

Columbia University Human Research Protection Office/IRBs

Newsletter #12 – March 2025



When to submit a Closure Report?

A Closure Report must be submitted to the IRB in Rascal for each study when:

- All research participants have completed all study-related interventions and procedures, including any follow-up;
- The research team has completed all data collection and/or analysis of identifiable data for which Columbia is responsible; or,
- When the study is closed prematurely or for any reason by the sponsor, Columbia has no remaining responsibilities.

In cases when Columbia University is the lead institution with responsibility for the research conducted at other sites, the closure report should not be submitted until all study procedures are completed at all sites, and any remaining lead institution responsibilities are satisfied.

For additional information on how to submit a Closure report in Rascal, please follow the steps described on the [HRPO website](#), under the “Maintaining IRB Approval” page.



Automated stamping of IRB-approved documents

This is a reminder that any document that will be given to, used with, or read to a research participant (e.g., consent/assent form, script, questionnaires, instructions, dose diaries, recruitment materials) must be stamped* as approved for use. In general, such documents are pre-stamped by HRPO staff during the administrative pre-review process and stamped automatically upon approval of new Protocols and Renewals. At the time of approval of a Modification, only updated documents submitted with the Modification will be stamped.

Below are instructions for facilitating quick processing of your stamped materials. This automatic feature in Rascal can only be used with documents that are in PDF format, are unsecured and don't require a password to open.

Thank you for checking/confirming the following requirements are being followed before submitting your event for review:

- Letter size documents may be converted to PDF through use of Adobe Professional or Microsoft Office software, or through scanning.
- The Rascal generated stamp requires a 1-inch high by 4-inch-wide space in the lower right-hand corner of your PDF document. Every effort should be made to ensure that your document has enough room for this stamp and to leave this space open when formatting your study materials. The stamp has been designed to be translucent if information cannot be removed from this area of your document.
- When attaching documents to your Rascal submission, please name documents in such a manner that the type of document (e.g., consent form), and when applicable, version date, are clear, e.g., “consent form v3”. The ‘Document Identifier’ is the information that will be listed in approval correspondence and letters from the IRB to identify the document that was approved.

*Documents that will not require a stamp (e.g., external protocols, documents demonstrating tracked changes, etc.), because they are not intended to be “approved”, are not required to be submitted in PDF format. In addition, active subject-facing documents reviewed and approved by an external IRB will not be stamped in Rascal with the CU IRB approval stamp upon approval of the initiation of the study at Columbia.



Recent Enhancements made to the Rascal Human Subject Module

Under the Hazmats Attachments Page: The Help text next to each appendix option  was updated with current information.

Upcoming Presentations



Rascal Submission Workshops (via Zoom)

To register, please follow the link provided below for each workshop:

- Monday, March 24, 2025, 3:00 PM - 4:00 PM
[IRB Rascal Workshop: New Protocol involving Minimal Risk Procedures](#)
- Monday, April 28, 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 Promotions

We are pleased to announce the following staff promotions and team changes that have occurred since our last update:

- Pilar Borvice, promoted to Senior Manager of IRB1 & IRB 2
- Daniel Melvin, promoted to Assistant Manager, IRB 2
- Janelle Ortega, promoted to Manager, IRB EXP
- Qiana Quiles, Senior Manager, is now overseeing IRB 5 in addition to IRB 4.

New HRPO Staff

We welcome the following staff members who have recently joined our team:

- Katherine Greenberg, IRB EXP Specialist
- Dixia Patel, IRB 1 Specialist

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

<p>If you have not yet submitted the protocol in Rascal and/or have specific questions about how to submit a new protocol</p>	<p>For research originating from CUIMC: Please contact IRB Liaison, Tasha Smith, at ts2257@cumc.columbia.edu or 929-996-1455.</p> <p>For research originating from the Morningside and Lamont-Doherty campuses: Please email askirb@columbia.edu</p>
<p>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)</p>	<p>Add a protocol-specific correspondence in Rascal Or Email the IRB Specialist assigned to your protocol (see above HRPO Directory)</p>
<p>If you have questions about the conduct of an IRB-approved study or to clarify an IRB request before resubmission</p>	<p>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</p>
<p>General questions not related to a specific protocol</p>	<p>Email irboffice@columbia.edu</p>
<p>Questions about reliance</p>	<p>Email irbreliance@cumc.columbia.edu</p>
<p>Questions about emergency use or subject safety issues</p>	<p>Contact Laurence Butaud-Rebbaa at lb2643@cumc.columbia.edu or 917-679-3867</p>
<p>Questions about an issue related to CITI courses.</p>	<p>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.</p>

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