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

Utilizing an IRB Agreement or Authorization

PURPOSE

The purpose of this document is to outline to investigators and research teams the different types of agreements that can be utilized to provide IRB oversight when an investigator or institution is engaged in human subjects research with an outside institution, person or entity.

REGULATORY DEFINITIONS

Assurance: A formal binding agreement between an institution and a federal agency by which the institution agrees to comply with applicable regulations governing human subjects research and that establishes standards for human subjects research.

Dual review: This refers to a situation in which more than one IRB oversees and reviews a research study; i.e., there is duplicate IRB review.

Engagement: MD Anderson applies the definition of engagement provided on the website of the federal Office for Human Research Protections (OHRP) to all research, regardless of the source of the research funding.

PROCEDURES

MD Anderson stipulates that any research conducted that involves human subjects be reviewed by an Institutional Review Board and that, when applicable, appropriate agreements or authorizations are in place to ensure the protection of participants participating in this research at all sites.

There are certain provisions under which an agreement must be executed whenever an MD Anderson employee or agent is engaged in a collaborative or multi-site research project where a component of the research is distributed across more than one institution or some, or all, of the research procedures occur at more than one site.

When utilizing IRB Authorization Agreements, the external site must have and maintain a Federalwide Assurance document and must conduct research in accordance with the terms and conditions as outlined in the IAA. An exception would be a site that does not conduct federally sponsored research; in this case, the site may not have an FWA.

TYPES OF AGREEMENTS

Type of Agreement	Definition	When Will the Agreement be Utilized
Authorization Agreements	Term to refer collectively to agreements about IRB review with other institutions or individuals. Agreements may cover single studies, categories of studies, or all	The term includes: IRB Authorization Agreements, Cooperative Agreements, Individual Investigator Agreements, and agreements/contracts with a central or independent IRB.

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	human subjects research under an organization's Federalwide Assurance (FWA). The Federalwide Assurance (FWA) is the only assurance of compliance that is accepted by the U.S. Department of Health and Human Services (HHS) for research supported or conducted by HHS. Other federal departments and agencies may also rely on the FWA for the research they conduct and support.	
Cancer Network Agreements	A formal written agreement between MD Anderson and a site that has been designated as a Cancer Network (CN) affiliate. These agreements cover collaborative research projects between the Cancer Network site and an MD Anderson investigator. Since there is a master research agreement that has been executed for each CN affiliate, the institution allows for the use of an abbreviated IRB authorization agreement to be utilized for collaborations on specific research studies.	A CN Agreement is used when an MD Anderson investigator wishes to conduct collaborative research with a CN site. The institution may choose to utilize an abbreviated authorization agreement for these arrangements. Examples of Cancer Network sites: Banner Healthcare, Baptist and Cooper University Health Care. For a complete listing, please contact the Cancer Network.
Central IRB (CIRB) Agreement	Central IRB is a single board that reviews research studies for multiple sites. A Central IRB can be any registered IRB that functions to review multiple sites but most commonly the term Central IRB references an independent IRB. Central IRB Agreements are intended to cover broad categories of research (e.g., adult oncology trials or pediatric oncology trials funded by the National Cancer Institute). These agreements are negotiated in consultation with Legal Services.	This agreement is used whenever an investigator wants to participate in a study sponsored by a federal agency (e.g., the National Cancer Institute), a cooperative group or a consortium. MD Anderson maintains the following Central IRB Agreements: • National Cancer Institute Central IRB (NCI CIRB) • National Marrow Donor Program (NMPDP) Centralized IRB review is one review for a number of sites.
Cooperative Agreements	A formal written agreement between MD Anderson and another institution that identify the IRB of record for classes or categories of	Cooperative agreements are typically established between institutions who frequently collaborate on research studies. The agreements specify which

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	research such that a study-specific authorization agreement between the institutions is not required.	IRB will do the review for both institutions, under which circumstances. These agreements **do** specify which IRB will serve as the reviewing IRB. For Cooperative agreements, please contact OHSP.
For Profit IRB Agreements	For Profit IRB Master Agreements can be utilized when multiple studies are ceding review to a specific external IRB. For Profit IRB Agreements may be reciprocal in that signatory institutions can act as the site providing IRB review and oversight or the site relying.	External IRB Agreements may be used for the following: • multi-center industry sponsored studies • when there is an Institutional Conflict of Interest; or • Sponsor requirement • NCI studies managed by CIRB • External Cooperative Groups • NIH-funded studies requesting to utilize single IRB • SMART IRB requests The MD Anderson IRB currently has external IRB agreements in place with the following external IRB's: • Western IRB (WIRB) • Advarra
Individual Investigator Agreements (IIA)	An investigator or collaborator is an individual whose involvement in the research meets the definition of engagement. This is a formal binding agreement signed by individuals who are collaborating on research conducted by an institution, but who themselves are not acting as employees or agents of an institution. Individual Investigator Agreements can also be used by an institution that does not have a FWA and does not regularly conduct human subjects research. The agreement describes the expectations and responsibilities for the individual or institution.	Examples of an individual investigator include: an outside physician asked to administer an investigational agent as part of a protocol treatment plan. For non-MD Anderson investigators, it is important to determine whether the individual is acting as an employee or agent of MD Anderson or some other institution in order to identify the need for an IRB Authorization Agreement, an Individual Investigator Agreement, or neither.
IRB Authorization Agreements (also IRB Reliance Agreements)	IRB Reliance is when an IRB agrees to rely on the IRB review and approval of another IRB.	Agreements can be with other academic institutions or independent for-profit IRBs.

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	This is a formal agreement between two institutions, that each have a FWA. Though often negotiated by IRB offices, it is in fact an agreement between two institutions rather than the IRBs. The agreement: • Specifies that one institution agrees to rely upon the IRB used by the other institution for some or all components of a study and • Defines the responsibilities for the IRB and for each institution IRB Authorization, or reliance, agreements are generally used to cover a designated protocol or protocols.	When an MD Anderson investigator is collaborating with an external site that does have an IRB of record: • but wishes to rely on the MD Anderson IRB to relieve administrative burden and to avoid duplicative efforts; or • the MD Anderson IRB will provide regulatory oversight at the external (relying) site. **The** lead site is one that initiates or manages a research study involving multiple sites that conduct research procedures for the study. The lead investigator is one who oversees the operations of the study at the lead site and is ultimately responsible for coordination, management, reporting, and regulatory requirements between the multiple sites. The study team at the relying is the study team who relies on review by an IRB outside of their institution. It is the responsibility of the Relying Study Team to designate a single Point of Contact who will serve as the communication portal with other Relying Site IRBs and the Lead Site IRB.
IRB Reciprocity Agreements	The agreement allows a single IRB to provide oversight for research based on the institution's role in the research, the funding entity, the patient population or the complexity of the study. Responsibilities of each IRB is outlined in the agreement. These agreements are signed by the Institutional Official.	This agreement may be used whenever it is anticipated that multiple research projects will be conducted in collaboration with investigators at two or more sites. The determination to utilize the Reciprocity Agreement is made on a case by case basis. Additional protections for a specific study may need to be delineated in each application. All sites must have an active FWA. MD Anderson has the following IRB Agreements with independent IRBs: • WIRB • Advarra For IRB agreements with other academic institutions, please contact OHSP.

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Memorandum of Understanding (MOU)	A Memorandum of Understanding is a descriptive written agreement executed when one institution agrees to serve as the IRB of record for another institution. This type of agreement may be used when the proposed research is complex and requires more explicit details regarding the IRB arrangements, or when there will be multiple protocols impacted. The MOU will outline specific provisions and responsibilities for each party entering into the agreement.	A MOU may be used when MD Anderson is collaborating with an external site that does not have an IRB of record and the external site will rely solely on the MD Anderson IRB for review of the human subjects research activity. MOUs are generally used when covering an entire research program. MD Anderson has the following MOU's: • Harris Health System • Memorial Hermann – Texas Medical Center
UT Reciprocity Agreement	Under the agreement, one institution's IRB can serve as the IRB of record (Reviewing IRB), and other institutions can accept the approval of the IRB of record (Relying IRB). The Reviewing IRB is the internal IRB that assumes IRB responsibilities for another institution for a specific study, group of studies, or for all research conducted by the other institution; the Internal IRB exists within the institution engaged in the study.This relationship must be documented in advance by an IRB Authorization Agreement or a Cooperative Agreement. The Relying IRB is an external IRB that is relying on the review by another IRB. The external IRB is outside the institutional framework - it could refer to being external to the immediate institution or to a larger system or framework of coordinating agreements. External IRBs are also called remote IRBs as they are generally geographically removed from the performance site.	It is the institution rather than the IRB that is relying on the external IRB or IRB of Record. Each study will have an Overall PI at one institution, and each other institution involved must be represented by a Local PI. To expedite IRB approval for multi-site trials and studies among members of the Consortium, we have created an IRB reciprocity agreement among the 15 UT System institutions.
SMART IRB Agreements	SMART IRB (the **S**treamlined, **M**ultisite, **A**ccelerated **R**esources for **T**rials IRB Reliance platform) is designed to harmonize and streamline the IRB review process	Utilizing the SMART IRB Agreement: • Reduces hurdles for multisite collaborations • Supports small and large studies, regardless of funding • Helps you obtain trial results faster

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	for multisite studies, while ensuring a high level of protection for research participants. SMART IRB is not an IRB; rather, it's a platform that offers a master IRB reliance agreement (the SMART IRB Agreement) and a web-based system (SMART IRB's Online Reliance System) that provides a central process for participating institutions and their investigators to request, track, and document study-specific reliance arrangements. The SMART IRB Agreement: • Enables reliance on a study-by-study basis • Clearly defines roles and responsibilities • Eliminates the need to sign reliance agreements for each study	

REVISIONS

Date	Action	Initials	Description
6/27/2019	New	LG	Description of agreement types
1/5/2020	Rev	JH	Advarra acquired Quorum, references updated