

**WORKSHEET: External IRB Process for Non-Industry Sponsored Research**

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The purpose of this worksheet is to provide support for Designated Reviewers and Researchers to identify the process for relying on an external IRB. This process will be completed successfully when the Rutgers IRB issues a signed IRB Authorization Agreement and the study is approved in eIRB+ afterwards. It does not need to be completed or retained.

**1 Confirm whether Rutgers University will rely on an external IRB.**

<input type="checkbox"/>	Rutgers is willing to rely on an external IRB.
	<b>If unknown</b> , submit the following documents/data to the <i>Rutgers IRB Reliance Agreement Administrator</i> to confirm if Rutgers is willing to rely on an external IRB and whether you may continue the reliance agreement process.
<input type="checkbox"/>	Study Protocol (This must be a finalized document.)
<input type="checkbox"/>	Identify the name of the external IRB that will serve as the <u>IRB of Record</u> .
<input type="checkbox"/>	Identify the name of the Rutgers Principal Investigator and Rutgers study staff.

**2 Submit Your Study for Rutgers IRB Administrative Review in the Rutgers eIRB+ System:**

<input type="checkbox"/>	Required documents to include in your submission:
<input type="checkbox"/>	<i>Study Protocol</i> (Template provided by the IRB of Record)
<input type="checkbox"/>	<i>Investigator's Brochure, Package Insert, or Device Brochure</i> (if applicable).
<input type="checkbox"/>	<i>IRB Authorization Agreement</i> that will be signed by the Rutgers IRB and the External IRB <sup>1</sup> . <b>NOTE:</b> An authorization agreement may be established under the <b>SMART IRB</b> agreement portal or another <b>Master Agreement between Rutgers and the IRB of Record</b> . If you are not sure how to document the reliance agreement, it is recommended that you contact the <i>Rutgers IRB Reliance Team</i> for assistance.
<input type="checkbox"/>	Informed Consent Form <sup>2</sup> or a Consent Form Waiver.

**When submitting your study in eIRB+, you must select the following options:**

- Submission Type – Administrative Review - (Rutgers U is not the IRB of record)
- Note The Following Important Required Sections in the eIRB Application:
  - Section 4.1: List all Non-Rutgers Study sites (Domestic Sites) and Upload IRB approval from IRB of record)
  - Section 10.0: Upload the Main Site's Protocol.
  - Section 10.0: Upload the Main Site's Approved Informed Consent Forms (e.g., Adult, Parent, Child Assent etc.).
  - Section 10.0: Upload any other Supporting Documents related to the Project.

**3 Rutgers IRB Review Determination**

<input type="checkbox"/>	The Rutgers IRB will review the submission to determine the following <sup>3</sup>
<input type="checkbox"/>	Whether Rutgers is willing to rely on the External IRB identified.
<input type="checkbox"/>	The application is complete and contains the required documents.
<input type="checkbox"/>	The consent form includes required Rutgers template language (as applicable).
<input type="checkbox"/>	All applicable institutional policies and state and local requirements have been incorporated into the study.

<sup>1</sup> The IRB of Record determines how the reliance agreement will be documented. If you are not sure if this document is required, it is recommended you contact the Rutgers IRB Reliance Team for assistance. Please check with the IRB of Record or the lead site to see how they prefer to document the reliance agreement. The IRB of Record may request that a protocol specific IRB authorization agreement be executed and request that you complete their preferred template. If the IRB of Record provides you with a template IRB authorization agreement form to complete, you should use this form. If this is the first time you are executing an agreement with this IRB of Record, we recommend that you reach out to the Rutgers IRB Reliance Team before submitting in eIRB+ to see if there are any issues with using the IRB of Record's agreement template. If the IRB of Record or lead site is willing to use Rutgers's IRB Authorization Agreement, you should go to the Forms page of the IRB website and download the document titled "IRB Authorization Agreement."

The form will also ask you to identify and provide contact information for an Institutional Official. Please leave these fields blank. The Rutgers IRB will complete these fields. There may be other fields requesting information about the study and the Principal Investigator. Please complete these fields. If the form requires the PI signature, please upload a signed copy of the form to the eIRB+ application.

<sup>2</sup> The sponsor or lead site will likely provide you with a consent form template (RU Consent Forms Link: [Human Research Protection Program Toolkit | Rutgers Research](#) that has been approved by the IRB of Record. You can edit this template consent form. You do not need to use the Rutgers template consent. The template consent form will have several placeholder sections where you can input Rutgers specific information. Please complete all those fields.

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*Please make sure the consent form has the appropriate Rutgers template language and contact information that applies to your research.*

*3 If there are any issues identified, the application will be returned to you in eIRB+ with a list of concerns for you to address. You will be notified of this via email. Once you address the issues and resubmit, the application will be reassigned to the IRB staff who screened the first submission. Once all the issues have been addressed the IRB will formally acknowledge the submission and sign the IRB authorization agreement. An acknowledgment letter and signed agreement will be sent to you via email.*