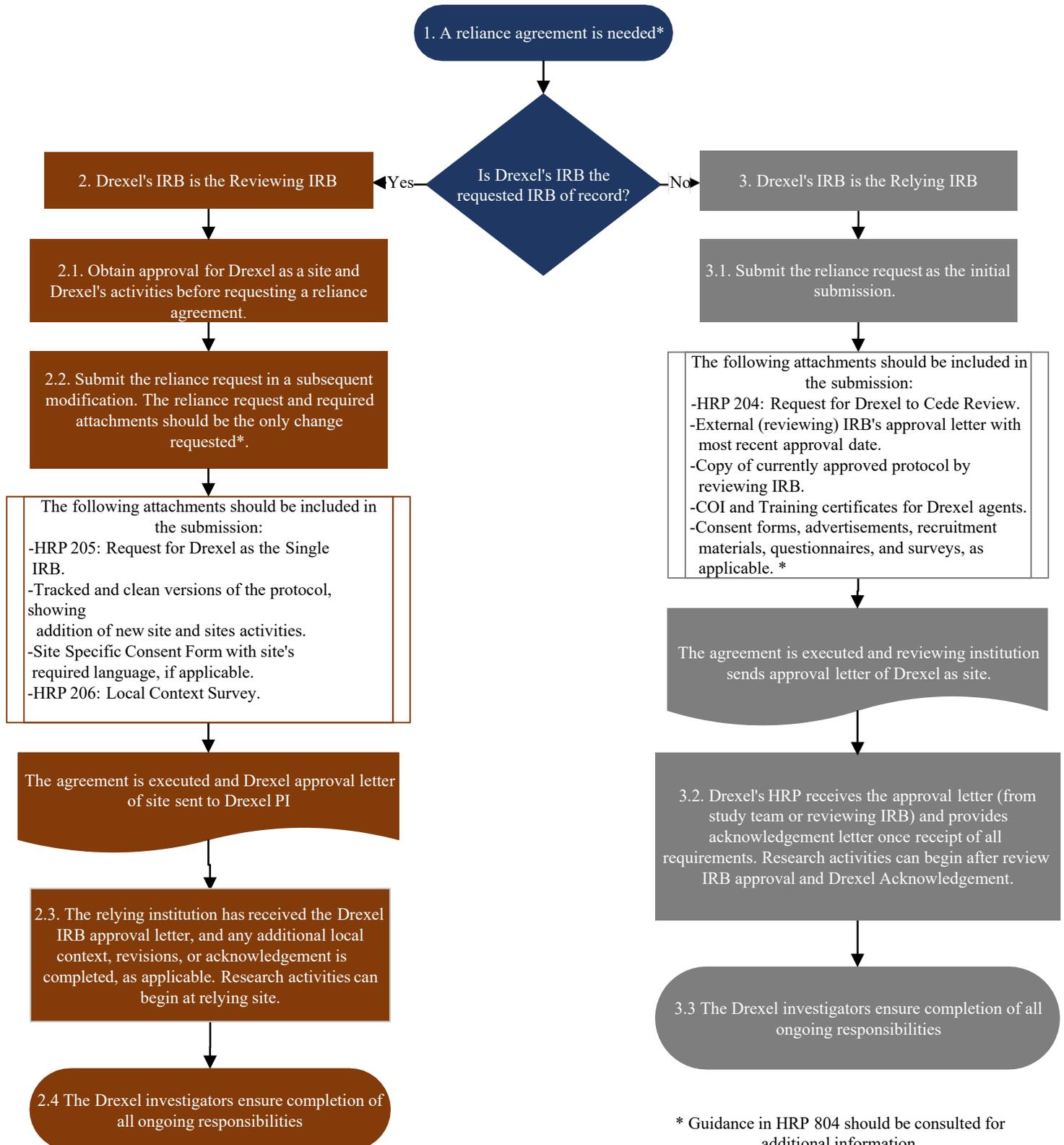




Investigator Guidance, Procedures for Review and Process Map: Reliance Agreements

Document No.:	Edition No.:	Effective Date:	Page:
HRP-804	003	November 1, 2021	Page 1 of 11

This guidance, procedures and process map are to be used by Drexel University Researchers when submitting a reliance agreement to the Drexel HRP Office, and by Drexel HRP Staff, and IRB members when reviewing reliance agreement submissions. The numbered sections of the flowchart are hyperlinked to below sections of the full HRP 804 guidance and procedures text.





Investigator Guidance, Procedures for Review and Process Map: Reliance Agreements			
Document No.:	Edition No.:	Effective Date:	Page:
HRP-804	003	November 1, 2021	Page 2 of 11

Document No.:	Edition No.:	Effective Date:	Page:
HRP-804	003	November 1, 2021	Page 2 of 11

Table of Contents

1. Overview	3
Purpose	3
When to use an IRB Authorization Agreement.....	3
SMART IRB.....	3
NIH Single IRB (sIRB) for Multi-Site Research	3
Letter of Support.....	4
2. Drexel as the Reviewing IRB.....	4
2.1 Review and Approval of Drexel Activities and Agents	5
Prior to requesting a reliance agreement for Drexel to be the IRB of record of another FWA holding institution, Drexel’s sites and activities should be approved first. This both confirms the level of review, consent language and allows the Drexel team to begin research activities while effectively onboarding additional sites after the initial submission. To create a new protocol that will include external sites;.....	5
2.2 Review and Approval of Relying Sites.....	5
Drexel IRB Review.....	6
2.3 Execution of Agreement and External Institutional Requirements.....	6
2.4 Investigator Responsibilities and Post-Approval requirements – Reviewing IRB Study Team	6
3. Drexel’s IRB as the Relying IRB.....	8
3.1 Submitting a Request for Drexel to Cede review.....	8
Drexel IRB Review of Institutional Requirements.....	9
3.2 Execution of Agreement and Relying IRB Institutional Requirements.....	9
3.3 Investigator Responsibilities and Post-Approval Requirements – Relying IRB Study Team ...	9



Investigator Guidance, Procedures for Review and Process Map: Reliance Agreements

Document No.:	Edition No.:	Effective Date:	Page:
HRP-804	003	November 1, 2021	Page 3 of 11

1. Overview

Purpose

When engaged in multi-site research, which may also be known as collaborative research, research involving external collaborators, or research that is otherwise under the jurisdiction of more than one IRB, Drexel University acknowledges that each organization is responsible for safeguarding the rights and welfare of human subjects and for complying with applicable federal regulations. Drexel University's HRP-IRB may choose to review the research in its entirety, only those components of the research Drexel University is engaged in, rely on the review of another qualified IRB, or make other arrangements for avoiding duplication of effort. When Drexel University is the prime awardee on an HHS grant, it will ensure that at least one IRB reviews the research in its entirety.

When relying upon another IRB or when serving as the reviewing IRB for an outside organization or external investigator, a formal relationship must be established between Drexel University and the outside organization or investigator through an IRB Authorization Agreement, Master Service Agreement, or other such written agreement. The written agreement must be executed before Drexel University will acknowledge or provide final approval for any human research proposals from the outside organization or investigator or rely on the review of an external IRB. These agreements may be study-specific, or institutions may have master agreements in place. Reliance agreements establish the authorities, respective roles, responsibilities, and communication of the reviewing IRB and the relying organization. The procedures for reliance, including for communication, information-sharing, and reports, may be outlined in the reliance agreement, in SOP's or other written materials. 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. Drexel University HRP staff will assess study specific details to determine what type of agreement is needed and communicate with the investigator if there are any additional requirements. To support compliance, Drexel University will make every effort to ensure as much consistency as possible across reliance agreements.

When to use an IRB Authorization Agreement

When a DU investigator seeks to work collaboratively with another institution and Drexel agents are either engaged in human subject research or Drexel University is the prime awardee of DHHS funds a reliance agreement may be appropriate, we ask that the following procedures in section 2 and 3 of this guidance 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, Full Review Level or otherwise require IRB review per the regulations.

If the research project was Exempt from the requirement of an IRB review and approval, the authorization agreement is likely not required and instead submitted to the Drexel University IRB for an exempt determination. Please ensure that you use Drexel's "TEMPLATE: Protocol (HRP-504)" for exempt determinations as Drexel IRB will not accept another institution's protocol.

SMART IRB

Drexel University has signed the SMART IRB joinder agreement. When the organizations participating in the research are signatories to the joinder agreement, IRB reliance may be requested and documented utilizing the SMART IRB online reliance platform. In collaboration with the other participating organizations, Drexel University will determine on a study-by-study basis whether the SMART IRB SOPs or alternative procedures will be utilized to implement the reliance.

Whenever possible, the Drexel HRP prefers that the SMART IRB agreement is utilized to ensure consistent terms and responsibilities, and increased efficiencies.

NIH Single IRB (sIRB) for Multi-Site Research

In June 2016, the National Institutes of Health (NIH) released a final policy requiring domestic awardees and domestic sites of NIH-funded multi-site research to use a single IRB (sIRB) for review of non-exempt human subject research unless there is justification for an exception. This policy is intended to streamline the IRB review process and reduce



Investigator Guidance, Procedures for Review and Process Map: Reliance Agreements

Document No.:	Edition No.:	Effective Date:	Page:
HRP-804	003	November 1, 2021	Page 4 of 11

inefficiencies and redundancies while maintaining and enhancing subject protections. The policy does not apply to career development, research training, or fellowship awards, nor to sites that are not conducting the same protocol as the other sites (e.g., sites providing statistical support or laboratory analysis only) or to foreign sites.

Exceptions to the policy are automatic when local IRB review is required by federal, tribal, or state law/regulation/policy and when the proposed research is the “child” of a grant that predates the requirement for sIRB review. Such exceptions and the basis (and information regarding the “parent” study, when applicable) should be cited in the proposed sIRB plan and, when the exception is based on law/regulation/policy, apply only to the site(s) to which the law/regulation/policy applies. Other exceptions will be considered when there is compelling justification. The site(s) and justification for why the site(s) cannot rely on the single IRB of record should be included in the proposed sIRB plan. The NIH will consider the exception request and inform the applicant of the outcome.

Investigators submitting applications for NIH-funded multi-site research must describe the sIRB plan in the funding proposal (grant application or contract proposal), and, if applicable, may request direct cost funding to cover additional costs related to the requirements of the NIH policy. The sIRB can be the IRB at one of the participating sites or an independent, fee-based IRB. When the sIRB is named in the proposal, the IRB must have agreed to take on this responsibility in advance. Requests for the Drexel University’s IRB to serve as the sIRB should be directed to the Drexel HRP Office and follow the procedures outlined in section 2 of this document and dependent upon resources and expertise. Requests for Drexel IRB to rely upon an external IRB as the sIRB should be submitted as early in the process as possible by following steps outlined in section 3 of this guidance.

Investigators should reach out to Pre-Award Administration and Drexel IRB as early as possible in the protocol planning stages. Please note that the Pre-Awards and Contracts offices will need to assist in establishing which institution will be responsible for meeting additional certification and requirements such as Certificates of Confidentiality or NIH Genomic Data Sharing Policy. 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. Many IRBs charge for single IRB review, and you will want to ensure that the approved budget includes those associated costs.

Letter of Support

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.

2. Drexel as the Reviewing IRB

Generally, Drexel University’s IRB does not serve as the IRB of record for an external organization unless Drexel University is also engaged in the research. The Drexel HRP Office will assess requests on a study-by-study basis to determine if Drexel IRB has the resources necessary to serve as the reviewing IRB and evaluate the following factors when considering a request for Drexel University IRB to serve as the IRB of record for a particular study or studies;

1. The terms of the external organization’s FWA;
2. Prior experience with the organization and investigators;
3. The accreditation status of the external organization’s HRPP;
4. The compliance history of the organization and investigators (e.g., outcomes of prior audits or inspections, corrective actions);
5. The research activities conducted by or at the external organization;
6. The willingness of the external organization to accept Drexel University’s reliance terms and procedures;
7. The ability of the organizations to collaboratively provide meaningful oversight of the proposed research, taking into account factors such as:
 - a. The risks and procedures of the research;
 - b. The resources available at each organization and ability to accommodate or collaborate with each other in observing the consent process, performing compliance reviews, investigations of potential noncompliance, and similar matters;



Investigator Guidance, Procedures for Review and Process Map: Reliance Agreements

Document No.:	Edition No.:	Effective Date:	Page:
HRP-804	003	November 1, 2021	Page 5 of 11

- c. The expertise and experience of the Drexel University IRB with the proposed research, subject population, and applicable regulations;
- d. The familiarity of the Drexel University IRB with the relevant local context considerations of the external organization; and/or
- e. The willingness or ability of the external organization to provide information and respond to questions regarding investigator qualifications, conflicts of interest, organizational requirements, local context, and other matters that may inform the IRB review.

When the Drexel University IRB serves as the reviewing IRB for another organization, the requirements and procedures outlined throughout the Drexel HRP's SOP's procedures, policies, and guidance apply unless an alternative procedure has been agreed to in the reliance agreement or outlined in a companion document.

For example, alternative procedures may be used for any of the following:

1. Management and documentation of scientific review, other ancillary reviews, and institutional permissions for research;
2. Training requirements and verification of qualifications and credentials for external investigators and staff, as typically each local IRB or institution is responsible for their own agents;
3. For-cause and not-for-cause compliance reviews;
4. The disclosure and management of conflicts of interest. In all cases, any COIs and CMPs identified and developed by the relying organization will be communicated to the reviewing IRB. The reviewing IRB will determine the acceptability of the plan in accordance with their policies and procedures.
5. Review and management of matters such as site-specific consent language, HIPAA (e.g., authorizations, waivers, alterations), noncompliance, unanticipated problems, and federal reports;
6. Procedures for and type of IRB review (e.g., expedited, convened) of additional sites after the research protocol is IRB-approved;
7. Procedures for submission and review of interim reports and continuing review materials; and/or
8. The communication of IRB determinations and other information to external investigators and organizations.

2.1 Review and Approval of Drexel Activities and Agents

Prior to requesting a reliance agreement for Drexel to be the IRB of record of another FWA holding institution, Drexel's sites and activities should be approved first. This both confirms the level of review, consent language and allows the Drexel team to begin research activities while effectively onboarding additional sites after the initial submission. To create a new protocol that will include external sites;

1. Create a new standard submission in COEUS, please do not include the site-specific reliance attachments at time of initial approval, please see 2.2.
2. The Drexel IRB will provide initial approval prior to starting the reliance process
3. After 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)"

2.2 Review and Approval of Relying Sites

When the sites agree that they would like to cede review to Drexel IRB, create an amendment to add each site. The Drexel HRP office recommends that separate modifications be submitted and approved for each site and not to include non-reliance related requests as part of the modification as this may cause delay.

Create an amendment in COEUS to add a new external site(s), and include the following required attachments;

- "FORM: Request for Drexel as the Single IRB (HRP-205)"
- Tracked and clean versions of the protocol to document the location of the new site
- A site-specific consent form with the site's required language (if applicable)
- Site-specific advertisements/recruitment materials/flyers or other subject facing material (if applicable)
- Completed "FORM: Local Context Survey (HRP-206)" signed by a representative of the external IRB.



Investigator Guidance, Procedures for Review and Process Map: Reliance Agreements			
Document No.:	Edition No.:	Effective Date:	Page:
HRP-804	003	November 1, 2021	Page 6 of 11

Document No.:	Edition No.:	Effective Date:	Page:
HRP-804	003	November 1, 2021	Page 6 of 11

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
 - Enrollment information
 - Data management plans
 - Whether ancillary reviews are required at the external site(s)
 - Whether there are state laws that should be taken into consideration regarding the review
 - Whether the IRB representative from the external site(s) has reviewed the study personnel’s institutional required training and certifications
 - Whether Conflicts of Interest exist at the external site(s) regarding the study in question and their applicable management plans
 - Other areas as outlined in section 2.0 of this guidance.
- The IRB will assess whether 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.

2.3 Execution of Agreement and External Institutional Requirements

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.

As many relying sites require acknowledgement of the reviewing IRB’s approval or have final system processes or compliance checks, human subject research activities should not begin until both the reviewing IRB has given approval, and relying IRB has given permission to do so, as applicable.

2.4 Investigator Responsibilities and Post-Approval requirements – Reviewing IRB Study Team

As the Overall Principal Investigator for a study for which research activities involving human subjects will be overseen by the Drexel IRB for all or most sites, you should be aware of your additional responsibilities in assuming that role, as well as the Drexel IRB’s responsibilities. Once you have agreed to collaborate with investigators at another institution(s) and intend to use the Drexel IRB for oversight of this study the following are required to be completed, and Drexel IRB will review as applicable per Drexel’s other guidance documents, SOP’s and processes

Investigator Responsibilities and Post Approval Requirements: Reviewing IRB Study Team	
Prior to IRB approval of external site:	
<input type="checkbox"/>	Complete the “FORM: Request for Drexel as the Single IRB (HRP-205).”
<input type="checkbox"/>	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)
<input type="checkbox"/>	Provide site investigators with the Drexel IRB policies, including policies for reporting unanticipated problems, noncompliance, subject complaints
<input type="checkbox"/>	Provide site investigators with IRB approved versions of all study documents (e.g., consent and authorization forms, protocol, recruitment materials)
<input type="checkbox"/>	Prepare and submit Drexel IRB amendment submissions on behalf of all sites, for initial reviews.
<input type="checkbox"/>	Distribute and collect “FORM: Local Context Survey (HRP-206)” for each relying site



**Investigator Guidance, Procedures for Review and
Process Map: Reliance Agreements**

Document No.:	Edition No.:	Effective Date:	Page:
HRP-804	003	November 1, 2021	Page 7 of 11

<input type="checkbox"/>	Assist relying site study teams in ensuring consent documents follow Drexel IRB’s template form and includes applicable site-specific required language
<input type="checkbox"/>	Notify site investigators of all Drexel IRB determinations and communications regarding site onboarding.
During IRB approval of external site:	
<input type="checkbox"/>	Prepare and submit Drexel IRB submissions on behalf of all sites; amendments, changes in principal investigator or site-specific study liaison, reportable events, and study-wide information for continuing review
<input type="checkbox"/>	Monitor and maintain training records to assure that the Drexel study team is in compliance with the institutional training requirements. Note: The study team may also be responsible for monitoring other sites training as part of study responsibilities (e.g. data coordinating center), however these records should not be submitted to the Drexel IRB.
<input type="checkbox"/>	Maintain compliance with all Drexel HRP policies, including “HRP-070 Investigator Obligations” and other Drexel institutional policies (e.g., data security, conflict of interest, conduct of research) as applicable.
<input type="checkbox"/>	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. Note: Relying institutions IRB’s may have their own reporting requirement and the local study team should submit accordingly, and the reviewing IRB should provide any requested documentation.
<input type="checkbox"/>	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
<input type="checkbox"/>	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
<input type="checkbox"/>	Provide access, upon request, to study records for audit by the relying institution, Drexel IRB, and other regulatory or monitoring entities
<input type="checkbox"/>	Follow all requirements of the relying institution with regard to ceded review.
<input type="checkbox"/>	Notify site investigators of all Drexel IRB determinations and communications, including continuing review, amendments, and reportable events
After closure at external site:	
<input type="checkbox"/>	Complete an amendment submission to the Drexel IRB, updating documents and advising that the relying site has completed human subject research activities. If all human subject research is complete across all sites, including data analysis of identifiable data, then a study closure can be submitted.
<input type="checkbox"/>	Notify site specific investigators of Drexel’s site closure by sending Drexel IRB’s documentation.
<input type="checkbox"/>	Notify site investigators of any additional relevant Drexel IRB determinations and communications, including communication from the sponsor or reportable events



Investigator Guidance, Procedures for Review and Process Map: Reliance Agreements

Document No.:	Edition No.:	Effective Date:	Page:
HRP-804	003	November 1, 2021	Page 8 of 11



Provide access, upon request, to study records for audit by the relying institution, Drexel IRB, and other regulatory or monitoring entities

3. Drexel's IRB as the Relying IRB

All non-exempt human subject research that Drexel University is engaged in must be reviewed and approved by the IRB or an external IRB that Drexel University has agreed to rely upon prior to the initiation of the research.

Drexel University has standing agreements in place to engage the services of external IRBs for the review of specific categories of research including:

- NCI's Pediatric CIRB for NCI research involving children

Research that falls within the above parameters must be registered with Drexel University prior to submission to the external IRB following the procedures outlined in Section 3.1 and post approval responsibilities still remain for the oversight of the study as summarized in Section 3.2

Drexel University may also choose to enter into an agreement to rely upon other external IRBs, most commonly when required as a condition of a grant or contract. Investigators should submit reliance requests as early in the grant/contract process as possible. The Drexel HRP evaluates the following factors, and others as appropriate, when considering a request to rely upon an external IRB:

1. The accreditation status of the proposed IRB;
2. The compliance history of the IRB (e.g., outcomes of prior audits or inspections, corrective actions);
3. Prior experience with the IRB;
4. The federal IRB registration and organizational FWA;
5. The expertise and experience of the proposed IRB (e.g., with reviewing the type of research, research procedures, and subject population(s));
6. The research activities that will be conducted at or by Drexel University;
7. The risks and complexities of the proposed research;
8. The proposed reliance terms and procedures including the procedures for collaborative management of matters such as conflicts of interest, noncompliance, unanticipated problems, and federal reports;
9. The plan for review and allowance of the incorporation of site-specific consent language; and
10. The plan for incorporation of other relevant local requirements or context information in the review process.

3.1 Submitting a Request for Drexel to Cede review

For protocols that are ready for IRB, create an initial COEUS submission and specify the Type as "Letter of Reliance."

Submit the following to COEUS:

- "FORM: Request for Drexel to Cede Review (HRP-204)"
- "FORM: External IRB Qualification (HRP-209)", if the reviewing IRB is non-accredited.
- The external IRB's approval letter with the most recent approval date
- All Drexel agents who will be conducting human subject research activities listed with COI forms and CITI training attached.
- The external institution's approved study documents:
 - Protocol
 - Drafted site-specific consent forms for Drexel participants, if applicable, otherwise if Drexel will not be enrolling then a copy of the enrolling sites consent form. If there will be no consent forms for the study as waivers have been given, please outline this information in HRP-204
 - 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 as a site.



Investigator Guidance, Procedures for Review and Process Map: Reliance Agreements

Document No.:	Edition No.:	Effective Date:	Page:
HRP-804	003	November 1, 2021	Page 9 of 11

Drexel IRB Review of Institutional Requirements

As a Fully Accredited AAHRPP organization, Drexel HRP-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 to ensure the application is complete
- The “FORM: Request for Drexel to Cede Review (HRP-204)” allows the Drexel IRB to gather information and evaluate the request using the criteria in section 3.0 of this guidance, including:
 - Accreditation status of reviewing IRB
 - Activities Drexel is conducting.
 - 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.

When reliance on a non-accredited IRB is proposed, the utilization of “FORM: External IRB Qualifications (HRP-209) is required to be submitted with the request to ensure the evaluation may also take into consideration one or more of the following based upon the risks of the research, the research activities that Drexel University will be involved in, and Drexel University’s familiarity with the IRB:

1. A statement of assurance from the proposed IRB that its review will be consistent with applicable ethical and regulatory standards, and that it will report any regulatory investigations, citations, or actions taken regarding the reviewing IRB, and, when applicable, to the organization’s FWA;
2. An attestation about, or summary of, any quality assessment of the reviewing IRB such as evaluation by an external consultant or internal evaluation of compliance using the FDA’s self-evaluation checklist or AAHRPP’s self-evaluation instrument;
3. The willingness of the external IRB to accommodate requests for relevant minutes and other records of the proposed study and/or to copy Drexel University’s HRPP office on correspondence such as determination letters and notices of suspensions or terminations of IRB approval;
4. The willingness of the external IRB to accommodate a request for someone from the relying organization to serve as a consultant to the IRB or to observe the review of the proposed study; and/or
5. An assessment of the external IRB’s policies and procedures.

3.2 Execution of Agreement and Relying IRB Institutional Requirements

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, consent form, and approval document from the reviewing institution. After the modification approval documents are received the Drexel IRB will send the Drexel PI the IRB Authorization Agreement and a Letter of Reliance acknowledged letter, and the study will be “approved” in COEUS.

Study teams should not begin human subject research activities until the study has been approved by the reviewing IRB, the approval has been acknowledged by Drexel University and as applicable all local ancillary reviews have been completed.

3.3 Investigator Responsibilities and Post-Approval Requirements – Relying IRB 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 and that the study team is still responsible for certain activities.

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



**Investigator Guidance, Procedures for Review and
Process Map: Reliance Agreements**

Document No.:	Edition No.:	Effective Date:	Page:
HRP-804	003	November 1, 2021	Page 10 of 11

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:

Investigator Responsibilities and Post-Approval Requirements-Relying IRB Study Team	
Prior to final Drexel acknowledgement:	
<input type="checkbox"/>	Complete the “FORM: Request for Drexel to Cede Review (HRP-204)” and any other submission requirements outlined in section 3.1 of HRP 804 Guidance.
<input type="checkbox"/>	Provide an application to the Drexel IRB which contains the submission materials initially approved by the external IRB, including the approved template consent.
<input type="checkbox"/>	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).
<input type="checkbox"/>	Incorporate Drexel’s required language into the consent template to be used by the Drexel study team (as applicable).
	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.
<input type="checkbox"/>	Once approved as a site by the external IRB provide the initial approval letter to Drexel IRB.
<input type="checkbox"/>	Ensure that study activities will not begin until all ancillary reviews have been completed.
During IRB Approval:	
<input type="checkbox"/>	Monitor and maintain training records to assure that the Drexel study team is in compliance with the institutional training requirements.
<input type="checkbox"/>	Maintain an active record of all submissions to the IRB of record.
<input type="checkbox"/>	Submit any modifications to Drexel IRB that require local review. Examples include: <ul style="list-style-type: none"> a) The addition or removal of any Drexel study personnel. Note: Drexel personnel cannot begin research activities until their addition has been approved by Drexel and if required, the reviewing IRB. b) Changes in conflicts of interest c) Change in sponsor, study title, or the addition of funding as this may require conflict of interest disclosures to be completed or other funder requirements. d) Only protocol revisions which will require review by an of Drexel HRP’s ancillary committees (e.g., radiation safety, biosafety, COI, Privacy, etc.) e) Consent forms if the consent form has never previously been reviewed by the Drexel HRP-IRB (e.g., a new arm/phase or expanding enrollment to children) or the sponsor/CRO has modified the subject injury language in the consent documents. It is the investigator’s responsibility to confirm that the subject injury language has not been modified without the appropriate changes to the CTA
<input type="checkbox"/>	Provide the annual re-approval letter to Drexel IRB prior to expiration of the protocol
<input type="checkbox"/>	All potential safety events (including subject injuries and complaints) and noncompliance occurring at or involving Drexel should first be submitted to the reviewing IRB for review. Report any determination by the reviewing IRB of an Unanticipated Problem



Investigator Guidance, Procedures for Review and Process Map: Reliance Agreements			
Document No.:	Edition No.:	Effective Date:	Page:
HRP-804	003	November 1, 2021	Page 11 of 11

Document No.:	Edition No.:	Effective Date:	Page:
HRP-804	003	November 1, 2021	Page 11 of 11

	Involving Risk to Subjects or Others (UPIRSO), Serious Noncompliance or Continuing Noncompliance involving Drexel participants or researchers, and Suspension or Termination of IRB approval of research as described in HRP-071- Prompt Reporting Requirements
<input type="checkbox"/>	Provide, upon request, access to study records for audit by the local institution, the reviewing IRB's institution, and other regulatory or monitoring entities.
<input type="checkbox"/>	Maintain compliance with all other Drexel institutional policies (e.g., data security, conflict of interest, conduct of research).
<input type="checkbox"/>	Inform the Drexel IRB of any issues affecting the IRB of record and their ability to review the study according to the executed agreement, including any suspension, restriction, termination, or expiration of its FWA; any failure to maintain registration of its IRB(s); or any loss of or change to its HRPP accreditation status or other assessment standard.
After closure of Drexel as site	
<input type="checkbox"/>	When the reviewing IRB has indicated that the IRB approval for the Drexel site has ended and the Drexel site may close, please submit documentation along with a closure report in the Drexel electronic IRB system.
<input type="checkbox"/>	Notify Drexel IRB of any additional relevant reviewing IRB determinations and communications, including communication about reportable events
<input type="checkbox"/>	Provide access, upon request, to study records for audit by the reviewing institution, Drexel IRB, and other regulatory or monitoring entities