

Step 1: Submit CU IRB Reliance Request Form
https://cumc.co1.qualtrics.com/jfe/form/SV_cJ9WZhuNgRIpLut

Step 3: If CU agreed to rely on external IRB, a tracking protocol should be submitted in Rascal with the following docs attached:

- Initial IRB approval letter from the Reviewing IRB,
- Approved master protocol,
- Approved master study instruments/recruitment material,
- Approved master consent form templates,
- Tracked and clean Columbia-specific consent forms,
- Local context form,
- and Reliance agreement.

Step 7b: Respond to tasks and resubmit

Step 5: Assign event to HRPO Reviewer -> Study team receives email from Rascal signaling event is under review

Step 4: Protocols TriageD Daily -> Assigned to Fac Rev if relying on External IRB

Step 6: Conducts local review of submission confirming all local requirements (state laws, local policies) are satisfied.

Step 7a: Route reliance agreement for signature by Institutional Official

Await clearance of Ancillary Reviews (if applicable);
Await Execution of Reliance Agreement (if applicable)

Step 9: Coordinate with Lead Site for Submission to the Reviewing IRB

Await approval from Reviewing IRB for CU as a study site.

Step 10: Resubmit in Rascal with the following attached: approval from Reviewing IRB for CU as a site and docs approved on CU behalf (with stamp from Reviewing IRB, if applicable)

Step 8: Return Submission to Study Team with permission to submit CU Site Application to Reviewing IRB

Step 12: Approve Protocol in Rascal

Step 13: Release Determination Letter

Step 11: Reviews resubmission to confirm required materials are attached

Are required materials missing?

11a. Log in for approval

Are there documents missing or does the submission not align with local requirements?

6a. Log in for approval

6b. Return to study team with lists of tasks to address

11b. Return to study team

Potential COI review by RCT team

Cleared

Go to Step 8

Appendixes are reviews by respective committees:

- (1) Appendix A: (biosafety@columbia.edu)
- (2) Appendix D (lasersafety@columbia.edu)
- (3) Appendix E: (occusafety@columbia.edu)
- (4) Appendix H: (rso-clinical@columbia.edu)
- (5) Appendix I: (controlled@columbia.edu)
- (6) Appendix M: (biosafety@columbia.edu)
- (7) Appendix R (mri-appendixrs@lists.cumc.columbia.edu)

Not Approved

Approved

Go to Step 6b

Go to Step 8

PRMC

Not Cleared

Cleared

Go to Step 6b

Go to Step 8