

What is a Reliance Agreement?

A Reliance Agreement (also called an IRB Authorization Agreement (IAA), Cooperative Agreement, or Memorandum of Understanding (MoU)) is a document signed by two or more institutions engaged in human subject's research that permit one or more institutions to cede review to or rely on another IRB. Reliance agreements cover single studies, categories of studies, or all human subjects research conducted under an organization's Federal-wide Assurance (FWA).

Reliance agreements document the respective authorities, responsibilities, and communication between the organization/institution conducting the regulatory review of human subject research and the institution(s) relying on the reviewing IRB. Even when the Harris Health IRB cedes IRB review to a central/single IRB, submission to the Harris Health IRB for administrative approval is still necessary and is required in order for our IRB to maintain its responsibilities under the reliance agreement. As a relying site, we are approving that our local review is complete and research activities can occur within Harris Health.

For more information, see *The Reliance Procedures* below.

Does Harris Health Utilize Reliance Agreements?

Yes, the Harris Health IRB may agree to rely on an IRB at an affiliate or collaborating institution or an independent IRB (central/single IRB). A reliance agreement avoids duplicate IRB initial review and continued oversight when multiple IRBs have jurisdiction for the same multi-site research protocol.

Current Agreements with Affiliate Institutions

The Harris Health IRB maintains reliance agreements with multiple partner institutions, including:

- Baylor College of Medicine
- MD Anderson Cancer Center
- UTHealth - Houston
- Prairie View A&M
- Texas Woman's University – Houston
- University of Houston Clearlake
- University of Houston
- UTMB - Galveston

Under these agreements, the Affiliate Institution is the IRB of record (i.e., the **reviewing** IRB) responsible for reviewing studies performed at Harris Health. In some cases, if there is a 3rd institution serving as the reviewing IRB, this is allowed, if put in writing. However, the Harris Health IRB (the **relying** IRB) maintains the following responsibilities for local oversight of the performance of studies:

- Ensuring the safe and appropriate performance of the research;
- Overseeing conduct of the research;
- Monitoring protocol compliance; and
- Maintaining compliance with state, local, and institutional requirements.

You will need to register these studies with the Harris Health IRB through an administrative review application via **eProtocol**.

The study may not be initiated at Harris Health until **institutional administrative approval** is granted by the Harris Health IRB and an approval letter is issued in eProtocol. When the Reviewing IRB reviews revisions, continuations, unanticipated problems, study closure, etc. for the study under the agreement, these outcome letters and supporting document approvals should be submitted to the Harris Health IRB via eProtocol, in a timely manner. The Harris Health IRB will review and approve the submission via eProtocol.

My external IRB Application receives a “Notice of Approval for Human Research” from Harris Health. What does this mean?

As a relying site, we approve that our local review is complete and research can begin at Harris Health. This means that the Harris Health IRB approves the research activities to occur within Harris Health. As part of the review, the Harris Health IRB will obtain Harris Health institutional administrative approval and any Harris Health ancillary approvals as necessary.

The external (reviewing) IRB approved a revised protocol, other modifications or updates. Do I need to submit these to Harris Health IRB?

When relying on an external IRB, it is important to recognize that the Harris Health IRB and the institution still retain important responsibility for oversight and ongoing local conduct. You should submit modifications that results in changes that affect Harris Health, such as:

- Changes to research team
- Changes to funding
- Any changes to consent form
- Changes to the overall protocol that impact/affect Harris Health
- Changes to documents related to use of drug and/or device (e.g. investigator drug brochure, drug dispensation, dosing or the targeted population, instructions for use), if utilized within Harris Health
- Changes to material to be used with Harris Health population (questionnaires, interview questions, recruitment)
- Change to local recruitment plan
- Change in Harris Health site (e.g. adding a pavilion)

along with the IRB of record review and approval, to the Harris Health IRB for institutional review. Failure to provide copies of revisions to the protocol, other modifications or updates may result in the Harris Health termination of the study, meaning no research-related activity may be done within Harris Health facility.

Does Harris Health IRB stamp documents from the external IRB?

Yes, the Harris Health IRB will stamp local site-specific recruitment flyers/posters that will be displayed within Harris Health facilities. The practice of stamping informed consent documents is no longer done.

What are my obligations when an external IRB is responsible for reviewing my research study?

The responsibilities of the research team remain largely the same, and include:

- Obtaining initial approval from the Reviewing IRB
- Submitting and obtaining approval for an Administrative Review in eProtocol, which is used to track reliance relationships with external IRBs and obtain institutional approval.
- Complying with the Reviewing IRBs policies (e.g., reporting noncompliance, unanticipated problems, etc.)
- Complying with the determination of the Reviewing IRB
- Using the most current IRB-approved documents, including the protocol, consent forms, recruitment documents
- Complying with applicable policies from Harris Health
- Provide Harris Health any determinations made by the Reviewing IRB that affect Harris Health within a reasonable timeframe following the Reviewing IRB's determination. Excessive delays without adequate justification will be considered non-compliance with local requirements. Applicable types of submissions include:
 - Modifications that result in changes that affect Harris Health.
 - Continuing review approval and consent, if applicable.
 - IRB closure
 - Suspension or termination of IRB approval
 - Determinations of serious or continuing noncompliance
 - Determination of unanticipated problems.