Reliance by Columbia IRB on a non-Columbia IRB Review.

1. If a Columbia PI wishes to be involved in a multi-site study that is eligible for IRBshare, either the Columbia PI or the Columbia IRB may propose to the other that the Columbia IRB rely on another institution’s IRB that has posted a review on IRBshare (an “IRBshare Review”). Proposals from a Columbia PI should be sent to the attention of the IRB Assistant Director through an email to IRBoffice@columbia.edu. Neither the Columbia PI nor the Columbia IRB may initiate the process of relying on an IRBshare Review without the prior written approval of the other.

2. Regardless of whether the Columbia PI or the Columbia IRB proposes to use IRBshare, and prior to any decision to use IRBshare, the Columbia University IRB Executive Director (“IRB Executive Director”) must make an initial determination that reliance on the proposed IRBshare Review institution IRB is reasonable and will yield a review that is compliant with applicable regulations, accreditation standards, and the internal standards of the Columbia IRB. The determination shall be made through consideration of one or more of the following factors regarding the proposed institution:
   - Accreditation status, with requirement for accreditation for independent IRBs
   - Status as a CTSA institution
   - Federalwide assurance registered with OHRP and, if applicable, FDA
   - Review of compliance determinations by OHRP and/or FDA
   - Review of IRB policies and procedures, if available, for comparison with Columbia standards
   - Prior experience with the institution and/or its IRB
   - Consultation with the other institution’s IRB leadership
   - Consultation with Columbia’s institutional officials

   This determination does not require the review of the relevant IRBshare review(s) although that may be included. If more than one institution has posted an IRBshare Review, the IRB Executive Director shall select the institution(s) that he/she believes is most likely to yield a review that is compliant with applicable regulations, accreditation standards, and the internal standards of the Columbia IRB. If the IRB Executive Director concludes that reliance is not acceptable, the Columbia IRB will not use IRBshare and will instead continue its regular review process.

3. If the IRB Executive Director determines that it is reasonable to rely on another institution’s IRB, the IRB Executive Director must obtain the written consent of the Columbia PI to use IRBshare, assuming that all institutional and other local requirements are met.

4. If the IRB Executive Director determines that participation in IRBshare is reasonable and the Columbia PI consents in writing to such participation, the Columbia PI shall submit the study protocol (the “IRBshare Protocol”) in Rascal via the IRB’s Abbreviated
Submission Process. The submission shall include the following screens completed and/or information attached:

- General, Personnel and Subjects screens
- Investigational Products section, if applicable
- Human Specimen section, if applicable
- Protocol, grant application and/or investigational drug brochure
- Study instruments
- Consent documents

5. Prior to the completion of the Columbia IRB review process for a facilitative review, all other Columbia-specific requirements must be completed as applicable (e.g. Human Subjects Training, Radiation Safety, Biosafety, Cancer Center Protocol Review and Monitoring Committee, Conflict of Interest, etc.)

6. The IRB Executive Director or designee shall assign the study to an IRB Manager and an IRB Chair, Vice Chair or experienced IRB member, who shall complete an administrative and abbreviated scientific review, respectively. The reviewers shall be responsible for reviewing the documentation posted on IRBshare. The applicable Chair must enter evidence of approval into Rascal.

7. Upon satisfaction of all administrative items and documentation by the IRB Chair of approval, the protocol shall be approved in Rascal, and correspondence documenting the approval dates and IRB of Record shall be transmitted and posted in Rascal. Enrollment may commence upon receipt of the approval correspondence in Rascal.

8. The IRB Executive Director may at any point in the IRBshare Protocol review process determine that the IRB should not proceed with the IRBshare Review, in which case the applicable protocol shall be reviewed by the Columbia IRB under its usual procedures. The IRB Executive Director shall notify the Columbia PI of such determination.

9. Upon Columbia’s acceptance of the IRBshare Review, the expiration date of the IRBshare Review shall become the expiration date for the Columbia protocol.

10. Any Modification, Unanticipated Problem Report or renewal of the IRBshare Protocol must be reviewed and approved by the Columbia IRB, by full Board or expedited review, as appropriate.

11. Compliance oversight shall remain the responsibility of the Columbia IRB and audits may be conducted by the Columbia Compliance Oversight Team.
Reliance by a non-Columbia institution on a Columbia IRB Review.

1. If a Columbia PI wishes to be involved in a multi-site study that is eligible for IRBshare, either the Columbia PI or the Columbia IRB may propose to the other that the Columbia IRB serve as the IRB of record for other institutions who participate in IRBshare. Proposals from a Columbia PI should be sent to the attention of the IRB Assistant Director through an email to IRBoffice@columbia.edu. Neither the Columbia PI nor the Columbia IRB may initiate the process of posting a Columbia review in IRBshare without the prior written approval of the other.

2. Regardless of whether the Columbia PI or the Columbia IRB proposes that the Columbia IRB serve as the IRB of record and prior to any decision to serve as IRB as record, the IRB Executive Director must make an initial determination that doing so is reasonable and consistent with Columbia’s research objectives. The determination shall be made through consideration of one or more of the following factors:

   - The agreement of the sponsor for use of IRBshare;
   - The agreement of the sponsor for proprietary protocol documents to be posted in IRBshare;
   - The timing of the Columbia IRB review of the study;
   - The delineation of responsibilities between the Columbia IRB, as the IRB of record, and the sites that would rely on the Columbia IRB, and the ability of Columbia to fulfill its responsibilities.

3. If the IRB Executive Director determines that it is reasonable for the Columbia IRB to serve as the IRB of record, the IRB Executive Director must obtain the written consent of both the Columbia PI and the sponsor to use IRBshare, assuming that all institutional and other local conditions are met.

4. If the IRB Executive Director determines that participation in IRBshare as IRB of record is acceptable and the Columbia PI consents in writing to such participation, the Columbia PI shall submit the study in Rascal, completing a full application and clearly indicating that Columbia wishes to serve as the IRB of record for other institutions.

5. Review by a convened Columbia IRB shall proceed as usual following preliminary review by IRB staff. During the initial Columbia review, when the IRB is evaluating the clinical trial from the perspective of Columbia as a study site, the possibility that the IRB may serve as IRB of record for other institutions should be raised. The IRB shall then have the opportunity to comment on any concerns they may have about the IRB serving in this role, consent to the possibility of the Columbia IRB serving as IRB of record for other institutions, and/or recommend special conditions.

6. Upon approval by the Columbia IRB, correspondence that documents the approval date and an acknowledgement that the Columbia IRB may serve as the IRB of record for other institutions shall be posted in Rascal. Enrollment at Columbia may commence upon receipt of the approval correspondence in Rascal.
7. The study protocol, IRB application, investigator’s brochure, recruitment document(s), consent form(s), redacted meeting minutes and approval letter, to the extent relevant to the study, shall be posted in IRBshare.

8. The IRB Executive Director may at any point determine that the Columbia IRB should not serve as the IRB of record. The IRB Executive Director shall notify the PI of such determination. Documents that have been posted to IRBshare shall remain posted even if the offer to serve as IRB of record has been withdrawn.

9. The expiration date for the Columbia protocol shall become the expiration date for any institution relying upon the Columbia IRB review.

10. The Columbia IRB will not serve as the IRB of record in connection with any Modification, Unanticipated Problem Report or renewal relating to the study on behalf of any non-Columbia institution.

11. Compliance oversight for each reliant institution shall remain the responsibility of the respective institution.