

1. PURPOSE

- 1.1. This procedure establishes the process when the Rutgers University IRB agrees to rely on WCG (formerly WIRB) IRB for review (i.e., cede review).
- 1.2. The process begins when the Principal Investigator submits an application in eIRB+ requesting the use of WCG 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ends when the IRB Authorization Agreement is no longer needed because the project is closed or one of the parties has withdrawn from the agreement.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. 12/13/2023.

3. POLICY

- 3.1. In accordance with 1.001 (HRP-101) - Human Research Protection Program Plan, the Rutgers University HRPP/IRB Office:
 - 3.1.1 Reviews and determines if the application meets the requirements to be submitted to WCG IRB for review.
 - 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 WCG IRB /Compliance team.
- 3.2 The use of WCG IRB may be warranted when all the following are applicable:
 - 3.2.1 The study is industry-sponsored, i.e., the industry sponsor has written the protocol, is funding the research, and will monitor the conduct of the study.
 - 3.2.2 The research will be conducted at a Rutgers University performance site(s). Site(s) is (are) owned and operated by Rutgers University)
 - 3.2.3 The investigator(s) is (are) Rutgers University employees
 - 3.2.4 The investigator(s) is (are) in good standing with the Rutgers IRB (e.g., no compliance issues, no expired studies, etc.)
 - 3.2.5 All study personnel involved in human research have completed all educational requirements required by the Rutgers IRB

4. RESPONSIBILITIES

- 4.1. Rutgers University Principal Investigator:
 - 4.1.1. Complies with all submission and reporting requirements of WCG 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.
 - 4.1.3. Obtains all appropriate institution/organization approvals (i.e., IRB, SRB, 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 (HRP-101) 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 WCG 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 WCG IRB to Rutgers University IRB.

- 4.1.7 Maintains documentation of WCG 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 Services (CAS), and IRB Administrator (IRBA) 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 and consent form (using specific Rutgers boilerplate language).
- 5.1.1.1.2 Local context supplement.
- 5.1.1.1.3 Performance Site Approvals/Authorizations (if applicable).
- 5.1.1.1.4 Investigator's brochure (if applicable).
- 5.1.1.1.5 Embryonic Stem Cell Approval (if applicable).
- 5.1.1.1.6 SRB Approval (if applicable).
- 5.1.1.1.7 CTA/Contract Agreement.
- 5.1.1.1.8 PIs CV.
- 5.1.1.1.9 PIs Medical License.

5.1.1.2 All other relevant documents the PI would like to be reviewed need to be submitted and uploaded in the eIRB+ application.

5.1.2 The CAS or IRBA reviews the new study application in eIRB+:

5.1.2.1 Conducts the preliminary administrative review (PAR) using the procedures outlined in the Commercial IRB Desk Procedures. Any clarifications/change request must be completed before sending the application to the WCG IRB Committee Member (CM) for review. The CM reviews the application and determines if the application meets the submission criteria for review by WCG IRB or if further clarification/change requests are needed.

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, contact information, research injury and HIPAA language).

5.1.2.3 Ensures the eIRB+ new study application contains all study documents needed for review.

5.1.2.4 Finalizes and issues a motion in eIRB+, "External IRB- Request Clarifications/Changes".

5.1.2.5 With a motion issued of "External IRB- Request Clarifications/Changes", the CAS or IRBA will then release an eIRB+ local institutional clearance memo, prompting the study team to submit directly to WCG IRB via the Connexus system.

5.1.2.6 The Principal Investigator is required to notify Rutgers IRB via a response to the eIRB+ WCG Initial Study when the WCG IRB Notice of Approval is received:

5.1.2.7 The CAS or IRBA finalizes and issues in eIRB+, 3.312 - LETTER: Notice of Acknowledgement for Initial Administrative Review.

5.2 Continuation, Modification, Reportable New Information & Final Report:

5.2.1 The Principal Investigator must submit all continuing reviews, modifications, reportable new information and final reports directly to WCG IRB for processing. The WCG IRB Submission Chart is designed to assist principal investigator(s) with the order or submissions between WCG IRB and Rutgers IRB based on the application type: [Revised-WCG-IRB-Submission-Chart.pdf \(rutgers.edu\)](https://rutgers.edu/Revised-WCG-IRB-Submission-Chart.pdf)

5.2.2 Progress Report

5.2.2.1 The Principal Investigator is required to notify Rutgers IRB via an eIRB+ Progress Report when the WCG IRB Continuing Approval is received:

5.2.2.2 The CAS or IRBA conducts the PAR then sends the Progress Report to the

CM for review.

5.2.2.3 The CM reviews the Progress Report.

5.2.2.4 The CAS or IRBA finalizes and issues in eIRB+, 3.317 - LETTER: Notice of Progress Report Administrative Review.

5.2.3 Modification

5.2.3.1 The Principal Investigator is required to notify Rutgers IRB via eIRB+ modification if any of the following changes are made:

- Updates to Principal Investigator.
- Updates to Study Personnel.
- Updates to Performance Site(s).
- Updates in Investigator Financial & Other Personal Interests.
- Addition of Surrogate Consent Process.

5.2.3.2 The CAS or IRBA conducts the PAR then sends the modification to the CM for review.

5.2.3.3 The CM reviews the modification.

5.2.3.4 The CAS or IRBA finalizes and issues in eIRB+, 3.316 – LETTER - Notice of Modification 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 10.004 (HRP-024) - Reportable New Information.

5.1 Final Report

5.1.1 The Principal Investigator is required to notify Rutgers IRB via an eIRB+ Final Report when the WCG IRB Notice of Closure is received:

5.1.1.1 The CAS or IRBA conducts the PAR then sends the Final Report to the CM for review.

5.1.1.2 The CM reviews the Final Report.

5.1.1.3 The CAS or IRBA finalizes and issues in eIRB+, 3.315 -LETTER: Notice of Final Report Approval.

6. MATERIALS

6.1. 1.001 (HRRP-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) – SOP – Processes for Review and Management of Institutional Conflicts of Interest.

6.5. 3.312 – LETTER - Notice of Acknowledgement for Initial Administrative Review (*Automatically generated by eIRB+*).

6.6. 3.315 - LETTER – Notice of Final Report Approval (*Automatically generated by eIRB+*).

6.7. 3.316 – LETTER - Notice of Modification Administrative Review (*Automatically generated by eIRB+*).

6.8. 3.317 - LETTER: Notice of Progress Report Administrative Review (*Automatically generated by eIRB+*).

6.9. 10.004 (HRP-024) – SOP – Reportable New Information.

6.10. 14.201 – WORKSHEET - WCG IRB Submission Chart.

7. REFERENCES

7.1. Commercial IRB Desk Procedures.