

**Columbia University**  
**Central Institutional Review Board**  
**Standard Operating Procedure:**  
**Reliance Process**  
**XXX Consortium**

**Effective Date: March 18, 2016**

## **I. Background**

The XXX Consortium (the “Consortium”) has been formed to conduct one or more research studies (each, a “Consortium Study”) involving multiple research sites (each, a “Site”). A central Institutional Review Board (“IRB”) will be used for all Consortium Studies. The Columbia University (“Columbia”) IRB has been designated as the central IRB (the “CU CIRB”) for the Consortium. As the central IRB, the CU CIRB will be responsible for the review of protocols relating to Consortium Studies (each, a “Consortium Protocol”) and the oversight of those aspects of Consortium Studies that are within the purview of an IRB (“IRB Oversight”). This standard operating procedure (“SOP”) establishes the process for a Site to cede responsibility to the CU CIRB for the review of the Consortium Protocol and the IRB Oversight of each Consortium Study in which the Site will participate.

Capitalized terms used herein without definition are defined in Section II.

## **II. Definitions**

As used in this SOP, the following terms are defined as follows:

**Authorization Agreement:** an Authorization Agreement between Columbia and another institution pursuant to which such institution agrees to rely on the CU CIRB for the review of a Consortium Protocol and for IRB Oversight of the Consortium Study relating to such Protocol.

**CIRB Facilitator:** with respect to any Consortium Study, the CU employee who serves as the facilitator on behalf of the Consortium among the CU IRB, the Lead PI and the PIs and research coordinators at the Participating Sites.

**CIRB Liaison:** with respect to any Consortium Study, the CU IRB employee who serves as the liaison between the CU CIRB and the IRBs at the Participating Sites.

**Columbia:** as defined in Section I.

**Consortium:** as defined in Section I.

**Consortium Protocol:** as defined in Section I.

**Consortium Study:** as defined in Section I.

**CU CIRB:** as defined in Section I.

**CU CIRB Conflict of Interest SOP:** the Columbia University Central Institutional Review Board Standard Operating Procedure: Conflict of Interest and Financial Disclosure Requirements for Relying Sites, dated February 23, 2016, relating to the Consortium.

**CU CIRB Reporting SOP:** the Columbia University Central Institutional Review Board Standard Operating Procedure: Reporting Requirements for Relying Sites, dated February 23, 2016, relating to the Consortium.

**CU HRPO:** the Columbia University Human Research Protection Office.

**FCOI:** as defined in the CU CIRB Conflict of Interest SOP.

**FWA:** Federal Wide Assurance.

**IRB:** as defined in Section I.

**IRB Oversight:** as defined in Section I.

**Lead PI:** with respect to any Consortium Study, the PI at the primary Participating Site.

**Modifications:** Study-Wide Modifications and Site-Specific Modifications.

**Participating Site:** with respect to any Consortium Study, any Relying Site that is participating in such Study.

**PI:** with respect to any Consortium Study, the principal investigator at a Participating Site.

**Relying Site:** with respect to any Consortium Study, the institution at a Relying Site that has entered into an Authorization Agreement with Columbia.

**Reportable Event:** as defined in the CU CIRB Reporting SOP.

**RS Designee:** as defined in Section V (A).

**RS Information Sheet:** as defined in Section III(A)(1)(a).

**Site:** as defined in Section I.

**Site-Specific Consent Form:** as defined in Section VI (A)(7).

**Site-Specific Modification:** as defined in Section VI (A)(5)(a).

**SOP:** as defined in Section I.

**Study-Wide Modification:** as defined in Section VI (C)(1).

### **III. Process for Ceding Review**

#### **A. Relying Site Information**

- 1.** Each Site that wishes to participate in any Consortium Study must provide the CIRB Liaison with the following documentation to be incorporated into a research binder for such Site and used as a reference during the CU CIRB review process:
  - a.** A Relying Site Information Sheet (a "RS Information Sheet") that solicits Site-specific information, including: the Site name, description, location and FWA number, the name and contact information of the responsible institutional



## VI. CU CIRB Review

### A. Initial Review

1. The RS Information Sheet completed by each Relying Site that wishes to participate in a Consortium Study must provide all information necessary to inform the CU CIRB of the local research context as relevant to the Consortium Protocol relating to such Study. This information shall include specific requirements of state or local laws, regulations, policies, standards or other factors applicable to the Relying Site or such Consortium Study that would affect the Relying Site's conduct of such Study, including, but not limited to:
  - a. Requirements for enrollment of adults with impaired decision-making capacity;
  - b. Policies for surrogate consent, i.e., a description of the legally authorized representatives who can provide consent for individuals who lack capacity to provide their own consent to participate in research;
  - c. Age of majority;
  - d. Circumstances under which children may consent to their own participation in research (emancipated minors, mature minors, etc.);
  - e. Requirements for wards of the state or other special populations (child or adult) to participate in research;
  - f. Requirements for obtaining assent of children to participate in research;
  - g. Processes or requirements for enrollment of non-English-speaking participants;
  - h. Other information about the local consent process, including practices regarding recruitment and compensation of participants;
  - i. Requirements for confidentiality of specific types of health information;
  - j. Processes or requirements for incidental findings from research procedures such as imaging procedures;
  - k. Requirements for reporting compensation earned from research participation (e.g., for tax purposes);
  - l. Specific HIPAA requirements;
  - m. Requirements for data security plans involving the use, storage or transmission of electronic research data constituting sensitive data;
  - n. Requirements for research involving genetic testing; and
  - o. Special characteristics of the Relying Site or its community (i.e., Religious Affiliation).
2. Comments and information from each Participating Site relating to the Consortium Protocol and Consent Form template must be submitted in writing to the CIRB Facilitator within 10 business days of the date such Protocol and Consent Form template were received by the Participating Site. The CIRB Facilitator will in turn send such comments and/or information to the CIRB Liaison.
3. Upon receipt of the comments and/or information from all Participating Sites, the CU CIRB will formally review the Consortium Protocol, the Consent Form template, the information from the Participating Sites and any other required documentation. Depending on the proposed Consortium Study activities, the Consortium Protocol will either be reviewed by the CU CIRB via an expedited

review process or at a convened IRB meeting.

4. Following the CU CIRB review, the CIRB Liaison will work with the CIRB Facilitator to address any stipulations, modifications or requests required of the Participating Sites by the CU CIRB.
5. When all IRB review criteria are met, the CU CIRB will approve the Consortium Protocol. The approved Consortium Protocol and associated documents will describe the research activities to be conducted at all Participating Sites.
  - a. Whenever possible, modifications to the Consortium Protocol that are required by a particular Participating Site and acceptable to the CU CIRB (each, a “Site-Specific Modification”) will also be approved at this time.
  - b. Depending on the nature of the Site-Specific Modification, the Modification will either be reviewed by the CU CIRB via an expedited review process or at a convened IRB meeting.
6. The CIRB Liaison will send the approved Consortium Protocol and Consent Form template to the CIRB Facilitator, who will in turn send them to the RS Designee at each Participating Site and each approved Site-Specific Modification to the RS Designee at the applicable Participating Site.
7. Each Participating Site will be responsible for revising the Consent Form template that will be used at such Site (each, a “Site-Specific Consent Form”) to comply with any local requirements and sending a copy of such Consent Form to the CIRB Facilitator, who will in turn send them to the CIRB Liaison.
  - a. If only contact information has been updated, administrative review of the Site-Specific Consent Form will be conducted by the CU CIRB.
  - b. For Site-Specific Consent Forms with other non-substantive changes, expedited review may be conducted by the CU CIRB.
  - c. For Site-Specific Consent Forms with substantive changes, review by the convened CU CIRB will be required if such review was initially required for the applicable Consortium Protocol.
8. Once approved, the CIRB Liaison will return the approved Site-Specific Consent Forms to the CIRB Facilitator, who will in turn send them to each applicable Participating Site.

## **B. Continuing Review**

1. Continuing Review of any Consortium Protocol will be required prior to the expiration date of such Protocol as determined by the CU CIRB.
2. The CIRB Facilitator will notify each Participating Site with respect to the information required for continuing review, including updated information regarding the local research context. Each Participating Site will submit its information to the CIRB Facilitator no later than 60 days in advance of the expiration date.

3. The CIRB Facilitator will submit to the CU CIRB such continuing review information from all Participating Sites.
4. The CU CIRB will conduct continuing review and communicate the results thereof to the CIRB Liaison. The CIRB Liaison will send the approved continuing review documents to the CIRB Facilitator, who will in turn send them to the RS Designees at the Participating Sites.

### **C. Protocol Modifications**

1. The CIRB Facilitator will submit all Consortium Protocol modifications that apply to all Participating Sites (“Study-Wide Modifications”) and all Site-Specific Modifications to the CU CIRB for review.
2. The CU CIRB will review all Modifications except those providing for changes in research personnel (other than the PI) at a Participating Site and when such Modifications have been approved, will notify the CIRB Facilitator, who will in turn notify the RS Designees at the applicable Participating Sites.
3. The CU CIRB will not be responsible for the review of changes in Participating Site research personnel, except for changes in a PI. Participating Sites will report changes in research personnel (when the change does not include the PI).

### **D. FCOIs**

Any FCOIs relating to a Consortium Study will be determined and managed in accordance with the CU CIRB Conflict of Interest SOP.

### **E. Study Closure**

1. Upon completion of any Consortium Study, the CIRB Facilitator will submit relevant documentation for study closure to the CIRB Liaison for submission to the CU CIRB, including plans for the storage and disposition of specimens and data at each Participating Site, consistent with applicable law, policies and regulations.
2. The CU CIRB will maintain appropriate IRB records relating to each Consortium Study for a minimum of three years after the closure of such Study or longer if required by law, the applicable sponsor or the Participating Site’s institutional policies.

## **VII. General Concepts**

- A. Each Relying Site will be responsible for ensuring its ethical conduct of research,, educating and training its investigators and research staff to perform human subjects research in an ethical and compliant manner, maintaining documentation of all required training and of up-to-date relevant qualifications, credentialing and privileging for such individuals (as applicable), and ensuring that its investigators and research staff are informed of and comply with all applicable laws, regulations and standards.

- B.** Relying Sites must conduct relevant local ancillary reviews (e.g., radiation safety, biosafety, etc.) as required by their institutional policies. These reviews will not be monitored during the CU CIRB review and approval process, but research may not commence at any Participating Site until all ancillary reviews are completed and required approvals obtained.
- C.** The CU CIRB will be the Privacy Board for consideration of HIPAA matters that require Privacy Board review (i.e., partial or complete waivers of authorization). Each Consent Form will be a combined Informed Consent Document and HIPAA Authorization Form, when HIPAA Authorization is required. Relying Sites with policies that require a separate HIPAA form will inform the CU CIRB in the initial RS Information Statement. Use of a separate HIPAA form will generally be accepted if required by a Relying Site's policies.
- D.** IRB fees may be charged for the review and IRB Oversight of any Consortium Protocol that is funded by a non-government sponsor.

### **VIII. Reporting**

All reporting of Reportable Events by Relying Sites must be made in accordance with the CU CIRB Reporting SOP.

### **VIII. Record Keeping**

- A.** Each Relying Site will maintain appropriate records of all activities relating to each Consortium Study in which it participates for a minimum of three years after completion of such Study or longer if required by law, the applicable sponsor or such Site's institutional policies.
- B.** Upon request, each Relying Site will provide copies of such records to the CU CIRB.