RUTGERS UNIVERSITY
Office for Research

Collaborative Institutional Agreement (CIA) for Non-FWA Holding Sites Relying on the Rutgers, The State University of New Jersey

This form should be used when a Rutgers University Principal investigator and another party are collaborating for research purposes for a single research study.

Institution or Organization Providing IRB Review **(Institution A):**

Rutgers, The State University of New Jersey

Name of Institution A (IRB of Record)

# FWA00003913	**IORG0000357**
Federal Wide Assurance (FWA)	IRB Registration Number

Rutgers Principal Investigator:

Institution or Organization **Relying** on the Designated IRB **(Institution B):**

Institution of Site Principal Investigator (Relying Institution):

Role in Research Project:

Address: [Street Address] [City, State, Zip]

Parties and Studies

The Officials signing below agree that **Institution B** may rely on the designated IRB of Rutgers University for review and continuing oversight of **Institution B**'s human subjects research described below. This agreement is limited to the following specific research project (one study only):

Study Title(s)

Rutgers eIRB+ Protocol Number(s)

Agreement

A. Responsibilities of Reviewing IRB ('IRB'):

For research covered by this Agreement, **'IRB'** will be responsible for the following:

1. Assuring that the membership of the IRB at all times meets applicable federal regulations.

2. Performance of initial and continuing review and review of amendments, review of unanticipated problems that may involve risks to subjects or others, and review of other documents/information related to the approval and continuing oversight of the research (as applicable) in compliance with applicable federal regulations and state and local requirements that meet the FWA requirements for the protection of human subjects.

3. Fulfilling all regulatory reporting requirements related to studies for which the **'IRB'** provides coverage.

4. Consideration of local context information provided by the **INSTITUTION**.

5. Consideration of any applicable conflict of interest management plan for investigators and key personnel in the study.

6. Review of research-related authorizations (as applicable and when combined with consent forms) or requests for waiver or alteration of the Privacy Rule's authorization requirement for uses or disclosures of protected health information in compliance with applicable regulations.

7. Secure and confidential maintenance of required records (e.g., IRB application, protocol, consent document(s), minutes, investigator correspondence, correspondence from sponsoring agencies, etc.) related to the review and approval(s) of the research in compliance with applicable regulations.

8. Prompt notification to **INSTITUTION** of findings and actions with respect to any unanticipated problems involving risks to subjects or others, subject injuries, or subject complaints which are related to or may affect subjects participating in research at **INSTITUTION**.
    a. Additionally, **'IRB'** will ensure prompt notification to **INSTITUTION** of any findings of serious and/or continuing noncompliance and/or any suspensions or terminations of **IRB** approval for that portion of a study taking place at **INSTITUTION**.

9. Prompt notification to **INSTITUTION** of allegations of scientific misconduct involving **INSTITUTION**'s investigator or study team member(s).
    a. **INSTITUTION** maintains the right and responsibility to control the investigation of allegations of scientific misconduct involving its employees according to its own institutional policies.

10. Full cooperation with any inquiry or audit of **INSTITUTION** by any federal agency or other governmental body regarding research conducted under this Agreement.
    a. Such cooperation will include, but is not limited to, providing research records and related information, meeting with representatives from **INSTITUTION**, and helping to carry out all corrective action(s), as applicable.

B. Responsibilities of Relying IRB ['INSTITUTION']:

INSTITUTION retains primary and ultimate responsibility for the protection of human subjects with respect to the conduct of the research covered by this Agreement and will be responsible for the following:

1. Acceptance of **'IRB's'** record review, determination, and continuing oversight of research covered by this Agreement.
2. Performance of the research in compliance with applicable federal regulations and state and local requirements to meet the FWA requirements for the protection of human subjects.

3. Prompt notification to **'IRB'** if there is a suspension or restriction or resignation of principal investigator or sub-investigator's status to conduct human subjects' research.

4. Prompt notification to **'IRB'** of allegations of scientific misconduct involving the investigator or study team member(s) that has the potential to affect the safety of subjects in the study under review.
    a. Each party maintains the right and responsibility to control the investigation of allegations of scientific misconduct involving its employees according to its own institutional policies.

5. Promptly notify the **'IRB'** with information about changes to the local context that effect the conduct of the study (e.g., change of location, new investigator) .

6. Assure that there will not be changes in the protocol and informed consent form that affect the meaning of IRB-approved requirements, without prior written approval of such changes by **'IRB'**.

7. Ensure appropriate qualification and training of the investigators and other staff at **INSTITUTION** who are conducting the protocol consistent with '**IRB's'** standards for eligibility to conduct research.

8. Review and management of any personal financial conflicts of interest related to research conducted under this Agreement and provide disclosures and when applicable management plans to **'IRB'** prior to IRB review. Confidential **INSTITUTION** information may be redacted from such disclosures or management plans.

9. Full cooperation with any inquiry by **'IRB'** regarding research conducted under this Agreement.
    a. Such cooperation will include, but is not limited to, providing research records and related information, meeting with representatives from **'IRB'** upon request, and helping to carry out all corrective action(s) related to the conduct of the research under review, as applicable.

10. Prompt notification to **'IRB'** of any communication regarding research covered by this Agreement to/from the **INSTITUTION** and FDA, OHRP, and/or other regulatory agencies, as applicable.

11. Prompt notification to **'IRB'** of any event or action affecting the **INSTITUTION'S** regulatory compliance with 45 CFR 46 (e.g., changes in FWA or accreditation status or legal action related to the research under review).

12. Verification of protocol compliance with all other applicable institutional requirements prior to authorizing study activation.

13. Monitoring the conduct of the research to safeguard the rights and welfare of research subjects and to maintain compliance with the determinations of **'IRB'**, federal regulations, and all applicable state, local, and institutional requirements relating to human subjects research.
    a. **INSTITUTION** reserves the right to conduct for cause and not for cause audits of the research approved under this Agreement. Issues of noncompliance in a protocol for which **'IRB'** is the IRB of record will be communicated to the **'IRB' within 5 business days of discovery**.

14. Use local site procedures to receive, distribute and review materials for protocols to be considered by this Agreement.
    a. For each protocol that is submitted by a local investigator, **INSTITUTION** will:
        i. Review the protocol materials.
        ii. Determine if **'IRB'** will serve as the IRB of record or conduct a separate local IRB review.
        iii. Determine if there are any local context issues that must be addressed by **INSTITUTION** or by **'IRB'**, including any local stipulations or substitutions in the informed consent documents.
        iv. Promptly notify **'IRB'** if there is ever a change in the acceptance of **'IRB'** as the IRB of record.
15. Establish a point of contact to maintain open communication with **'IRB'**.

C. Miscellaneous

1. Protected health information will not be shared between **INSTITUTION** and **'IRB'** unless there is: (1) appropriate authorization to use and disclose such information for the purposes of research, or; (2) an appropriate waiver of such authorization has been granted by a duly constituted review body in accordance with the HIPAA privacy rule, or; (3) the information is a Limited Data Set and the information is shared pursuant to a Data Use Agreement as those terms are defined in HIPAA.

2. This Agreement will become effective upon the date the last party signs. The Agreement will remain in effect until study closer or until such time that either **'IRB'** or **INSTITUTION** provides written notice of termination to the other party. Following termination of this Agreement, **'IRB'** agrees, if requested by **INSTITUTION**, to provide continued oversight for ongoing protocols for 90 days in an effort to provide appropriate transfer of oversight of the protocol(s) to **INSTITUTION**.

3. This Agreement does not preclude **INSTITUTION** from taking part in research not covered by this Agreement, or from participating in other IRB Agreements.

4. **INSTITUTION** may relinquish deferral and assume IRB review responsibilities internally at any time upon required written notification to **'IRB'** as noted in section 2 above.

5. Usual and customary fees for IRB review may be charged by the **'IRB.'**

6. This document must be kept on file by **'IRB'** and **INSTITUTION** and be provided to OHRP upon request.

Signature

I am the official at Institution B with the authority to commit this institution to enter into this research agreement with the **Rutgers, The State University of New Jersey**. I hereby approve this agreement. I will allow access by the IRB or its agents to any research-related documents, including medical records, if required by the IRB to carry out its responsibilities under its FWA. I affirm that Institution B maintains professional liability insurance in limits of not less than one million dollars per occurrence and three million dollars in the aggregate for the individuals conducting research activities covered by this Assurance.

AGREED TO BY INSTITUTION B:

SIGNATURE:
FULL NAME:
TITLE:
ADDRESS:
DATE SIGNED:

APPROVED BY Rutgers, The State University of New Jersey:

SIGNATURE:

RUTGERS SIGNATORY OFFICIAL:
TITLE:
ADDRESS:
DATE SIGNED:

ADDENDUM: NON-RUTGERS STUDY SITE INVESTIGATOR ASSURANCES

This addendum is required when Institution B is a Principal Investigator who is not affiliated with an Institution and does not have his/her own Federal Wide Assurance (FWA).

STUDY DETAILS
Study Title
Protocol Number (Rutgers University)

RESPONSIBILITIES

1. I acknowledge that on behalf of the Institution B, I am responsible for safeguarding the rights and welfare of each research participant; that the participant's rights and welfare must take precedence over the goals and requirements of the research; and I will ensure that research personnel under my direction fulfill these obligations.

2. I have reviewed 1) *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research*; 2) the U.S. Department of Health and Human Services (DHHS) regulations for the protection of human subjects at 45 CFR 46 (the Common Rule); 3) the terms of Institution B's Federal-wide Assurance (FWA); and 4) the relevant Rutgers policies and procedures for the protection of human subjects. I agree to comply with these ethical standards and regulatory requirements.

3. If conducting research involving FDA-regulated products, I will comply with all applicable FDA regulations; and will fulfill all investigator responsibilities (or investigator-sponsor responsibilities where required) including, but not limited to, those described at 21 CFR 50, 56, 312, 600 & 812.

4. Prior to submitting an IRB application, all investigators and all individuals involved in the research project will have successfully completed the Rutgers-approved Human Subject Protection training and, if applicable, the research-related privacy requirements of the Health Insurance Portability and Accountability Act (HIPAA)

5. I will ensure human subjects research activities are conducted in accordance with the policies of the IRB designated under Institution B's FWA cited above and accept the final authority and decisions of the IRB including, but not limited to, directives to suspend or terminate participation in designated research activities under this Agreement.

6. I will not enroll subjects in research under this Agreement prior to the IRB review and approval of this study and my receipt of this fully executed Agreement.

7. I will obtain, document, and maintain records of informed consent from each subject as stipulated by the IRB and as required by DHHS, FDA and other applicable federal regulations (or other international or national equivalent).

8. I will promptly report to the IRB any proposed changes in the research conducted under this Agreement and will not initiate changes in the research without prior IRB review and approval unless necessary to eliminate apparent immediate hazards to subjects

9. I will promptly inform the IRB of all protocol deviations/violations.

10. I will immediately report to the IRB any and all unanticipated problems involving risks to subjects or others in research covered under this Agreement.

11. I will comply with the IRB's requirements for initial and continuing review, record keeping and reporting and will provide all information as requested by the IRB, including the required final progress report at the end of the study.

12. I will permit and facilitate any Rutgers site visits, audits, investigations, and inquiries, including unfettered access to all research-related documents.

SIGNATURE

Non-Rutgers Study Site Investigator:

SIGNATURE:
FULL NAME:
TITLE:
DATE SIGNED: