

## **IRB Authorization Agreement (IAA) Information & Procedures**

### **What is an IRB Authorization Agreement?**

It is a written document that provides a mechanism for an institution engaged in research to delegate institutional review board (IRB) review to another IRB.

IAAs avoid duplicate IRB regulatory review for the life of the study when multiple IRBs have jurisdiction for the same multi-site research protocol. However, the relying IRBs must still conduct administrative institutional reviews of the study and therefore must receive a registration application from the Principal Investigator and must receive the reviewing IRB's determinations about the study for the life of the study.

*For Glossary and FAQs, please see the end of this document.*

### **When is an IRB Authorization Agreement used?**

These agreements are used when:

Faculty, staff, students, residents, or fellows from an FWA-holding institution that is not affiliated with UTHSC wish to conduct research *in conjunction with* UT faculty, staff, students, residents, or fellows; or with employees of any of our affiliate institutions.

There are times, however, when an agreement is not necessary, but this can be a complicated issue. Therefore, please contact the IRB at 901-448-4824 to discuss.

Our affiliates are Regional One Health, Methodist Healthcare Hospitals, and Le Bonheur Children's Hospital, and we serve as the IRB for all of these institutions.

**Note:** The UTHSC IRB maintains IRB Authorization agreements with St. Jude Children's Research Hospital, University of Memphis, Department of Defense, National Cancer Institute Central IRB, National Institutes of Health, and others. For more information about these agreements, call the IRB or consult the IRB webpage on Reliance Agreements at <http://www.uthsc.edu/research/compliance/irb/researchers/reliance-agreements.php>.

**At current time, the UTHSC IRB cannot serve as the IRB of record (i.e., the reviewing IRB) for a multicenter study where all the sites are not local. Please contact the IRB with any questions.**

**If the UTHSC IRB will NOT be the IRB of record (we will rely on another IRB for the review of the study):**

1. FIRST, contact the IRB at 901-448-4824 in order to determine whether your study meets the criteria for the use of an IAA and whether UTHSC IRB will approve ceding review to a specific IRB for a specific study.

Once you have UTHSC IRB's agreement to act as the relying IRB for a specific study, you may complete the following steps.

2. Remember that in addition to obtaining a reliance agreement (which this document discusses), you must ALSO fulfill requirements to obtain institutional approval (i.e., permission to conduct human subjects research at a site) at all non-UTHSC institutions at which you will conduct your research study. The IRB will ask for the letter of permission/institutional approval from each non-UTHSC institution at which you will conduct your study.

Contact information and/or institutional requirements for UTHSC affiliate sites are posted on UTHSC's [IRB Affiliates webpage](#). For any other sites, contact their administration directly to find out how to obtain a letter of institutional approval.

Seeking to fulfill these requirements in the beginning of the process may help to inform your study design.

3. Note that BEFORE the reviewing IRB's initial review of the study, UTHSC's [informed consent boilerplate language](#) as well as applicable local laws and policies should be incorporated into the initial submission and consent form, and/or provided to the reviewing IRB. Doing so should significantly expedite the process and avoid the need for a post-IRB approval amendment/revision to incorporate UTHSC's required language and local context information.
4. If the other institution is a [SMART IRB Participating Institution](#), download a copy of the [SMART IRB Letter of Acknowledgment](#) from the [SMART IRB website](#). Complete it as follows:

- The other institution would be the **Reviewing IRB Institution**.
- UTHSC would be the **Relying Institution** that has agreed to cede IRB review to the reviewing institution's IRB.
- Enter the **Study Title, Overall PI** (i.e., PI at the Reviewing Institution), and **Relying Site Investigator** (i.e., UTHSC PI) in the appropriate fields.
- Enter the **Point of Contact Name, Email and Telephone** for the main IRB Reliance Agreement contact at the Reviewing IRB (that institution's IRB or study team will probably need to assist you with this).

If the other institution is NOT a [SMART IRB Participating Institution](#), download a copy of the IAA template from the UTHSC IRB website. UTHSC is also amenable to utilizing the Reviewing IRB's IAA template, as they may have their own. Complete it as follows:

- UTHSC would be the **Relying Institution**, and our FWA # is 00002301.
  - The **Reviewing Institution** is the other institution where the majority of the research is going to occur and where the IRB review will occur.
  - Check and complete the 2<sup>nd</sup> option: “This agreement is limited to the following specific protocol(s)...”
  - Obtain the **Reviewing Institution’s** Signature of Signatory Official or Designee (that institution’s IRB will probably need to assist you with this).
5. Begin a new study application in iMedRIS (the UTHSC IRB electronic research application system), and in Section (418) select: *I am submitting my research in accord with an IRB Authorization Agreement*. At the end of your application, be sure to attach the appropriate study documents, e.g., the initial approval letter from the primary IRB, the most recent continuing review approval letter (if applicable), the IRB-approved protocol/application, the IRB-stamped-approved consent form(s), any IRB-approved surveys, etc. You will also need to attach the agreement IRB Authorization Agreement signed by the **Reviewing IRB**, and the UTHSC IRB will ensure that the Signatory Official or Designee for UTHSC signs the agreement.
  6. Upon receipt of your study application and attached documents, the UTHSC IRB will complete an administrative review, and an outcome letter will be issued via iMedRIS.
  7. If you have already submitted the study application in iMedRIS by the time that the IAA is signed by UTHSC, the IRB will attach a copy of the signed IAA to your study application for you.

## **Glossary**

**FWA** - The **Federalwide Assurance (FWA)** is the only type of **assurance** currently accepted and approved by OHRP. Through the **FWA**, an institution commits to HHS that it will comply with the requirements in the HHS Protection of Human Subjects regulations at 45 CFR part 46. More information can be found on the UTHSC IRB [Federalwide Assurance \(FWA\) & Registration webpage](#).

**Authorization Agreement** - a written agreement between two or more institutions that is used to document the delegation of IRB review responsibilities (regulatory and administrative institutional review). This agreement may also be referred to as a reliance agreement, cooperative agreement, or cede-review agreement.

**Cede review** - the act of transferring IRB regulatory review and oversight.

**Reviewing IRB** - the IRB of record performing regulatory review on behalf of one or more institutions, also referred to as the single IRB and/or central IRB.

**Relying Institution** - the entity that agrees to rely upon the reviewing IRB.

**SMART IRB** – SMART IRB is a platform designed to ease common challenges associated with initiating multisite research and was created to provide a roadmap for institutions to implement the NIH Single IRB Review policy (effective date: January 25, 2018). Freely available for institutions and investigators, SMART IRB is an integrated, comprehensive platform that allows flexibility in the size and scope of collaboration to enable IRB reliance for multisite studies across the nation, regardless of funding status.

### **Frequently Asked Questions**

*What is the main difference between an Individual Investigator Agreement (IIA) and an IRB Authorization Agreement (IAA)?*

IIAs are used for engaged study collaborators who are either i) not affiliated with any institution or ii) affiliated with an institution that does not possess an IRB or FWA (e.g., a private practice, Walgreens, a church, etc.). IAAs, on the other hand, are used for engaged study collaborators whose institutions do possess an FWA (i.e., they have or routinely use an IRB with an FWA).

*Why do I have to submit everything approved and/or reviewed by the reviewing IRB to the UTHSC IRB, which sometimes recommends changes? Haven't we ceded review to the other IRB?*

While another institution is the IRB of record for this study, the UTHSC IRB retains the responsibility to ensure that the performance of the study at this site complies with determinations and the terms of the UTHSC Federalwide Assurance. Further, UTHSC has responsibilities under the reliance agreement that have to be fulfilled throughout the life of the study.

*As the UTHSC PI, do I still have responsibilities when UTHSC is relying on another IRB?*

- Yes, you must provide to the UTHSC IRB, an initial registration form (via the *Form 1: Study/Project Application*) in iMedRIS with all of the documents that have been reviewed and approved by the reviewing IRB.

You must also submit via a *Documents from Reviewing IRB* form in iMedRIS, copies of any documents and the reviewing IRB's determination letters on any future actions that it takes with respect to this study (such as review of revisions, continuations, unanticipated problems, protocol

deviations, any suspension of subject enrollment or of the study itself, etc.).

*How can I streamline the process and reduce the number of recommendations the UTHSC IRB and/or other relying institution IRBs provide post-IRB approval?*

- Communication is KEY! The generation of new applications and amendments should be a collaborative process involving study teams at all engaged sites.
- Be aware that each institution tends to have unique local requirements that not only continually need to be met throughout the life of the study but are also subject to change.
- A lack of collaboration has typically led to unnecessary multiple amendments being submitted to the IRB of record.
  - In these cases, UTHSC's required consent form language was either not initially incorporated or was incorrectly modified due to a communication breakdown between study teams at both sites.

*I would like to administer a survey at another institution, but I will not be doing it in conjunction with anyone there. Do I need a reliance agreement?*

- If you will not collaborate with any faculty, staff, students, residents, or fellows from the institution at which the survey will be administered, a reliance agreement will not be needed. However, you must obtain written permission from the appropriate official(s) at that institution in order to conduct your research there. Documentation of the site's permission must be submitted to the UTHSC IRB before any activities may commence. You will want to verify this by contacting the IRB.

*I would like to add a site to my research study that was approved by the UTHSC IRB. The site will be sending us **de-identified** data collected from chart reviews. Do I need to do anything?*

- Although sharing of de-identified data may not trigger the human subjects research definition, a Form 2 still needs to be submitted in order to add the site to your study since the overall study meets the definition of human subjects research.
- When you submit the *Form 2: Change Request and Amendments*, enter the site information in section (1200) of your application and also upload a spreadsheet containing all data points that will be sent to you.
  - **Note:** If the data points you will receive are an exact match to what has already been approved (e.g., other sites are already sending you the same data points), you can state this in the *Form 2* in lieu of providing the spreadsheet.
- The investigators at the other site must contact the appropriate officials at their institution in order to set up the data transfer. This may require IRB review and/or the execution of a Data Use Agreement (DUA). The institution providing the data to UTHSC will draft the

DUA. Incoming and outgoing DUAs are processed by the UTHSC [Office of Sponsored Programs](#); please contact them for the appropriate steps to take or additional guidance.

*What is the difference between a reliance agreement and a data use agreement (DUA)? Do I need to have both?*

- In a nutshell, reliance agreements cover investigators while data use agreements cover the physical or electronic transfer of data between unaffiliated institutions.

Below are a few examples:

- *You can have a reliance agreement without a DUA:*
  - Investigators at two or more institutions are engaged in the same human subjects research study, but all data is collected and stored at the investigators' respective institutions. Investigators only access the data at the other sites through that site's VPN but no data physically or electronically leaves the site at which it's stored (meaning no data is downloaded or recorded at the external site).
- *You can have a DUA without a reliance agreement:*
  - Investigators at UTHSC will receive a Limited Data Set (LDS), which does not contain any of the 16 direct HIPAA identifiers, and UTHSC's IRB grants a Not Human Subjects Research (NHSR) determination indicating that IRB oversight is not required. However, the site providing the LDS to UTHSC may still require a DUA to cover the physical or electronic transfer of the data.
- *You can have both a reliance agreement and a DUA:*
  - Investigators at UTHSC will provide a data set containing HIPAA identifiers to their study collaborators at another institution. Before providing the identifiable data set to their collaborators, the UTHSC study team works with the UTHSC Office of Sponsored Programs to execute a DUA with the other institution. At the same time, because both institutions are engaged in the conduct of the same human subjects research protocol, a reliance agreement is established between the two institutions such that both study teams report to a single IRB (i.e., the IRB of record).