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1. PURPOSE

This procedure establishes the workflow process when the Rutgers University IRB serves as the Single IRB or IRB of Record for a Multi-Site Study or Collaborative Study.

- 1.1. The process begins when the Principal Investigator submits an application in the eIRB+ system for Rutgers University to consider serving as the Single IRB or IRB of Record.
- 1.2. The process ends when the study is completed.
- 1.3. 13.007 (HRP-801) – SOP - Establishing Authorization Agreements, IRB Approval has been completed in eIRB+, and an IRB Approval Letter has been issued to the Rutgers University Principal Investigator.

2. PREVIOUS VERSION

- 2.1. 10/4/2023.

3. POLICY

- 3.1. In accordance with 1.001 (HRP-101) - Human Research Protection Program Plan, the Rutgers University HRPP/IRB Office staff:
 - 3.1.1. Reviews and determines if it is appropriate to execute an Authorization Agreement (e.g., Reliance Agreement) for the Rutgers University IRB to serve as the Single IRB or IRB of Record for a Multi-Site Study or Collaborative Study.
 - 3.1.2. Performs routine post-approval monitoring activities or conduct directed (for cause) reviews of study records. These oversight activities may be accomplished remotely, in collaboration with the external institution's IRB/Compliance team located at the participating research site.

4. RESPONSIBILITIES

- 4.1. The executed Authorization Agreement delineates the roles and responsibilities of the external institution and Participating Site Principal Investigator, including adhering to the Participating Site's required institutional approvals, notifications and other reporting requirements.
- 4.2. Rutgers University Principal Investigator:
 - 4.2.1. Follows procedures below to submit a new study application in eIRB+, including the relevant study information in order for the IRB Office staff to make an initial assessment, and facilitates uploading materials into eIRB+ on behalf of the Participating Site for subsequent submissions.
 - 4.2.2. Obtains all appropriate institution/organization approvals (i.e. IRB, IBC, COI, etc.), prior to implementation of procedures at Rutgers University.
 - 4.2.2.1. If, in reviewing a site that is relying on the Rutgers University IRB:
 - 4.2.2.1.1. a management plan is uploaded, or
 - 4.2.2.1.2. a consent form is submitted that has disclosure information for an investigator at the site;
 - 4.2.2.1.2.1. The IRB Reliance Administrator will notify the Rutgers University Conflict of Interest Office via email or ancillary review.
 - 4.2.2.2. Provides all Rutgers University IRB approved study documents and other pertinent correspondence to the Participating Site.
 - 4.2.3. Complies with applicable local New Jersey laws, regulations, and Rutgers University policies, such as the 1.001 (HRP-101) - Human Research Protection Program Plan and 1.002 (HRP-103) - Investigator Manual and/or 1.005 (HRP-103p) – pSite Investigator Manual.
 - 4.2.4. Ensures that all collaborators and study staff are appropriately qualified, have completed Human Research Protections training, and have been adequately trained to conduct the study in alignment with the IRB approved protocol.
 - 4.2.5. Promptly reports any Unanticipated Problems Involving Risks to Subjects or Others (UPIRSOs), termination or suspension of the study. For reporting requirements and timeframes, please consult the IRB Office's Reportable New Information website.
 - 4.2.6. Maintains documentation of IRB approval and other study documentation in accordance with 1.002 (HRP-103) - Investigator Manual and/or 1.005 (HRP-103p) – pSite Investigator Manual.

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5. PROCEDURE

The Rutgers University Principal Investigator, IRB Administrator (IRBA) and Reliance Administrator (RA) conduct the following procedures:

5.1. Initial Review

5.1.1 The Rutgers University Principal Investigator submits a new study application in eIRB+ and includes the following documents in the submission:

- 5.1.1.1 The study protocol and draft consent form.
- 5.1.1.2 Investigator's brochure (if applicable).
- 5.1.1.3 13.302 (HRP-890) – FORM – Single Study Authorization Agreement with Rutgers University site information.

5.1.2 The IRB Router/IRBA conducts the preliminary administrative review (PAR) before re-assigning the application to the RA:

- 5.1.2.1 Using the procedures outlined in 13.204 (HRP-1801) - WORKSHEET: Authorization Agreement Review, the RA determines if it is appropriate for Rutgers University's IRB to serve as the Single IRB or IRB of Record. The RA also assesses on a case-by-case basis whether it is feasible for Rutgers University's IRB to serve in that capacity.
 - 5.1.2.1.1 If it is both appropriate and feasible, the RA follows the process outlined in 13.007 (HRP-801) - SOP: Establishing Authorization Agreements and forwards the partially executed Authorization Agreement to the local Rutgers University research team via eIRB+ for full execution by the external institution, when appropriate.
- 5.1.2.2 Finalizes and issues in eIRB+, 3.319 – Non-Administrative Review Initial Approval Letter along with all applicable IRB approved documents (i.e. protocol, consent form, etc.)

5.1.3 The Rutgers University Principal Investigator provides all IRB approved study documents to the external institution(s) or Participating Site Principal Investigator.

5.2. Progress Reports and Modifications (please refer to the HRPP website [IRB Applications | Rutgers Research](#) regarding submitting Progress Reports and Modifications)

5.2.1. The Rutgers University Principal Investigator:

- 5.2.1.1. Facilitates submission of the Participating Site study modifications and continuing reviews to the Rutgers University IRB via eIRB+.
- 5.2.1.2. Provides to the external institution contact or Participating Site Principal Investigator, any IRB determination letters, approval letters and other pertinent IRB correspondence.
- 5.2.1.3. Facilitates modification submission in eIRB+ for IRB approval of any new (additional) Participating Site. The modification should include details about the study procedures to be performed at the new Participating Site.
- 5.2.1.4. The CAS or IRBA finalizes and issues in eIRB+, 3.314 – Notice of Approval Modification Non-Administrative or 3.313 – Notice of Approval CR PR Non-Administrative

5.3 Reportable New Information

5.3.1 The Rutgers University Principal Investigator:

- 5.3.1.1 Performs RNI reporting to the Rutgers University IRB in accordance with IRB reporting requirements as outlined on the IRB Office website.
 - 5.3.1.1.1 Submits a Reportable Event in eIRB+ for UPIRSOs and other types of relevant Reportable Events that occur at Rutgers University
 - 5.3.1.1.2 Facilitates Reportable Event submission in eIRB+ for UPIRSOs and other relevant Reportable Events that occur at any Participating Site.
 - 5.3.1.1.3 Provides the external institution contact or Participating Site Principal Investigator, any IRB determination letters or other pertinent IRB correspondence.

5.4 Study Closure

5.4.1 The Rutgers University Principal Investigator:

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- 5.4.1.1 Submits the study closure in eIRB+.
- 5.4.1.2 Provides the study closure documentation to the Participating Site Principal Investigator.
- 5.4.1.3 Maintains study records in accordance with record retention requirements outlined in 1.002 (HRP-103) - Investigator Manual and/or 1.005 (HRP-103p) – pSite Investigator Manual.

5.4.2 The CAS or IRBA finalizes and issues in eIRB+, 3.315 – Notice of Final Report Approval.

6. MATERIALS

- 6.1. 1.001 (HRP-101) - Human Research Protection Program Plan.
- 6.2. 1.002 (HRP-103) – Investigator Manual.
- 6.3. 1.005 (HRP-103p) – pSite Investigator Manual.
- 6.4. 3.006 (HRP-055) – SOP – Financial Conflicts of Interest
- 6.5. 3.313 – LETTER - Notice of Approval CR PR Non-Administrative (*Automatically generated by eIRB+*).
- 6.6. 3.314 – LETTER - Notice of Approval Modification Non-Administrative (*Automatically generated by eIRB+*).
- 6.7. 3.315 – LETTER - Notice of Final Report Approval (*Automatically generated by eIRB+*).
- 6.8. 3.319 – LETTER – Non-Administrative Review Initial Approval Letter (*Automatically generated by eIRB+*).
- 6.9. 13.007 (HRP-801) - SOP: Establishing Authorization Agreements.
- 6.10. 13.302 (HRP-890) - FORM: Single Study Authorization Agreement.
- 6.11. 13.304 – FORM - Relying Site Local Considerations.

7. REFERENCES

- 7.1. [NOT-OD-16-094: Final NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research.](#)