Columbia University Human Research Protection Office/IRBs

Newsletter #9 – August 2024

Policy/Guidance

The IRB [Incidental Findings from Imaging Procedures Conducted for Research Studies Policy](#) has been updated. The type of images to which the policy applies has been clarified. It applies to studies conducted by Columbia University investigators in which the imaging procedures produce images that provide anatomic or physiological data (Required Review Images).

Submission of a new protocol versus a new modification

Any changes to an IRB-approved protocol must be submitted to the IRB promptly before these changes can be initiated. Most proposed changes including changes in the conduct of the research [e.g. changes to eligibility criteria, changes to a procedure, etc.] should generally be submitted via a modification in Rascal.

When substantive changes are proposed, it is important to assess before submitting to the IRB if they significantly change the research focus.

In general, **significant changes** to:

- the aims of the research,
- the study rationale,
- the study design,
- the study population,
- the addition of new funding proposal associated with new research aims or new analysis

will require the submission of a separate **new protocol** in Rascal. Please contact the HRPO staff who support the IRB to which the initial protocol is assigned if you need to confirm whether the submission of a new protocol is warranted. This assessment may facilitate review of the proposed changes and will avoid multiple returns of an event.

HRPO Staff Updates

- **Congratulations** to:
  - Ashley Halinski, promoted to Assistant Director for IRB Management (expedited and exempt research)
  - Adrian Gloss Reyes, promoted to Assistant Manager, IRB 4
  - Jason Sanchez, promoted to Assistant Manager, IRB 5

- **Welcome** to Diana Bae who recently joined the HRPO team as IRB Specialist for the convened IRBs

- Julissa Borbon-Marcelin, IRB Specialist, transitioned from IRB 3 to Reliance effective July 29, 2024.
- Avanish (Avi) Arjune, IRB Specialist, transitioned from IRB 4 to IRB 3 effective July 29, 2024.

The following open HRPO positions are posted on the Columbia [Careers webpage](#):
   · [Senior IRB Specialist-Manager](#) (2)

Upcoming Presentations

Workshops (via Zoom): To register, please follow the link provided below for each workshop:

- Monday, August 26, 2024, 3:00 PM-4:00 PM
[IRB Rascal Workshop: Consent Form Builder](#)

- Monday, September 23, 2024, 3:00 PM-4:00 PM
[IRB Rascal Workshop: New Protocol involving more than minimal risk procedures](#)

- Monday, October 28, 2024, 3:00 PM-4:00 PM
[IRB Rascal Workshop: Renewal/Annual Report/Modification](#)

- Monday, November 18, 2024, 3:00 PM-4:00 PM
[IRB Rascal Workshop: New Protocol involving minimal risk procedures](#)

- Monday, December 16, 2024, 3:00 PM-4:00 PM
[IRB Rascal Workshop: Consent Form Builder](#)

Recent Presentations

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

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: Please 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
New information: **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.