10/16/2026

Columbia University (CU) and New York State Psychiatric Institute (NYSPI) Workflow for IRB Reliance and Related Processes

The following procedures are applicable **when RFMH/NYSPI is the Prime Awardee, and CU is the Subawardee.**

Early coordination is essential to ensure that each institution's research activities and responsibilities are clearly defined and aligned across the protocol, Scope of Work, and subaward. This coordination also allows Columbia to determine promptly whether it is engaged in human subjects research and, if so, to complete the required IRB reliance and related institutional processes.

Required Documents for Columbia HRPO's Review

To assist Columbia HRPO in determining whether it is engaged in the research and to support any required IRB reliance process, the following documents should be provided as early as possible:

- ✓ NYSPI's final protocol for review by CU HRPO liaison to determine CU engagement
  - The protocol should be the same version that will be submitted to Advarra and Rascal for ceding review.
  - The protocol should clearly delineate roles, responsibilities, and activities of NYSPI and CU faculty, research locations/sites, and data flow, as applicable.
- ✓ Finalized Informed Consent Form with Columbia-specific language, HIPAA authorization provisions, and data sharing, as applicable
- ✓ Draft of subaward agreement or Scope of Work
- ✓ Rascal Proposal Tracking Number for inbound subaward to CU
- ✓ Partially executed reliance documents.
- ✓ NYSPI – CU Reliance Master Tracker is updated by NYSPI's central research administration with new grants/protocol requests.

Scenario 1: New Grant and Protocol with Columbia Subaward

NYSPI or CU Research Team provides the final protocol to CU HRPO (irbreliance@cumc.columbia.edu) before submission to Advarra for CU determination or engagement and alignment with the Scope of Work.

If Columbia is engaged:

1. CU PI/research team submits in Rascal a request to cede IRB review with the following documents:
   - the Advarra- contingently approved protocol. The protocol should be the same protocol initially submitted for engagement determination provided no changes have been made.
   - informed consent form (ICF) (if applicable) and;
   - partially executed reliance documents provided by NYSPI/Advarra.

2. CU HRPO executes the study-specific reliance agreement and provides all required reliance materials to the Research team for submission to Advarra.
3. After the reliance agreement has been executed, the CU PI/Research team provides the final Advarra approval letter in RASCAL. CU HRPO will then issue its approval letter.

Note: Submission to Advarra may proceed in parallel with the submission in Rascal to cede review. However, Advarra approval of Columbia's participation is contingent upon execution of the reliance agreement and protocol verification.

Scenario 2: Previously Paused Grants and Protocols approved for Re-start

NYSPI or CU Researcher/ team provides the final protocol and Scope of Work to CU (irbreliance@cumc.columbia.edu) for CU determination of engagement. For older protocols, CU will need to reassess whether it is engaged.

If Columbia is engaged:

1. CU PI/research team submits in Rascal a request to cede IRB review with the following documents:

    - current approval letter from Advarra
    - approved protocol, and
    - informed consent form (ICF) (if applicable)

2. CU HRPO will complete its local context review including ICF review and executes the reliance agreement.
3. Advarra may then approve Columbia's participation after the reliance agreement has been executed

    Note: Submission to Advarra may proceed in parallel with the submission in Rascal to cede review. However, Advarra approval of Columbia's participation is contingent upon execution of the reliance agreement and protocol verification.