Columbia University Human Research Protection Office/IRBs

Newsletter#7 – March 2024

Policy/Guidance

- Updated Guidance for the Classification of Quality Improvement Activities versus Research with Human Subjects has been released. The guidance includes a tool to assess the differences between QI and research with human subjects.

Lyft Car Concierge Program for Research Participants

Columbia University offers a Lyft car concierge program for research participants. Please follow the link to Lyft's Concierge platform for the detailed process for booking rides via a web-based portal. Rides can be requested for riders who don't have the Lyft app and for riders who do not have access to the Lyft dispatching platform themselves. This service can only be used for non-employee research participants.
Departments interested in using this service may contact columbiatravel@columbia.edu to establish the Lyft account. Once the account has been established, the program can be self-managed by the Department program Administrator via the Lyft Portal.

Description of Lyft service in the IRB application:
The use of Lyft service program should be described in the procedures section in Rascal unless it is described in the standalone protocol. For those studies that are industry-sponsored and offer Lyft or a similar service, it should be confirmed that identifiable participant information will not be provided to the sponsor.

The consent form should describe the option and offer the opportunity to consent to the use of the service and sharing of their contact information with Lyft for the specific study. The service allows research teams to schedule the rides for participants, or participants may use the app to schedule their ride. If the latter option is proposed or offered, additional information about the optional use of the app should be provided, including whether there will be any costs to participants for using the app and providing instructions on how to use the service. Such instructions may be provided in a standalone document.

Facilitating Efficient IRB Review: New feature in Rascal

An algorithm incorporating the IRB training requirements* has now been integrated into the Rascal Human Subjects Module. It is used to notify initiators if any research personnel listed in the IRB protocol have not completed all required trainings. A warning message is automatically prompted to researchers in the personnel section based on the information included in the Rascal application. HRPO staff have access to this information when reviewing IRB protocols. These training validations will not prevent an Investigator from submitting an Event in Rascal if a required training is missing. The functionality paves the way for further development to automate approval of personnel changes in the near future.

*IRB Training Requirements:

- 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 [TC0087] including Research with Minors and/or FDA-regulated Research, as applicable – required for all personnel engaged in human subject research.
- S-I (FDA Requirements for Sponsor-Investigators) training [TC0096] - only required for Principal Investigators (PI) and Investigators holding an IND or IDE.
- Clinical Research Coordinator [TC0098] - required for greater than minimal risk studies for Clinical Research Coordinators or personnel with roles such as Regulatory Coordinator, Research Nurse, Data Manager, or Research Assistant.
- Informed Consent in genetic research [TC3700] - 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 to participants.
- GCP training [TC3450 or third-party training]/GCP refresher training (TC3452) - required for personnel on NIH-funded clinical trials.

HRPO Staff: Contact Information

HRPO Directory

HRPO main line number: 212.305.5883.

This phone line voicemail is checked daily – Please leave a message

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 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

HRPO Staff Updates

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

- Senior IRB Specialist-Manager (2)
- IRB Specialist (2)

Note that Diana Lozano, IRB 1 Specialist, and Elaine Baulsir, IRB 4 Specialist, are no longer with the HRPO. We wish them well in their new endeavors.
Michael Minyetty has now joined the IRB 1 team.

Upcoming Presentations

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

IRB Rascal Workshop: New Protocol - Minimal Risk
Mon, March 25, 2024, 3:00 PM - 4:00 PM

IRB Rascal Workshop: Consent Form Builder
Mon, April 22, 2024, 3:00 PM - 4:00 PM
Recent Presentations

Monthly Investigator meetings (MIM)
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.