THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center
Making Cancer History®

Responsibilities Matrix for Utilizing a Single or External IRB Mechanism and an IRB Authorization Agreement (IAA)

PURPOSE

The purpose of this document is to provide guidance to investigators about the responsibilities of Investigators, MD Anderson IRB, Institution, and the External Site when utilizing a single or external IRB.

Additionally, the purpose of this document is to provide guidance to investigators about the responsibilities of the Reviewing IRB and the Relying IRB when utilizing an IRB Authorization Agreement.

INVESTIGATOR RESPONSIBILITIES

The MD Anderson investigator is the primary conduit between the external site's IRB and the MD Anderson IRB.

The MD Anderson investigator will assure the following when engaging in research with an external site:

- Will coordinate with OHSP staff to determine whether MD Anderson'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.
- Will attach the PI Survey and Local Considerations to the research study;
- Will identify in the protocol, the proposed external site(s) and describe the types of research activities proposed for each site for review by the MD Anderson IRB Will assure that the MD Anderson IRB has reviewed and approved the research prior to participation with the external site(s);
- Will provide documentation of the external site(s) IRB approval and FWA documentation;
- Will notify the IRB promptly of changes to research which might affect safety or willingness of subjects to participate;
- Will notify the external(s) site of MD Anderson IRB decisions that might affect subject participation;
- Will assure the protocol has a data safety monitoring plan in place consistent with the complexity of the research;
- Will assure the protocol provides for appropriately monitoring the external site(s) and that data is reported in a timely fashion;
- Will comply with the external site's policies and procedures related to the conduct of research activities;
- Will provide written documentation of the external site's willingness to participate in the research study, upon request;
- Will maintain copies of annual review IRB approval reports for all external site(s), and submits upon request;

- Will provide copies of external data safety monitoring board reports and/or interim analyses reports as required by study reporting guidelines and submits along with the MD Anderson IRB Continuing Review form;
- Will submit protocol amendments when an external site is added or removed;
- Will inform and train in research-related procedures, as necessary, all external site personnel involved in the research.
- Adhere to MD Anderson IRB's reporting requirements for unanticipated problems, participant complaints, protocol deviations, and other events.

MD ANDERSON IRB RESPONSIBILITIES

The MD Anderson IRB will assure the following when engaging in research with an external site:

- Will assure documentation of IRB approval at the external site is on file;
- Will obtain a consultation from an individual familiar with the cultural background, local considerations, and community attitudes of the location in which the research is being conducted in order to meet its local context review requirements, if necessary;
- Will review the contract or agreement as necessary;
- Will evaluate need for other types of agreements with external site(s);
- Will require training, as necessary, of external site staff participating in research;
- Will consult Institutional Official for review and approval of arrangements with the external site(s), as necessary.

INSTITUTIONAL RESPONSIBILITIES

MD Anderson as an institution will assure the following when engaging in research with an external site:

- Will provide policies and procedures to ensure compliance with federal, state and local regulatory requirements;
- Will audit or monitor the research at the external site(s) to ensure subject safety, as necessary;
- Will assure Departments have appropriate resources to conduct the research;
- Will review and sign agreements, as necessary.

EXTERNAL SITE RESPONSIBILITIES

The external site will assure the following when engaging in research at MD Anderson:

- Will provide documentation of an approved FWA, upon request;
- Will review the research and the informed consent document to ensure that it is appropriate to the context of the local research environment;
- Will provide monitoring of the research in the local research environment to ensure subject safety;
- Will provide resources and facilities appropriate for the nature of the research;
- Will assure staff engaged in research have appropriate education and training;
- Will promptly communicate changes to the research, which might affect a subjects willingness to participate in the research to the MD Anderson Investigator.

RESPONSIBILITIES OF THE REVIEWING IRB AND RELYING IRB WHEN UTILIZING AN IRB AUTHORIZATION AGREEMENT (IAA)

An IRB Authorization Agreement (IAA), also known as a reliance agreement, is a written agreement identifying one institution's IRB as the IRB of record. IRB Authorization Agreements allow the IRB of one institution to rely on the IRB review of another.

The Reviewing IRB is the IRB of record and assumes IRB oversight of the Relying IRB. When MD Anderson agrees to serve as the Reviewing IRB, or IRB or record, the types of agreements that can be utilized are the following:

- Individual Investigator Agreement (IIA)
- IAA
- MOU

The Relying IRB of record cedes IRB oversight to the Reviewing IRB. When MD Anderson is acting as the Relying IRB, the most commonly utilized IRB agreements are the following:

- IRB Authorization Agreement
- Memorandum of Understanding (MOU, e.g., the SMART IRB Agreement)

REVIEWING IRB RESPONSIBILITIES

1. Maintain an FWA with OHRP and maintain IRB registration with both OHRP and the FDA, as applicable.
2. The membership of the IRB(s) will meet applicable federal regulations and human subject protection requirements of the FWA.
3. Make available to Relying IRB,the Reviewing IRB policies and procedures.
4. Conduct reviews of initial, continuing, and amendment submissions; unanticipated problem reports, DSMB reports; and any other documentation submitted by the Principal Investigator (PI).
5. For federally funded studies, determine that the proposed research is consistent with the federal award.
6. Maintain and make accessible to the Relying IRB the IRB application, protocol reviews, letters to Principal Investigators, approvals and disapprovals, and approved informed consent documents upon request or provided through the PI.
7. The Reviewing IRB will perform those determinations required by the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and its implementing regulations with respect to the mechanist for permitting the use and disclosure of Protected Health Information (PHI).
8. Investigate and manage any event that appears to rise to the level of an unanticipated problem involving risks to subjects or others and/or serious or continuing noncompliance.
9. Notify Relying IRB promptly if a determination of serious or noncompliance is found, and the corrective actions deemed necessary by the IRB. The Reviewing IRB may request that the Relying IRB conduct its own investigation and report back to the Reviewing IRB.
10. If the Reviewing IRB determines that an event must be reported to oversight entities, such as OHRP and FDA, it will notify the Relying IRB in advance and provide the opportunity for the Relying IRB to review and comment on the report before it is sent.
11. Notify the Relying IRB promptly if it decides to suspend, disapprove, or terminate a study covered by this agreement.
12. Notify the Relying IRB Investigators of any lapses of approval
13. Maintain a post approval monitoring program to ensure compliance with IRB approved protocols and adherence to regulatory requirements.
14. Provide a mechanism for research subjects enrolled at the Relying IRB to address concerns or ask questions pertaining to the rights of research subjects.

15. Notify the Reviewing IRB of any correspondence regarding this study to or from the FDA, OHRP and /or other regulatory agency.

RELYING IRB

1. Maintain a Federal Wide Assurance {FWA) and human research protection program as required by the DHHS OHRP.
2. Educate and train its investigators to perform research in compliance with human subjects' protection regulations.
3. Provide the Reviewing IRB with information pertaining to any specific requirements of local laws, regulations, policies, standards or other factors applicable to the conduct of research.
4. Ensure that resources are adequate to carry out the research planned to take place at the Relying IRB.
5. Ensure that the investigators and other personnel at the Relying IRB) who are involved in the study are appropriately qualified and meet the relying site's standards for eligibility to conduct research. This includes, but is not limited to, having the required professional staff appointments, credentialing, insurance coverage, and background checks for their assigned role in the study.
6. Notify the Reviewing IRB of any special local considerations that must be considered during IRB review.
7. Maintain policies and procedures to address Conflicts of Interest in research that comply with DHHS regulations. Ensure that the Relying IRB investigators and study personnel disclose financial interests according to the Relying IRB policy. Ensure that conflicts of interest are reviewed and a management plan is implemented, if required by the Relying IRB policy. Provide all management plans to the Reviewing IRB for IRB review. Ensure compliance of all management plans related to the study. If the Relying IRB does not maintain policies and procedures compliant with DHHS requirements, ensure that all research personnel identified as Conflict of Interest Investigators complete the Reviewing IRB financial interest disclosure requirements; cooperate with the Reviewing IRB in the development of management plans, if applicable; and adhere to any associated management plans.
8. If the Relying IRB chooses to provide its own HIPAA Authorization, the Relying IRB will ensure that the Authorization explicitly permits PHI to be used and shared by and with the Reviewing IRB and all participating study sites and their investigators as necessary for conducting, reviewing, and overseeing all studies.
9. Remain independently responsible for its own HIPAA compliance and obligations in connection with research covered under this Agreement other than the initial determinations regarding mechanisms for use and disclosure of PHI.
10. Perform local review by other local ancillary committee reviews as applicable per Institution B policies, such as radiation safety or pharmacy. Provide any relevant results of the reviews that may impact the conduct of this study as part of the information provided to the Reviewing IRB.
11. Assure that research activities at the Relying IRB are not initiated until IRB approval is obtained.
12. Notify the Reviewing IRB within twenty-four hours of becoming aware of a suspension or restriction of a Relying IRB investigator or other personnel involved in research.
13. Maintain policies and procedures for dealing with injuries to human research subjects and share these policies and procedures with the Reviewing IRB as requested. To the extent of its own policies, the Relying IRB will provide or arrange for treatment of injuries to human subjects, if any, that may result from study-related procedures that occur at the Relying

IRB. This agreement does not preclude the institutions from making other arrangements between or among them at the outset of a specific study to allocate differently the responsibility for costs associated with injuries to human subjects that might occur in the course of the study.

14. Ensure a mechanism exists by which complaints about research can be made by local study subjects or others. Promptly report such complaints to the Reviewing IRB if they meet the criteria of a potential unanticipated problem as defined by the Reviewing IRB policies.
15. Cooperate with and use all reasonable efforts to ensure the Relying IRB investigators' cooperation with any inquiry by the Reviewing IRB post approval monitoring requests relating to the study.
16. Inform the Reviewing IRB if the site plans to no longer rely upon the Reviewing IRB for IRB review.
17. Notify the Reviewing IRB of any correspondence regarding this study to or from the FDA, OHRP and /or other regulatory agency.

REFERENCES

- SOP: Utilizing a Single or External IRB Mechanism
- SOP: NIH Policy on Single IRB Review for NIH Funded Research
- GUIDANCE: Utilizing an IRB Agreement or Authorization and Definitions

REVISIONS

Date	Action	Initials	Description
06/07/2019	New	JH	New document created
06/27/2019	Rev	JH	Revised guidance document reference