Columbia University Human Research Protection Office/IRBs

Newsletter #13 – April 2025

Policy/Guidance

- The IRB Noncompliance in Human Subjects Research Policy has been updated. The changes are effective April 2, 2025 and affect most sections of the policy, e.g., adding or revising definitions, describing authority to suspend or terminate IRB approval, and adding detail to or revising processes. It is recommended that researchers, HRPO staff, IRB members and other stakeholders thoroughly read the entire policy due to the scope of the changes.

Process for IRB Review

What is facilitated review?

When Columbia University (CU) relies on an external IRB to review protocols, CU remains responsible for the conduct of the research at Columbia and for ensuring compliance with institutional policies for the protection of human subjects and other components of its Human Research Protection Program, e.g., approval from applicable ancillary committees such as the Institutional Biosafety Committee or the MR Safety Committee and compliance with University data security policies. In addition, it is critical that the Columbia Research Administration Offices such as the Human Research Protection Office (HRPO) and Sponsored Projects Administration (SPA) are aware of and can provide proper oversight throughout the conduct of the research. As such, once it has been established that CU will rely on another IRB through the execution of a reliance agreement, a protocol must be submitted in Rascal.

Upon submission of the application in Rascal, the HRPO IRB Specialists will start the administrative review, aka *Facilitated review,* of the protocol and associated documents, to confirm that all Columbia requirements to conduct human subjects research are met. They may request revisions, similar to a standard IRB review process. However, the protocol will not be routed to review by a CU IRB to confirm the IRB approval criteria listed at 45 CFR 46.111 and other applicable regulations are met, as those will be confirmed by the external reviewing IRB. The Facilitated review will be finalized and approved in Rascal upon verification of the final IRB approval by the external reviewing IRB for Columbia's participation, which must be documented by attachment in Rascal of an approval letter from that IRB.

Any questions related to **reliance agreements** should be directed to IRBreliance@cumc.columbia.edu.

- When human subjects research is involved, Columbia applicants **to the NIH or other federal agencies** must complete a **Columbia University IRB Reliance Request Form** and submit it to the HRPO **prior to proposal submission** if their application proposes to:
  - Conduct non-exempt human subjects research; **AND**
  - Conduct research at more than one site in the United States.

The HRPO will respond back indicating whether a Single IRB is required, confirming or clarifying which institution will serve as the Single IRB, providing a letter of support, and providing the costs for the relying institutions, if Columbia is serving as the Single IRB.

- For more information, see HRPOs' Single IRB Information webpage.

Questions related to **Facilitated review of protocols** reviewed by an external IRB should be directed to the HRPO Reliance team, which includes four members:

- Senior IRB Specialist Tasha Smith [ts2257@cumc.columbia.edu/(929) 996-1455] and,
- IRB Specialists:
  - Julissa Borbon-Marcelin [jgb15@cumc.columbia.edu/(929) 746-0558]
  - Mariella Hernandez [mh4382@cumc.columbia.edu/ (917) 580-2151]
  - Meenakshi Seetharaman [ms7059@cumc.columbia.edu/ (929) 996-1456.].

Until recently, protocols undergoing Facilitative review were assigned to IRBs 1-5 and IRB EXP. They have just been transferred to a queue specific to the Facilitated review team, which will enable more efficient processing. The committee Assignment in the Protocol Overview page in Rascal will show "Fac Review" for these protocols.

Short Form Consent Process

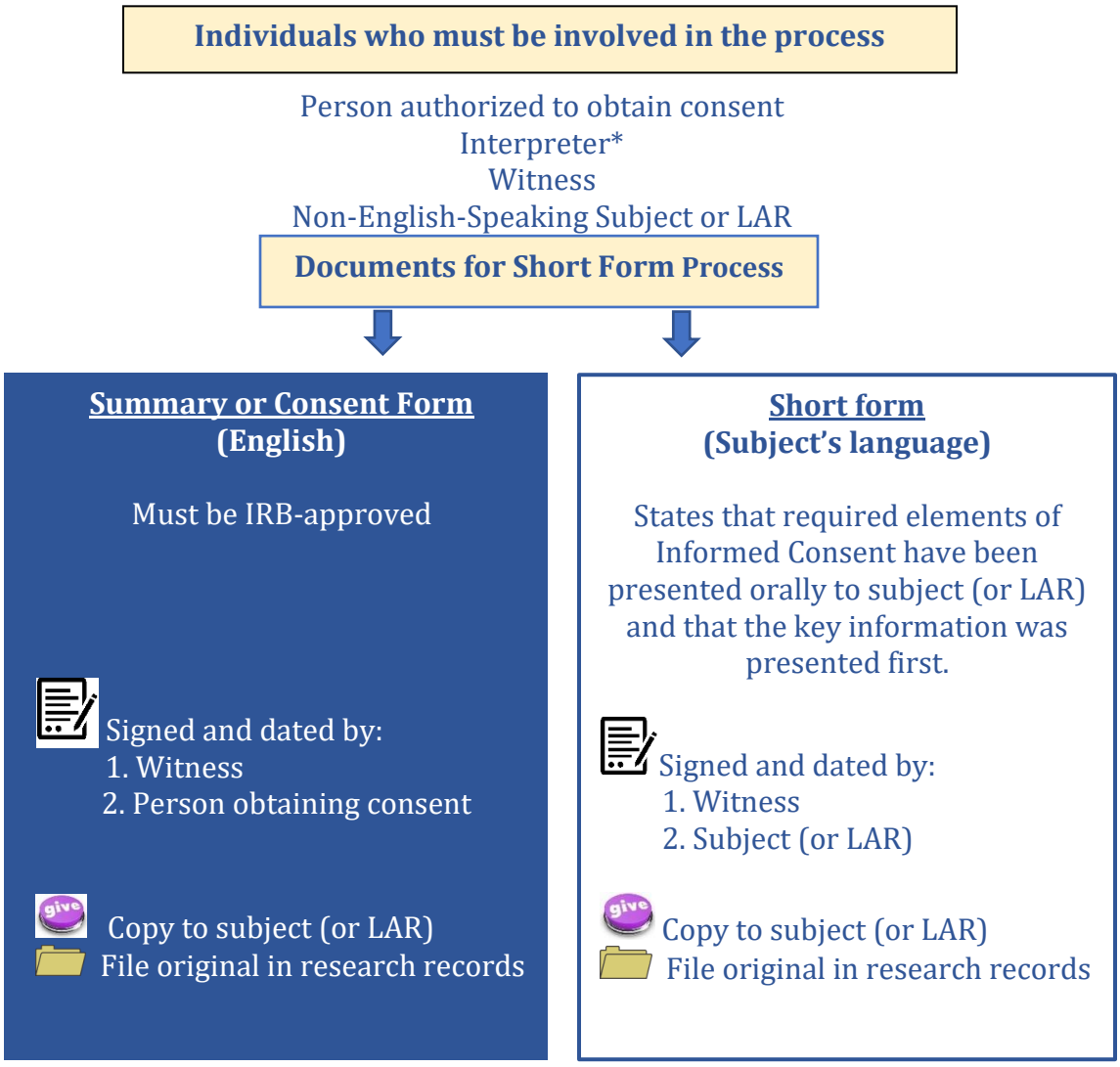
The Columbia University (CU) policy on Enrollment of Non-English-Speaking Subjects in Research describes the procedures to be followed when using the short form process.

The regulations for the protection of human subjects require that informed consent information that is given to the subject or the legally authorized representative (LAR) be presented "in language understandable to the subject or the legally authorized representative". The regulations also permit the use of a short form written informed

consent form to document that the elements of informed consent have been presented orally to the subject or the subject's LAR.

Obtaining consent with the use of a short form is acceptable for the enrollment of an **unexpected non-English speaking subject**, when an IRB-approved consent form in the language spoken by the research subject is not available. Short form templates in several languages are available on the HRPO/IRB website for use. The contact information and title should be added to the short form template, which should be used verbatim and does not need IRB approval of that document.

Short Form Process for Non-English-Speaking Subjects



**An interpreter is needed if the person authorized to obtain consent is not fluent in the language spoken by the subject. The interpreter may also serve as the witness if he/she is a professional* interpreter. *Note that NYPH interpreters are not permitted to serve as a witness per NYPH policy.*

Upcoming Presentations

Rascal Submission Workshops (via Zoom):

Below is the list of upcoming workshops. As per our recent announcement, additional workshops have been scheduled for the summer 2025. To register, please follow the link provided below for each workshop:

Monday, April 28, 2025: 3:00 PM - 4:00 PM
IRB Rascal Workshop: Consent Form Builder

Tuesday, May 27, 2025: 3:00 PM - 4:00 PM
IRB Rascal Workshop: New Protocol - More than Minimal Risk

Monday June 23, 2025: 3:00 PM - 4:00
IRB Rascal Workshop: Renewal - Annual Report - Modification

Monday, July 28, 2025: 3:00 PM - 4:00 PM
IRB Rascal Workshop: New Protocol - Minimal Risk

Monday, August 25, 2025: 3:00 PM - 4:00 PM
IRB Rascal Workshop: Consent Form Builder

Recent Presentations/Announcement

- Monthly Investigator Meetings (MIM):

  Slides of recent MIM presentations are available on the HRPO website (Informational Materials) at https://research.columbia.edu/human-subjects-protection-training-program-educational-resources

- All HRPO newsletters are available on our website with a list of topics that are addressed in each newsletter.

HRPO Staff: Contact Information

HRPO Directory

HRPO main phone line: 212.305.5883
This line is answered by HRPO Staff during normal business hours.
For calls outside of normal business hours, please leave a message and HRPO Staff will respond on the next business day.

Tips on How Best to Contact HRPO Staff

If you have not yet submitted the protocol in Rascal and/or have specific questions about how to submit a new protocol	For research originating from CUIMC: Please contact IRB Liaison, Tasha Smith, at ts2257@cumc.columbia.edu or 929-996-1455. For research originating from the Morningside and Lamont-Doherty campuses: email askirb@columbia.edu.
If you need a determination letter posted in Rascal or documents stamped for an approved event (these documents are expected to be available approximately one week following approval of the event)	Add a protocol-specific correspondence in Rascal. Or Email the IRB Specialist assigned to your protocol (see above HRPO Directory).
If you have questions about the conduct of an IRB-approved study or to clarify an IRB request before resubmission	Add a protocol-specific correspondence in Rascal. **Or** Email your questions to the HRPO team assigned to your protocol (see above HRPO Directory) or ask for a phone consultation.
General questions not related to a specific protocol	Email irboffice@columbia.edu.
Questions about reliance	Email irbreliance@cumc.columbia.edu.
Questions about emergency use or subject safety issues	Contact Laurence Butaud-Rebbaa at lb2643@cumc.columbia.edu or 917-679-3867.
Questions about an issue related to CITI courses	Contact Mark Leneker at ml2307@cumc.columbia.edu or 917-634-0625. Requests to update CITI training information in Rascal should be made via email and include the name of the person whose training requires updating, their UNI, and the name of the specific training.

Please contact us with any questions and/or feel free to provide us with feedback at irboffice@columbia.edu.