provide relying site investigators with the IRB-approved versions of all study documents.

8) Help prepare and submit IRB applications on behalf of all sites. This includes initial review, modifications, personnel updates, reportable new information and continuing review information for all sites.

9) Establish a process for obtaining and collating information from all sites and submitting this information to the reviewing IRB. This includes site-specific variations in study conduct, such as the local consent process and language, participant identification and recruitment processes and local variations in study conduct.

10) Ensure that consent forms used by relying sites follow the consent template approved by the reviewing IRB and include required language as specified by the relying sites.

11) Provide site investigators with all determinations and communications from the reviewing IRB.

12) Submit reportable new information from relying sites to the reviewing IRB in accordance with the terms outlined in the authorization agreement or communication plan.

13) Report the absence of continuing review information from relying sites if they do not provide the required information prior to submission of the continuing review materials to the
reviewing IRB. Notifying the relying site of their lapse in approval and applicable corrective actions.

14) Provide study records to the relying institution, reviewing IRB or regulatory agencies upon request.

**What are my obligations as an investigator when relying on an external IRB?**

1) Obtain appropriate approvals from OHSP prior to seeking reliance on an external IRB (except for NCI CIRB).

2) Submit the external IRB study in ePRTCL for review and reliance confirmation.

3) Ensure that local study team members satisfy training requirements.

4) Comply with determinations and requirements of the external IRB.

5) Provide the external IRB with requested information about local requirements or local research context issues relevant to the IRB’s determination prior to IRB review.

6) Notify the reviewing IRB when local policies that impact IRB review are updated.

7) Cooperate in the external IRB’s responsibility for initial and continuing review, record keeping and reporting and providing all information requested by the external IRB in a timely manner.

8) Disclose conflicts of interest as required by the external IRB and complying with management plans that may result.

9) Promptly report to the external IRB any proposed changes to the research and not implementing those changes to the research without prior IRB review and approval, except where necessary to eliminate apparent immediate hazards to the participants.

10) When enrolling participants, obtain, document and maintain records of consent for each participant or each participant's legally authorized representative.

11) Promptly report to the external IRB any unanticipated problems involving risks to participants or others according to the requirements specified in the reliance agreement.

12) Provide the external IRB with data safety monitoring reports in accordance with the external IRB’s reporting policy.

13) Report non-compliance, participant complaints, protocol deviations or other events according to the requirements specified in the reliance agreement.

14) Specify the contact person and providing contact information for researchers and research staff to obtain answers to questions, express concerns, and convey suggestions regarding the use of the external IRB.

15) Update the ePRTCL study record when the following are issued by the external IRB:

   a. Continuing review approval;
   b. Determinations of Serious Non-Compliance; Continuing Non-Compliance; Suspension of IRB Approval; Termination of IRB Approval; or Unanticipated Problem Involving Risks to Subjects or Others for an event that occurred locally at MD Anderson; and
   c. Closure of the study at MD Anderson.

16) Update local study members and any study team changes in ePRTCL for those who require access to the ePRTCL external IRB study record.
17) Manage any MD Anderson ancillary reviews required for modifications to external IRB studies.

**How do I document consent?**

Please refer to SOP 04_Informed Consent Process which can be found at: https://mdandersonorg.sharepoint.com/sites/clinical-research-administration/SitePages/Policies-and-Procedures.aspx for detailed information about how to obtain and document consent.

Use the consent forms approved by the IRB. Complete all items in the signature block, including dates.

The following are the requirements for ICDs:

- The participant 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 to the oral presentation, the witness signs and dates the consent document.
- For participants who cannot read and whenever required by the IRB or the sponsor, a witness to the oral presentation signs and dates the consent document.
- A copy of the signed and dated consent document is to be provided to the participant.

The following are the requirements when using the VTPS (short form consent):

- The participant or representative signs and dates the VTPS.
- The individual obtaining consent signs and dates the study summary (which is the same document as the ICD).
- The witness to the oral presentation signs and dates the VTPS and the study summary.
- Copies of the signed and dated VTPS and study summary are provided to the person(s) signing those documents.

**How do I submit a modification?**

Complete the Modification SmartForm in ePRTCL and attach all requested supplements, have the SmartForm submitted by the PI 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 without inclusion of the modification until IRB approval is received.

**How do I submit a continuing review?**

ePRTCL will send you a reminder 90, 60 and 30 days before the IRB approval end date of your study. Complete the Continuing Review SmartForm in ePRTCL and attach all requested supplements, and have the SmartForm submitted by the PI by clicking the “Submit” activity. Maintain electronic copies of all information submitted to the IRB in case revisions are required.
If the continuing review also involves any modification to the study, submit those modifications either as a combined Modification and Continuing Review or as a separate request for modification using the Modification SmartForm in ePRTCL.

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

If the approval of Human Research expires, the study record status in ePRTCL will transition to “Lapsed” and all Human Research procedures related to the protocol under review must cease, including recruitment, advertisement, screening, enrollment, consent, interventions, interactions, and collection or analysis of private identifiable information. Continuing Human Research procedures is a violation of institutional policy. If current participants will be harmed by stopping Human Research procedures that are available outside the Human Research context, provide these on a clinical basis as needed to protect current participants. If current participants will be harmed by stopping Human Research procedures that are not available outside the Human Research context, immediately contact the IRB chair and provide a written list of the currently enrolled participants and why they will be harmed by stopping Human Research procedures.

If after 30 days past the IRB approval end date you have still not submitted a continuing review application to the IRB, the following will occur:

- All of your active studies will be closed to new enrollment; and
- Your Department Chair will be notified.

If after 60 days past the IRB approval end date you have still not submitted a continuing review application to the IRB, the following will also occur:

- A Reportable New Information (RNI) item will be submitted by OHSP for your study indicating non-compliance with the requirements of the IRB;
- This RNI will be reviewed by the IRB for a determination; and
- For all studies where you are listed as a study team member, the PI of those studies will be notified to remove you from the study team.

Please note that if your continuing review application is reviewed prior to the IRB approval end date and the IRB requires modifications to secure approval BUT you have either not submitted the requested modifications or the IRB has not approved the submitted modifications prior to the IRB approval end date, the status of the study in ePRTCL will still transition to “Lapsed.” OHSP staff will contact you to follow up on the status of the requested modifications. During this period of time (between the IRB approval end date and when the modifications required to secure approval are approved by the IRB), you cannot enroll new participants in the study but may continue study-related procedures for currently enrolled participants.
How do I close out a study?

Complete the Continuing Review SmartForm in ePRTCL, attach all requested documents, and have the SmartForm submitted by the PI by clicking the “Submit” activity. Maintain electronic copies of all information submitted to the IRB in case revisions are required.

If you fail to submit a continuing review form to close out Human Research, you will be restricted from submitting new Human Research until the completed application has been received.

Please note that the following activities can still be carried out after a study is closed with the IRB (and the study does not need to be kept open with the IRB for these to occur):

- Invoicing the sponsor for research-related items and services.
- Receipt of final payment from a sponsor.
- Return of destruction of unused investigational drug(s).
- Preparation of a final research report provided the report does not involve the use or disclosure of protected health information/individually identifiable information of participants.
- Resolution of data queries from the sponsor or corrections that are required as a result of FDA or other regulatory body inspections after the research has been closed with the IRB.
- Data analysis required to respond to queries from journal editors, manuscript reviewers or readers, provided such analysis does not involve the use or disclosure of protected health information/individually identifiable information of participants.

How long do I keep records?

Maintain your Human Research records, including signed and dated consent documents for at least three years after completion of the research. Maintain signed and dated HIPAA authorizations and consent documents that include HIPAA authorizations for at least six years after completion of the research.

If your Human Research is sponsored, contact the sponsor before disposing of Human Research records.

What if I need to use an unapproved drug, biologic, or device and there is no time for IRB review?

Contact the OHSP or IRB chair immediately to discuss the situation. If there is no time to make this contact, see HRP-322 - WORKSHEET - Emergency Use for the regulatory criteria allowing such a use and make sure these are followed. Use HRP-506 - TEMPLATE - EIND or CIND ICD to prepare your consent document. You will need to submit a report of the emergency use to the IRB within five working days of the use. You should submit the request for emergency use or 5 day report of the emergency use in ePRTCL and complete the Report New Information SmartForm (choose the category “Emergency Use”).
If you fail to submit the report within working five days, you will be restricted from submitting new Human Research until the report has been received.

Emergency use of an unapproved drug or biologic in a life-threatening situation without prior IRB review is “research” as defined by FDA, the individual getting the test article is a “subject” as defined by FDA, and therefore is governed by FDA regulations for IRB review and informed consent. Emergency use of an unapproved device without prior IRB review is not “research” as defined by FDA and the individual getting the test article is not a “subject” as defined by FDA. However, FDA guidance recommends following similar rules as for emergency use of an unapproved drug or biologic.

Individuals getting an unapproved drug, biologic, or device without prior IRB review cannot be considered a “subject” as defined by DHHS and their results cannot be included in prospective “research” as that term is defined by DHHS.

What if I have an expanded access use/request for an unapproved drug, biologic or device?

Expanded access is a specific pathway for a patient with an immediately life-threatening condition or serious disease or condition to gain access to an investigational medical product (drug, biologic, or medical device) for treatment outside of clinical trials when no comparable or satisfactory alternative therapy options are available. Please visit FDA’s website for detailed information: https://www.fda.gov/news-events/public-health-focus/expanded-access

There are 3 different types of expanded access:
1. Expanded access for individual patients (referred to at MD Anderson as “CIND”), including for emergency use
2. Expanded access for intermediate-size patient groups
3. Expanded access for widespread treatment use

For emergency use, please refer to What if I need to use an unapproved drug, biologic, or device and there is no time for IRB review?

For any non-emergency use expanded access request, you will need to click Create New Study in ePRTCL and complete the initial study application. Refer to How do I submit new Human Research to the IRB?

- For individual patient expanded access (CIND) requests:
  - If you checked “Request for Authorization to Use Alternative IRB Review Procedures” on FDA Form 3926 (field 10.b.) or have a separate waiver request included with FDA Form 1571 for the purpose of obtaining concurrence from an IRB Chair or designee, include that information in the application.
  - Attach the proposed treatment plan for the patient in lieu of a research protocol.
  - Use HRP-506 - TEMPLATE - EIND or CIND ICD to prepare your consent document.
For individual patient expanded access requests (CIND) please contact: IND_PM@mdanderson.org

**How do I get additional information and answers to questions?**

This document and the policies and procedures for the IRB are available in the ePRTCL IRB Library.

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

- **Director, Human Subjects Protection**
  - 7007 Bertner Ave., Unit 1637
  - Houston, TX 77030
  - Email: IRB_Help@mdanderson.org
  - (713) 792-6477

If you have questions, concerns, complaints, allegations of undue influence, allegations or findings of non-compliance, or input regarding the Human Research Protection Program that cannot be addressed by contact the OHSP, follow the directions in HRP-101 - HUMAN RESEARCH PROTECTION PROGRAM PLAN under “Reporting and Management of Concerns.”
Appendix A-1  

**Additional Requirements for DHHS-Regulated Research**

1. When a subject decides to withdraw from a clinical trial, the investigator conducting the clinical trial should ask the subject to clarify whether the subject wishes to withdraw from all components of the trial or only from the primary interventional component of the trial. If the latter, research activities involving other components of the clinical trial, such as follow-up data collection activities, for which the subject previously gave consent may continue. The investigator should explain to the subject who wishes to withdraw the importance of obtaining follow-up safety data about the subject.

2. Investigators are allowed to retain and analyze already collected data relating to any subject who chooses to withdraw from a research study or whose participation is terminated by an investigator without regard to the subject’s consent, provided such analysis falls within the scope of the analysis described in the IRB-approved protocol. This is the case even if that data includes identifiable private information about the subject.

3. For research not subject to regulation and review by FDA, investigators, in consultation with the funding agency, can choose to honor a research subject’s request that the investigator destroy the subject’s data or that the investigator exclude the subject’s data from any analysis.

4. When seeking the informed consent of subjects, investigators should explain whether already collected data about the subjects will be retained and analyzed even if the subjects choose to withdraw from the research.

5. When research is covered by a certificate of confidentiality, researchers:
   a. May not disclose or provide, in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding, the name of such individual or any such information, document, or biospecimen that contains identifiable, sensitive information about the individual and that was created or compiled for purposes of the research, unless such disclosure or use is made with the consent of the individual to whom the information, document, or biospecimen pertains; or
   b. May not disclose or provide to any other person not connected with the research the name of such an individual or any information, document, or biospecimen that contains identifiable, sensitive information about such an individual and that was created or compiled for purposes of the research.
   c. May disclose information only when:
      i. Required by Federal, State, or local laws (e.g., as required by the Federal Food, Drug, and Cosmetic Act, or state laws requiring the reporting of communicable diseases to State and local health departments), excluding instances of disclosure in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding.
      ii. Necessary for the medical treatment of the individual to whom the information, document, or biospecimen pertains and made with the consent of such individual.

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iii. Made with the consent of the individual to whom the information, document, or biospecimen pertains; or

iv. Made for the purposes of other scientific research that is in compliance with applicable Federal regulations governing the protection of human participants in research.

d. Researchers must inform participants of the protections and limitations of certificates of confidentiality.

i. For studies that were previously issued a Certificate and notified participants of the protections provided by that Certificate, NIH does not expect participants to be notified that the protections afforded by the Certificate have changed, although IRBs may determine whether it is appropriate to inform participants.

ii. If part of the study cohort was recruited prior to issuance of the Certificate, but are no longer actively participating in the study, NIH does not expect participants consented prior to the change in authority, or prior to the issuance of a Certificate, to be notified that the protections afforded by the Certificate have changed, or that participants who were previously consented to be re-contacted to be informed of the Certificate, although the IRB may determine whether it is appropriate to inform participants.

e. Researchers conducting research covered by a certificate of confidentiality, even if the research is not federally funded, must ensure that if identifiable, sensitive information is provided to other researchers or organizations, the other researcher or organization must comply with applicable requirements when research is covered by a certificate of confidentiality.
Appendix A-2 Additional Requirements for FDA-Regulated Research

1. When a subject withdraws from a study:\(^2\)
   a. The data collected on the subject to the point of withdrawal remains part of the study database and may not be removed.
   b. An investigator may ask a subject who is withdrawing whether the subject wishes to provide continued follow-up and further data collection subsequent to their withdrawal from the interventional portion of the study. Under this circumstance, the discussion with the subject would distinguish between study-related interventions and continued follow-up of associated clinical outcome information, such as medical course or laboratory results obtained through non-invasive chart review, and address the maintenance of privacy and confidentiality of the subject’s information.
   c. If a subject withdraws from the interventional portion of the study, but agrees to continued follow-up of associated clinical outcome information as described in the previous bullet, the investigator must obtain the subject’s informed consent for this limited participation in the study (assuming such a situation was not described in the original informed consent form). IRB approval of informed consent documents is required.
   d. If a subject withdraws from the interventional portion of a study and does not consent to continued follow-up of associated clinical outcome information, the investigator must not access for purposes related to the study the subject’s medical record or other confidential records requiring the subject’s consent.
   e. An investigator may review study data related to the subject collected prior to the subject’s withdrawal from the study, and may consult public records, such as those establishing survival status.

2. For FDA-regulated research involving investigational products please refer to SOP07 Control and Accountability of Investigational Products.: 

Appendix A-3  Additional Requirements for Department of Defense (DOD) research

1. When appropriate, research protocols must be reviewed and approved by the IRB prior to the Department of Defense approval. Consult with the Department of Defense funding component to see whether this is a requirement.

2. Civilian researchers attempting to access military volunteers should seek collaboration with a military researcher familiar with service-specific requirements.

3. Employees of the Department of Defense (including temporary, part-time, and intermittent appointments) may not be able to legally accept payments to participate in research and should check with their supervisor before accepting such payments. Employees of the Department of Defense cannot be paid for conducting research while on active duty.

4. Service members must follow their command policies regarding the requirement to obtain command permission to participate in research involving human subjects while on-duty or off-duty.

5. Components of the Department of Defense might have stricter requirements for research-related injury than the DHHS regulations.

6. There may be specific educational requirements or certification required.

7. When assessing whether to support or collaborate with this institution for research involving human subjects, the Department of Defense may evaluate this institution’s education and training policies to ensure the personnel are qualified to perform the research.

8. When research involves U.S. military personnel, policies and procedures require limitations on dual compensation:
   a. Prohibit an individual from receiving pay of compensation for research during duty hours.
   b. An individual may be compensated for research if the participant is involved in the research when not on duty.
   c. Federal employees while on duty and non-Federal persons may be compensated for blood draws for research up to $50 for each blood draw.
   d. Non-Federal persons may be compensated for research participating other than blood draws in a reasonable amount as approved by the IRB according to local prevailing rates and the nature of the research.

9. When research involves large scale genomic data (LSGD) collected on DOD-affiliated personnel, additional protections are required:
   a. Additional administrative, technical, and physical safeguards to prevent disclosure of DoD-affiliated personnel’s genomic data commensurate with risk (including secondary use or sharing of de-identified data or specimens)
   b. Research will apply an HHS Certificate of Confidentiality

10. DoD Component security review

11. When conducting multi-site research, a formal agreement between institutions is required to specify the roles and responsibilities of each party.

12. Other specific requirements of the Department of Defense research be found in the “Additional Requirements for Department of Defense (DOD) Research” section in the IRB’s HRP-318 - WORKSHEET - Additional Federal Agency Criteria.
Appendix A-4  Additional Requirements for Department of Education (ED) Research

1. Each school at which the research is conducted must provide an assurance that they comply with the Family Educational Rights and Privacy Act (FERPA) and the Protection of Pupil Rights Amendment (PPRA).

2. Provide a copy of all surveys and instructional material used in the research. Upon request parents of children involved in the research must be able to inspect these materials.

3. The school in which the research is being conducted must have policies regarding the administration of physical examinations or screenings that the school may administer to students.

4. Other specific requirements of the Department of Education (ED) Research can be found in the “Additional Requirements for Department of Education (ED) Research” section in the IRB’s HRP-318 - WORKSHEET - Additional Federal Agency Criteria.

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3 Children are persons enrolled in research not above the elementary or secondary education level, who have not reached the age or majority as determined under state law.

4 Research or experimentation program or project means any program or project in any research that is designed to explore or develop new or unproven teaching methods or techniques.
single IRB Studies

1. That National Institutes of Health expects that all sites participating in multi-site studies involving non-exempt human subjects research funded by the NIH will use a single Institutional Review Board (sIRB) to conduct the ethical review required by the Department of Health and Human Services regulations for the Protection of Human Subjects at 45 CFR Part 46.
   a. This policy applies to the domestic sites of NIH-funded multi-site studies where each site will conduct the same protocol involving non-exempt human subjects research, whether supported through grants, cooperative agreements, contracts, or the NIH Intramural Research Program. It does not apply to career development, research training or fellowship awards.
   b. This policy applies to domestic awardees and participating domestic sites. Foreign sites participating in NIH-funded, multi-site studies will not be expected to follow this policy.
   c. Exceptions to the NIH policy will be made where review by the proposed sIRB would be prohibited by a federal, tribal, or state law, regulation, or policy. Requests for exceptions that are not based on a legal, regulatory, or policy requirement will be considered if there is a compelling justification for the exception. The NIH will determine whether to grant an exception following an assessment of the need.

2. The Office for Human Research Protections expects that all sites located in the United States participating in cooperative research must rely upon approval by a single IRB for that portion of the research that is conducted in the United States. The reviewing IRB will be identified by the Federal department or agency supporting or conducting the research or proposed by the lead institution subject to the acceptance of the Federal department or agency supporting the research.

The following research is not subject to this provision:
   a. Cooperative research for which more than single IRB review is required by law (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe); or
   b. Research for which any Federal department or agency supporting or conducting the research determines and documents that the use of a single IRB is not appropriate for the particular context.
   c. For research not subject to paragraph (b) of this section, an institution participating in a cooperative project may enter into a joint review arrangement, rely on the review of another IRB, or make similar arrangements for avoiding duplication of effort.
Appendix A-6  **Additional Requirements for Research Subject to EU General Data Protection Regulations (GDPR)**

1. Human Research involving personal data about individuals located in (but not necessarily citizens of) European Union member states, Norway, Iceland, Liechtenstein, and Switzerland is subject to EU General Data Protection Regulations.

2. For all prospective Human Research subject to EU GDPR, contact institutional legal counsel or your institution’s Data Protection Officer to ensure that the following elements of the research are consistent with institutional policies and interpretations of EU GDPR:
   a. Any applicable study design elements related to data security measures.
   b. Any applicable procedures related to the rights to access, rectification, and erasure of data.
   c. Procedures related to broad/unspecified future use consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens.

3. Where FDA or DHHS regulations apply in addition to EU GDPR regulations, ensure that procedures related to withdrawal from the research, as well as procedures for managing data and biospecimens associated with the research remain consistent with Appendices A-1 and A-2 above.