HRPO Update

Garcia, Karla P. <kg100@CUMC.COLUMBIA.EDU>

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To:cuhs-irb@LISTS.CUMC.COLUMBIA.EDU <cuhs-irb@LISTS.CUMC.COLUMBIA.EDU>

Dear Colleagues,

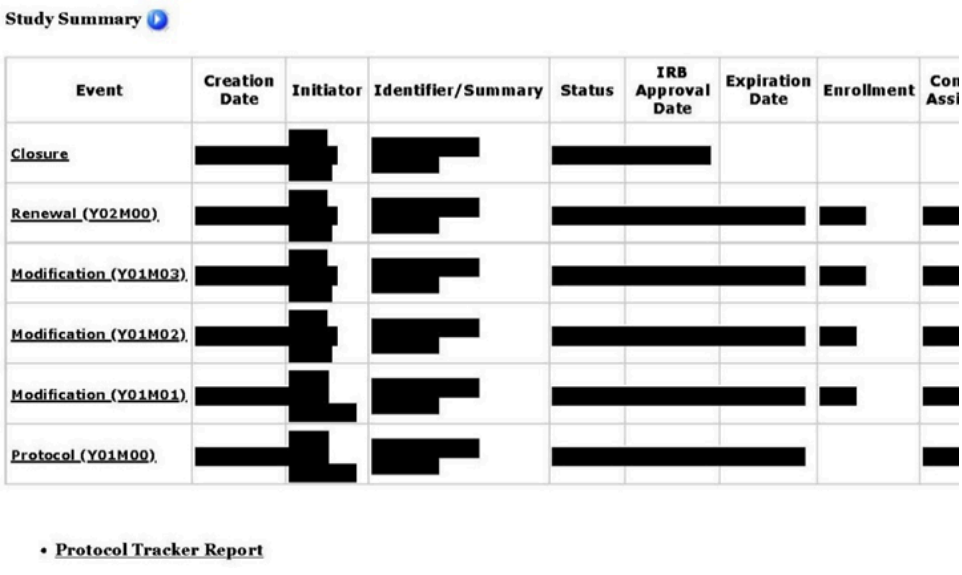
The Human Research Protection Office (HRPO) is excited to provide the following updates:

Policy/Guidance

- **Collaborative Research with a Non-CU Investigator** who is not involved as an affiliate of a research institution requires an Individual Investigator Agreement (IIA). Information about this agreement and the request for an IIA checklist have now been posted on the website. Refer to https://research.columbia.edu/human-research-policy-guide, **#8.**
    - Please note that this agreement would not be appropriate when an organization that does not usually conduct research and does not have an IRB is involved in collaborative research. In such cases, Columbia may opt to provide IRB services for the organization through a reliance agreement or the organization may obtain IRB review from a non-Columbia IRB. Please contact Tasha Smith (ts2257@columbia.edu) for guidance in these situations.
- **Change in Principal Investigator (PI):** The information communicated for this topic in our previous update has been included in a guidance document that is available at Guidance on Changes in Principal Investigator (PI)

Did you know the following resource is available in Rascal?

- A **Protocol Tracker Report** is available for each approved IRB protocol under the chart on the Protocol Overview page. It provides a summary of each Event submitted to the IRB, including a list of the new documents that were attached for that Event.



Facilitating IRB Review

- **Training requirements**: All personnel engaged in human subject research must have completed the following training requirements, as relevant to the research study and their role, before participating in study procedures.

  - **HIPAA** training [TC0019] - required for all research originating from the medical center campus, and for research originating from other campuses that involves PHI.
  - **HSP (Human Subject Protection) training** [TC-0087] including Research with Minors and/or FDA-regulated Research, as applicable – required for all personnel involved in human subjects research. Completion of the HSP basic course is valid for 3 years, after which the HSP refresher training is then required every 3 years.
  - **S-I (FDA Requirements of Sponsor-Investigators) training** [TC0096] - required for Principal Investigators (PI) and Investigators if they are the holder of an IND or IDE
  - **Clinical Research Coordinator** [TC0098] - required for greater than minimal risk studies for Clinical Research Coordinators or personnel with the following similar roles such as Regulatory Coordinator, Research Nurse, Data Manager, or Research Assistant.
  - **Informed Consent in genetic research** [TC3050] - required for research coordinators who are obtaining consent for genetic research that is subject to NYS 79-l and for which results are proposed to be returned.
  - **GCP training** [TC3450 or third-party training] - required for personnel on NIH-funded clinical trials. Completion of the GCP basic course is valid for 3 years, after which the GCP refresher training (TC3452) is then required every 3 years.

Researchers should access the training courses via the "**Training Center"** module in Rascal. Once the course is completed, the date of completion is updated in Rascal (personnel section). FYI, "TC" number refers to the course number in Rascal but these numbers are not reflected on the datasheet.

Note that an event will not be approved until **the principal investigator** has completed the required applicable trainings. If other members of the research team have not satisfied all the training requirements, they may not participate in the conduct of the study until all training requirements have been satisfied.

HRPO Staff: New Location and Contact Information

Our office has moved **from the 1st to 2nd floor of 154 Haven**. As a result, all staff phone numbers have changed. The new numbers are listed in the HRPO Directory below.

HRPO Directory

Note that the HRPO main line number remains the same: 212.305.5883.

Tips on How Best to Contact HRPO Staff

If you have never submitted a 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 HRPO team assigned to your protocol (see above HRPO Directory)
If you have questions about the conduct of an IRB-approved study or to clarify one IRB request before resubmission.	Add a 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

Correction to information communicated during our last MIM: HRPO staff members should not be contacted through Microsoft Team (call or chat).

New HRPO Staff

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

- Karla Garcia, Operations Manager
- Diana Lozano, IRB 1 Specialist
- Michael Sheffey, IRB EXP Specialist

Note that the following staff members are no longer with the HRPO: Kimberly Bazylewicz, Diana Lesmes and Catie Singer. We wish them well in their new endeavors.

The following open HRPO positions are posted on the Columbia Careers webpage:

- Senior IRB Specialist-Manager
- IRB Specialist
- Operations Specialist
- Quality and Data Specialist

Upcoming presentations

Monthly IRB Investigator meetings (MIM) will resume later this year. Research personnel are encouraged to attend the Columbia Town Halls, New NIH Policy on Data Management & Sharing, What Researchers Need to Know.

- Session 1: Thursday, October 27, 2022; 12:00pm – 1:00pm EST
- Session 2: Friday, November 18, 2022; 2:00pm – 3:00pm EST
- Session 3: Thursday, December 1, 2022; 12:30pm – 1:30pm EST

For further information, please contact Steph Scott (SPA): stephanie.scott@columbia.edu.

Rascal IRB workshops are being scheduled monthly for the rest of the calendar year, generally to occur on the last Monday of each month. A separate announcement and link to registration will be sent soon.

Recent presentations

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

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

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This message has been sent by the Columbia University Human Research Protection Office.

If you have questions, please contact us:
Medical Center: phone: 212.305.5883; e-mail: irboffice@columbia.edu
Morningside: phone: 212.851.7040; e-mail: askirb@columbia.edu

In addition, please visit our website for additional information: https://research.columbia.edu/irb

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