RUTGERS – HUMAN SUBJECTS PROTECTION PROGRAM (HSPP)
WESTERN INSTITUTIONAL REVIEW BOARD (WIRB) PROCEDURES

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SECTION 1: ELIGIBILITY OF PRINCIPAL INVESTIGATOR, CO-INVESTIGATORS AND STUDY STAFF

In order to be eligible to submit to WIRB the Principal Investigator (P.I.) must meet current human subjects research policy requirement as to “Who May Be a Principal Investigator for Human Subjects Research” (Attachment A).

In addition, all investigators and study staff must be Rutgers paid faculty or employees. All investigators must be in good standing. The Campus IRB Director will determine an investigator’s standing based on, but not limited to, the following criteria:

- Compliance issues
- Expired studies
- Adequate and appropriate resources to perform the research

SECTION 2: WHICH PROTOCOLS MAY BE REVIEWED BY WIRB

Those studies which are both industry initiated and industry-sponsored and whose study activities are at only Rutgers performance sites may be submitted to WIRB.

- “Industry-initiated,” as opposed to investigator-initiated, means the project is not the original idea of the Principal Investigator.
- “Industry-sponsored” means that the funding company has the regulatory responsibility for the study in addition to funding the study.
- A “University performance site” is generally a location which is owned or operated or otherwise controlled by the University. All staff members are usually considered employees of the university. A private-practice not owned or controlled by the University, even though the site of practice of its faculty, is not a “University performance site.”

An industry-sponsored study that will be performed at a non-University site, whether exclusively or as part of a multi-site study, cannot be sent to WIRB. A Rutgers IRB must review such a study.

SECTION 3: SUBMISSIONS TO WIRB

The Principal Investigator must submit the following to the HSPP WIRB Management Assistant:

- Rutgers Application for Review by WIRB (not required when using electronic submission via eIRB)
- WIRB Initial Review Submission Form
- FDA Form 1572, if any
- Protocol
- Investigator’s Brochure (if applicable)
- Current professional license for Principal Investigator (if already on file at WIRB, only yearly updates needed)
• Curriculum Vitae for Principal Investigator and each Sub-Investigator (if already on file at WIRB, only yearly updates needed)
• Rutgers Investigator Financial & Other Personal Interests Disclosure Form signed by all research personnel
• Sponsor’s consent form template (WIRB will format consent using Rutgers-approved language)
• Department letterhead (1 sheet)
• Other materials to be provided to the subjects that are not included in the protocol, such as advertisements, questionnaires, subject diaries, etc.

The Rutgers IRB Director of the campus on which the P.I. is located will pre-review all initial submissions to determine:
• the appropriateness of sending the study to WIRB or to retain the study for review by a Rutgers IRB due to significant local impact, and
• whether the PI is in good standing with the Rutgers IRB. Upon approval from the Campus IRB Director, the WIRB Management Assistant forwards the following documents to WIRB Client Services @ clientservices@wirb.com:

The WIRB Management Assistant sends an email notification to the investigator and his/her study coordinator advising them that the submission has been forwarded to WIRB.

WIRB transmits a tracking number to the P.I. and to the WIRB Management Assistant which is used to follow the status of the review. The WIRB Management Assistant sends a monthly report of all active and closed studies to the campus Research Dean or his/her designee.

SUBMISSION OF MODIFICATIONS TO WIRB
All proposed changes to the study following initial approval must be submitted directly to WIRB by the investigator. WIRB transmits a status tracking number to the P.I. and to the WIRB Management Assistant. Changes made to research personnel and performance site must be reported to the HSPP Office by submitting:
• an updated Rutgers application (or if study was submitted through the eIRB system, a modification request through eIRB)
• Investigator Financial & Other Personal Interests Disclosure Form
• FDA Form 1572, if any

SUBMISSION OF CONTINUING REVIEW TO WIRB
The P.I. will be notified by WIRB three (3) weeks prior to expiration of the study approval period. A Continuing Review Report Form (CRRF) is sent directly from WIRB to the P.I. notifying him/her that the IRB approval is about to expire. The P.I. must send the CRRF back to WIRB by the due date. A delinquency is considered a non-compliance issue which may take action to suspend the study. Such a suspension may trigger required reporting by the University
to the federal Office for Human Research Protections (OHRP), and therefore should be avoided by investigators who are urged to be timely in submitting CRRFs to WIRB.

Upon receipt of the WIRB Certification of Approval for the continuation of the study, the WIRB Management Assistant, will file the approval in the appropriate study electronic folder, and will update the WIRB database to indicate the new approval expiration date. The WIRB Management Assistant will contact the P.I. and request an updated Rutgers Investigator Financial & Other Personal Interests Disclosure Form to be signed by all research personnel.

**SECTION 4: BILLING FOR WIRB SERVICES**

Rutgers researchers submitting initial applications, continuing review applications and/or modifications of human subjects research to WIRB must indicate the name and address of the Sponsor in the “Billing Information” section of the WIRB submission form, in accordance with the Clinical Trial Agreement or study contract. This information will make clear to WIRB who will be responsible for paying the WIRB fees and whom WIRB should bill.

If the CTA or study contract indicates that the sponsor will reimburse the investigator for WIRB reviews rather than paying WIRB directly, the researcher must establish a purchase order (PO) payable to WIRB. The investigator must provide the PO number and mailing address to Rutgers-Accounts Payable in the “Billing Information” section of the WIRB submission form. This ensures compliance with the Rutgers accounting policy. The Rutgers Human Subjects Protection Program (HSPP) does not pay WIRB fees.

In addition to the WIRB charges, a one-time HSPP administrative submission service fee of $750 is charged for initial applications. Sponsors will be billed separately for this charge by the HSPP staff. If the sponsor will reimburse the investigator for WIRB-related expenses only, the researcher must identify who will receive the invoice in the “Billing Information” section of the Rutgers Application for Review by WIRB. The HSPP invoice will be forwarded to the individual responsible for processing payment through a Banner Index number.

**SECTION 5: AUDITS OF WIRB-APPROVED STUDIES**

**WIRB Site Visits**

Upon completion of a WIRB site visit of a WIRB-approved study at a Rutgers performance site, a copy of the On-Site Review Form will be forwarded to the WIRB Management Assistant, who will scan and file it in the investigator’s study folder located on the HSPP server “M” drive, “Western” folder. The Management Assistant will also send a copy to the Institutional Official, the Research Dean and Campus IRB Director.
HSPP Audits of WIRB studies
HSPP will conduct quality assurance assessments and audits of WIRB approved studies according to the same standard practice as Rutgers IRB approved studies.

SECTION 6: UNANTICIPATED PROBLEMS/ADVERSE EVENTS/DEVIATIONS IN WIRB-APPROVED STUDIES

In addition to providing reports to WIRB, the PI must submit all unanticipated problems/deaths to the HSPP office. THE WIRB Management Assistant will send the report electronically to the Executive Director of HSPP. Reports will be scanned and the electronic documents filed in the investigator’s study folder located on the HSP “M” server.

Reports will be forwarded to the Executive IRB for review and determination whether there should be any additional corrective actions taken. Quarterly deviation reports provided by WIRB will also be forwarded to the Executive IRB and review.

SECTION 7: WIRB-APPROVED STUDIES DATABASE

The WIRB Management Assistant will update the database when the following occurs:
1. Submission of new study to WIRB
2. Notification from WIRB that a study has been:
   a. initially approved or disapproved
   b. approved for continuation
   c. suspended
   d. closed
3. Change in study personnel

The WIRB Management Assistant will send to the Research Deans or their designee School-specific monthly status reports containing the following information:
1. Number of open studies
2. Number of closed studies
3. Number of protocol deviations submitted
4. Number of compliance issues

SECTION 8: STUDY CLOSURE

The Principal Investigator will notify WIRB when a study concludes. WIRB will notify the HSPP office by sending a Confirmation of Closure and Conclusion of IRB Oversight letter to the HSPP office. The Board’s letter will acknowledges receipt of closure notification by the principal investigator and will include the effective date of which WIRB closed the study.

Upon receipt of the Confirmation of Closure and Conclusion of IRB Oversight letter from WIRB, the WIRB Management Assistant will verify that there are no outstanding fees connected
to the study. If there are fees, the WIRB Management Assistant will contact the P.I. to determine the best method to collect the outstanding fees, e.g., PI to collect or HSPP to resubmit invoice to sponsor.

The WIRB Management Assistant will convert the closure notification into pdf document and save the file in the relevant protocol file. The WIRB database must be updated to indicate the date WIRB closed the study.