RUTGERS UNIVERSITY
Office for Research

SOP: Advarra IRB		
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1. PURPOSE

1.1. This procedure establishes the process when the Rutgers University IRB agrees to rely on Advarra IRB for review (i.e., cede review).

1.2. The process begins when the Principal Investigator submit an application in eIRB+ requesting the use of Advarra IRB.

1.3. The process ends when the IRB Authorization Agreement is no longer needed because the project is closed or one of the parties has withdrawn from the agreement.

2. PREVIOUS VERSION

2.1. None.

3. POLICY

3.1. In accordance with 1.01 (HRP-101) - Human Research Protection Program Plan, the Rutgers University HRPP/IRB Office:

3.1.1 Reviews and determines if it is appropriate to execute an Authorization Agreement for the Rutgers University IRB to cede IRB review to (i.e., rely on) Advarra IRB.

3.1.2 Performs routine post-approval monitoring activities or conducts 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(s).

3.2 The use of Advarra IRB may be warranted when one or more of the following are applicable:

3.2.1 Rutgers University is a sub-contracted site and IRB approval for the overall study has been provided by the external institution/organization.

3.2.2 The request is mandated by the funding agency per Single IRB (sIRB) or Cooperative Research requirements.

3.2.3 The request is mandated by the study sponsor or funding agency in order for the Rutgers University site to participate in the research.

3.2.4 The Rutgers University site is collaborating with the main research site for the study and receiving of identifiable information.

4. RESPONSIBILITIES

4.1. Rutgers University Principal Investigator:

4.1.1. Complies with all submission and reporting requirements of Advarra IRB.

4.1.2. Follows procedures below to submit a new study application to Rutgers University's IRB (via the eIRB+ system), including the relevant study information and Local Context Supplement in order for the IRB Office staff to make an initial assessment, and submits subsequent Advarra IRB study updates/renewals to Rutgers University's IRB, as applicable.

4.1.3. Obtains all appropriate institution/organization approvals (i.e., IRB, IBC, ORSP, COI, etc.), prior to implementation of procedures at Rutgers University.

4.1.4. 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.

4.1.5. Ensures that all collaborators and study staff are appropriately qualified, have completed Human Subjects Protections training, and have been adequately trained to conduct the study in alignment with the IRB approved protocol.

4.1.6. Promptly reports any Unanticipated Problems Involving Risks to Subjects or Others (UPIRSOs), termination or suspension of the study by Advarra to Rutgers University IRB.

(For reporting requirements and timeframes, please consult the IRB Office's Reportable Events website.)

4.1.7 Maintains documentation of Advarra IRB approval and other study documentation in accordance with 1.002 (HRP-103) - Investigator Manual and/or 1.005 (HRP-103p) – pSite Investigator Manual.

5. PROCEDURE

The Principal Investigator (PI), Coordinator of Administrative Servies (CAS), and Reliance Administrator (RA) conduct the following procedures:

5.1. Initial Review

5.1.1 The Principal Investigator submits a new study application in eIRB+:

5.1.1.1 Includes the following documents in the submission:

5.1.1.1.1 The study protocol, consent form and any other applicable documents

5.1.1.1.2 Local context supplement

5.1.1.1.3 Investigator's brochure (if applicable).

5.1.1.2 Rutgers University established a Master Agreement (MA) with Advarra IRB. This allows Advarra IRB to serve as the Reviewing IRB for submission(s) from a Rutgers University PI as outlined in section 3.2 of this policy. The MA replaces the completion of a study specific Institutional Authorization Agreement for each submission.

5.1.2 The RA reviews the new study application in eIRB+:

5.1.2.1 Conducts the preliminary administrative review (PAR).

5.1.2.2 Ensures that the Rutgers University consent form includes the required local context language (which includes, but is not limited to, conflict of interest, research costs, research injury and HIPAA language).

5.1.2.3 Ensures the eIRB+ new study application contains all study documents being submitted to Advarra IRB.

5.1.2.4 Finalizing the local Rutgers University IRB review, the RA provides a "Determination Notice" with a motion of Approval with Conditions to the PI in eIRB+ with the sign-off language required for Advarra IRB review. The RA uses the Reliance Frequently Used Language document for the sign-off language incorporated into the determination notice.

5.1.2.5 Upon Advarra IRB review and approval, the PI will submit the Advarra IRB initial approval along with the Advarra IRB approved supporting documents to Rutgers University IRB for administrative approval.

5.1.2.6 RA reviews the Advarra IRB approval and supporting documents. Finalizes and issues in eIRB+, 3.312 - LETTER: Notice of Acknowledgement for Initial Administrative Review.

5.2 Continuing Review and Modifications

5.2.1 The Principal Investigator is required to submit the Advarra IRB approval letters to Rutgers University via eIRB+, for study updates/renewals of Advarra IRB approved research that meet the following criteria:

5.2.1.1 Updates to Principal or co-Investigators

5.2.1.2 Updates to protocol or consent forms, or other approved documents

5.2.1.3 Advarra IRB Continuing review approval of the Rutgers study site

5.2.1.4 In the event that the Principal Investigator has failed to renew the study with Advarra IRB by the expiration date, the Principal Investigator must complete the expired study report form when submitting the progress report.

5.2.2 The router conducts the PAR then re-assigns the application to the RA.

5.2.2.1 Verifies all applicable local context information is included.

5.2.2.2 Finalizes and issues in eIRB+, 3.316 – LETTER - Notice of Modification Administrative Review or 3.317 – LETTER - Notice of Progress Report Administrative Review.

5.3 Reportable New Information

5.3.1 Unanticipated Problems Involving Risks to Subjects or Others (UPIRSOs) that involve Rutgers University or its affiliates' study participants are not required to be submitted to the Rutgers University IRB, unless the UP(s) is a death related to the research, a protocol deviation, or results in serious or continuing non-compliance in accordance with 10.001 (HRP-024) – SOP - Reportable New Information.

5.3 Study Termination

5.3.2 The Rutgers IRB Office considers study closure a change in status. Therefore, the Principal Investigator is required to submit the Advarra IRB closure documentation to the Rutgers University IRB. A Notice of Closure letter is issued for Advarra IRB closure applications.

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. 3.015 (HRP-055) – Financial Conflicts of Interest
6.5. 3.312 - LETTER: Notice of Acknowledgement for Initial Administrative Review
6.6. 3.316 – LETTER - Notice of Modification Administrative Review
6.7. 3.317 – LETTER - Notice of Progress Report Administrative Review
6.8. 10.001 (HRP-024) – SOP - Reportable New Information

7. REFERENCES

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