Table of Contents

Overview ...................................................................................................................................................... 2

Purpose ......................................................................................................................................................... 2

When to use an IRB Authorization Agreement ......................................................................................... 2

SMART IRB ............................................................................................................................................. 2

Drexel as the Relying IRB .......................................................................................................................... 3

 Investigator Guidance ............................................................................................................................... 3

 Drexel IRB Review of Institutional Requirements .................................................................................. 3

 Investigator Responsibilities – Relying Study Team ............................................................................. 4

Drexel as the Reviewing IRB ....................................................................................................................... 5

 Investigator Guidance ............................................................................................................................... 5

 If you are creating a new protocol that will include external sites ............................................................ 5

 If Drexel IRB has already approved the protocol, and you would like to add on a site ......................... 5

Drexel IRB Review .................................................................................................................................... 5

Multi-Site Studies ..................................................................................................................................... 6

 NIH Single IRB Policy ............................................................................................................................... 6

 Funding for Single IRB Review ................................................................................................................ 6

 Investigator Responsibilities – Lead Study Team ................................................................................... 7
Overview

Purpose
The Office for Human Research Protections (OHRP) allows the Institutional Review Board (IRB) of one institution to act on behalf another institution’s IRB via an IRB Authorization Agreement. The DU IRB refers to this IRB Authorization Agreement as a “Letter of Reliance”. These agreements may be study-specific, or institutions may have master agreements in place. Reliance agreements document respective roles, responsibilities, and communication between the institution that is providing the ethical review of human subjects, and the institution that is relying on their review. The intent of the agreement is to help minimize or reduce the burdens of review and redundancy in workload when two or more institutions will act together on the same protocol.

When to use an IRB Authorization Agreement
When a DU investigator seeks to work collaboratively with another institution, we ask that the following procedures be taken into consideration. Please note that the Letter of Reliance can only be executed with an institution:

1. which holds a valid Federal Wide Assurance number (FWA) that is not expired
2. whose review was approved at an Expedited or Full Review Level.

If the research project was Exempt from the requirement of an IRB review and approval, the authorization agreement is not required. However, application documents must be submitted to the Drexel University IRB for review. Please ensure that you use Drexel’s “TEMPLATE: Protocol (HRP-504).” Drexel IRB will not accept another institution’s protocol when applying for exempt review.

SMART IRB
The Streamlined, Multisite, Accelerated Resources for Trials (SMART) IRB Reliance Platform was developed to assist institutions in implementing the NIH Single IRB Policy (see page 6, “Multi-Site Studies”). SMART IRB developed a Master Common Reciprocal IRB Authorization Agreement, which many institutions are participating in, including Drexel University. Institutions that have signed onto this master agreement are able to use it as a means of reliance, meaning that IRB Authorization Agreements would not need to be executed on a study-by-study basis.

Drexel IRB will use the SMART IRB Master Common Reciprocal IRB Authorization Agreement as a means of reliance with other SMART IRB participating institutions.

If the reliance request involves an institution that is not signed onto the master agreement, Drexel IRB will need to execute an individual IRB Authorization Agreement with the other institution(s).
Drexel as the Relying IRB

Investigator Guidance

Ensure that the proposed reviewing IRB is AAHRPP Accredited, or holds a similar accreditation for the protection of human subjects. Check here to see if the institution is AAHRPP Accredited: http://www.aahrpp.org/learn/find-an-accredited-organization. Review page 4 for a full description of investigator responsibilities when relying on an external IRB.

If the request is for a grant application that requires a Letter of Support from Drexel IRB stating that we agree to cede review, fill out the “FORM: Request for Drexel to Cede Review (HRP-204).” Send the completed form and any available study documents via email to the IRB Coordinator.

For protocols that are ready for IRB, create a COEUS submission and specify the Type as “Letter of Reliance.” Submit the following to COEUS:

- “FORM: Request for Drexel to Cede Review (HRP-204)”
- The external IRB’s approval letter with the most recent approval date
- The external institution’s approved study documents:
  - Protocol
  - Consent (if applicable)
  - Advertisements/Recruitment materials/Flyers (if Drexel investigators will be recruiting subjects)
  - Questionnaire(s)/Survey(s) (if Drexel investigators will be conducting)
- Note: The protocol and consent forms should list Drexel University as a participating institution. In order for your reliance request to be approved, this will be required.
- The external IRB approval document for the modification which adds Drexel personnel

Drexel IRB Review of Institutional Requirements

As a Fully Accredited AAHRPP organization, Drexel IRB advises that institutions serving as the reviewing IRB for our studies will uphold the same or similar standards for human research protection.

- The IRB will review the COEUS application to determine
  - If we agree to cede review
  - The application is complete
  - The consent form includes the Drexel required language (please see HRP-508), as applicable
  - All applicable institutional policies and state and local requirements have been adequately addressed
  - If a conflict of interest management plan is required
  - Whether Drexel data is to be transferred outside of Drexel servers
    - If data is transferred outside of the university, a Data Use Agreement may be needed. Please consult with the Corporate Compliance and Privacy Office if you think you may need a Data Use Agreement.

If there are any issues with the application, the IRB will notify you via email. After the issues have been addressed, the IRB will sign the IRB Authorization Agreement. Once the IRB Authorization Agreement is signed by institutional officials at both institutions, Drexel IRB will request the modified protocol,
**Investigator Responsibilities – Relying Study Team**

When relying on an external IRB, it is important for investigators to recognize that the Drexel IRB still retains important responsibilities for the oversight of the study. An external IRB is responsible for reviewing the study materials to determine if the study as proposed meets the criteria for approval under the federal human subjects protections regulations. The relying institution (in this case Drexel University) retains responsibility for ensuring all local ancillary reviews required to conduct the research at this site are completed and for ensuring that any local requirements are communicated to the reviewing IRB. In order to facilitate this, each PI, seeking to rely on an external IRB, is responsible for the following:

- Complete the “FORM: Request for Drexel to Cede Review (HRP-204).”
- Provide an application to the Drexel IRB which contains the submission materials initially approved by the external IRB, including the approved template consent.
- Engage any research support offices at Drexel with oversight responsibility for the research and provide any additional materials needed to those entities in order to receive approval (e.g., Pre-Award, Biosafety Committee, Radiation Safety, Conflict of Interest Committee).
- Monitor and maintain training records to assure that the Drexel study team is in compliance with the institutional training requirements.
- Incorporate Drexel’s required language into the consent template to be used by the Drexel study team (as applicable).
- Once approved as a site by the external IRB provide the initial approval letter to Drexel IRB.
- Maintain an active record of all submissions to the IRB of record.
- Submit any modifications to Drexel IRB that require local review. Examples include:
  a) Personnel/PI changes
  b) Changes in conflicts of interest
  c) Changes to plans for research radiation exposure (including a change to the number of subjects exposed or the inclusion of a new population, e.g. minors)
- Provide the annual re-approval letter to Drexel IRB prior to expiration of the protocol.
- Become familiar with the reportable event policy of the reviewing IRB to ensure that you appropriately report protocol deviations, noncompliance, significant subject complaints, subject injuries, unanticipated problems, or other events required by the reviewing IRB to be reported and within the timeframes required.
- Promptly report to Drexel IRB any notifications of suspension or termination that you receive for the applicable study from the reviewing IRB.
- Provide, upon request, access to study records for audit by the local institution, the reviewing IRB’s institution, and other regulatory or monitoring entities.
- Ensure that study activities will not begin until all ancillary reviews have been completed.
Drexel as the Reviewing IRB

Investigator Guidance

Requests will be assessed on a study-by-study basis to determine if Drexel IRB has the resources necessary to serve as the reviewing IRB. Please review the Investigator Responsibilities checklist on page 7.

If the request is for a grant application that requires a Letter of Support from Drexel IRB stating that we agree to serve as the reviewing IRB, fill out the “FORM: Request for Drexel as the Single IRB (HRP-205).” Send the completed form as well as any available study documents via email to the IRB Coordinator.

For protocols that are ready for IRB review, and Drexel IRB has agreed to serve as the IRB of Record, see below:

If you are creating a new protocol that will include external sites

- Create a new standard submission in COEUS
- The Drexel IRB will provide initial approval prior to starting the reliance process
- When Drexel IRB provides initial approval, the Drexel study team will send to the external sites:
  a. The approved study documents
  b. “FORM: Local Context Survey (HRP-206)”
- When the sites agree that they would like to cede review to Drexel IRB, create an amendment to add on the sites. See below.

If Drexel IRB has already approved the protocol, and you would like to add on a site

- Create an amendment in COEUS with
  a. “FORM: Request for Drexel as the Single IRB (HRP-205)”
  b. Tracked and clean versions of the protocol to document the location of the new site
  c. A site-specific consent form with the site’s required language (if applicable)
  d. Completed “FORM: Local Context Survey (HRP-206)” signed by a representative of the external IRB.

Drexel IRB Review

- The IRB will review to ensure the application is complete
- The “FORM: Local Context Survey (HRP-206)” allows the Drexel IRB to gather regulatory information and individual institutional requirements from each site, such as
  o Enrollment information
  o Data management plans
  o Whether ancillary reviews are required at the external site(s)
  o Whether there are state laws that should be taken into consideration regarding the review
  o Whether the IRB representative from the external site(s) has reviewed the study personnel’s institutional required training and certifications
  o Whether Conflicts of Interest exist at the external site(s) regarding the study in question and their applicable management plans
- The IRB will assess whether data is to be transferred outside of Drexel servers

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If data is transferred outside of the university, a Data Use Agreement may be needed. Please consult with the Corporate Compliance and Privacy Office if you think you may need a Data Use Agreement.

If there are any issues with the application, the IRB will notify you via email. After the issues have been addressed, the IRB will sign the IRB Authorization Agreement. Once the IRB Authorization Agreement is signed by Drexel’s institutional official, as well as the external institutional official, the IRB will send the Drexel PI the IRB Authorization Agreement and an amendment approval letter adding the external site.

**Multi-Site Studies**

*NIH Single IRB Policy*

The National Institutes of Health issued a policy requiring single IRB review for new and re-competing grant applications for multi-site research, effective January 25, 2018. The purpose of the policy is to streamline the process for multi-site research, requiring that a single IRB conducts the review for each participating site. The policy applies to NIH-funded domestic, clinical, multi-site studies involving non-exempt human subjects research. Applicants planning to conduct multi-site research are expected to include a plan for the use of a single IRB in the application to the NIH.

Investigators should reach out to Pre-Award Administration and Drexel IRB as early as possible in the protocol planning stages. Protocols will be reviewed on a study-by-study basis to determine if Drexel IRB has the resources to serve as the reviewing IRB. Please consult with Drexel IRB in order to identify an appropriate reviewing IRB. Investigators should not indicate on a grant application that Drexel is willing to serve as the IRB of Record without first securing a letter of support from Drexel IRB.

The Lead Study Team will essentially serve as the study coordinators for all participating sites, and will be responsible for most communication between IRBs and Relying Site Study Teams. A descriptive list of responsibilities is included on the next page.

*Funding for Single IRB Review*

Many IRBs charge for single IRB review, and you will want to ensure that the approved budget includes those associated costs.
Investigator Responsibilities – Lead Study Team

As the Overall Principal Investigator for a study for which research activities involving human subjects will be overseen by a single IRB for all or most sites, you should be aware of your additional responsibilities in assuming that role. Once you have agreed to collaborate with investigators at another institution(s) and intend to use a single IRB for oversight of this study:

- Complete the “FORM: Request for Drexel as the Single IRB (HRP-205).”
- Work in collaboration with Drexel IRB to determine and document specific roles and responsibilities for communicating and coordinating key information to relying institutions (i.e. regular conference calls, site initiation procedures, and training materials)
- Provide site investigators with the Drexel IRB policies, including policies for reporting unanticipated problems, noncompliance, subject complaints
- Provide site investigators with IRB approved versions of all study documents (e.g., consent and authorization forms, protocol, recruitment materials)
- Prepare and submit IRB applications on behalf of all sites, including initial reviews, local amendments, personnel updates, local reportable events, and study-wide information for continuing review
- Distribute and collect “FORM: Local Context Survey (HRP-206)” for each relying site
- Assist relying site study teams in ensuring consent documents follow Drexel IRB’s template form and includes applicable site-specific required language
- Notify site investigators of all Drexel IRB determinations and communications, including initial review, continuing review, amendments, and reportable events
- When agreed upon in coordination with Drexel IRB, promptly report to site investigators any unanticipated problems involving risks to subjects, research-related injuries, significant subject complaints that are related to or may affect subjects participating in the research at the relying institution
- Reference the “FORM: Continuing Review (HRP-202)” to gather information from each relying site study team and submit to Drexel IRB as one, singular continuing review application
- If a relying site study team does not provide the lead study team with the required information before the continuing review application is submitted to the Drexel IRB, the lead study team reports the absence of this information as part of the continuing review and notifies the affected relying site study team of lapse in approval for their site and any applicable corrective action plans
- Provide access, upon request, to study records for audit by the relying institution, Drexel IRB, and other regulatory or monitoring entities
- Follow all requirements of the relying institution with regard to ceded review, ensure requirements have been met before study activation occurs at a relying institution