Columbia University Human Research Protection Office/IRBs

Newsletter #16 – October 2025

Policy/Guidance

The links to the released Guidance for the Classification of Quality Improvement (QI) Activities versus Research with Human Subjects and QI Program Evaluation and Self-Certification Tool have recently been posted on the HRPO website. The guidance, effective August 2025, was developed jointly by the NYP Quality Department, the Columbia University IRB, and the Weill Cornell Medicine IRB and it applies across all three organizations. It replaces the CU IRB Guidance for the Classification of QI versus Research with Human Subjects. The Self-Certification Tool to determine whether an IRB consultation or submission is necessary for a formal IRB determination was updated to document the researcher's assessment.

IRB Applications

When preparing an IRB application, investigators should ensure that all sections are detailed and clearly written. Each application must include **specific descriptions** of the following:

- Study aims, rationale, research questions and measurable objectives
- Methodology, including statistical assessments when relevant
- Research procedures, including monitoring for risk and benefits
- Subject population
- Recruitment procedures and informed consent requirements
- Data and safety management.

Protocols should address defined research questions. **Broad protocols that permit the addition of multiple future analysis, or don't present defined goals and analyses, do not meet the IRB submission requirements and will be returned by the IRB.** This

guidance applies to standard study designs. Adaptive clinical trials, which are designed to allow for pre-planned adaptive changes to the conduct of research, and do not always have very defined analyses, are not included in this description.

Specific goals will allow the IRB to assess the research risk-benefit, scientific merit or relevance and avoid burdening subjects.

As a reminder, to approve research, an IRB must determine that all the following criteria are satisfied:

1. **Risks to subjects are minimized**, through sound research design and by avoiding unnecessary exposure to risk.
2. **Risks are reasonable in relation to anticipated benefits**, considering the importance of the knowledge expected to result.
3. **Selection of subjects is equitable**, with attention to the study's purpose and the setting in which it is conducted.
4. **Informed consent will be sought** from each prospective subject or the subject's legally authorized representative, unless consent is waived by the IRB.
5. **Informed consent will be appropriately documented,** unless the IRB waives documentation of consent.
6. **When appropriate, the research includes provisions for monitoring the data collected** to ensure subject safety.
7. **Adequate provisions exist to protect the privacy of subjects and maintain data confidentiality.**
8. **When some or all of the subjects are likely to be vulnerable to coercion or undue influence** (e.g., children, prisoners, or individuals with impaired decision-making capacity), **additional safeguards are included** to protect their rights and welfare.

Recent Rascal changes

Recruitment and Consent Page

The "Recruitment and Consent" Page in Rascal has been updated to add a **new recruitment method** by which research participants will be recruited. Patients at Columbia University Irving Medical Center (CUIMC) have the option to consent within the Epic electronic health

record system to be contacted for research opportunities by someone other than a treating physician. The cohort of patients who have provided such consent is the **Consent to Contact for Research (CCR) Registry**. Columbia researchers may request, in a submission to the IRB, to use the CCR Registry for recruitment purposes. It is important to consult the information about CCR available on the Clinical Trial Office website, where instructions for how to submit the request to utilize the CCR registry in new protocols, renewals, and modifications can be found.

This option for recruitment method is available to be checked and listed as follows in the Rascal application:

☐ ***Epic Consent to Contact for Research (CCR) Registry***

Analysis of Existing Data Page

On the Analysis of Existing Data page, when "*Columbia and/or NYP*" and then "*Data to be analyzed were or will be collected for clinical care*" are selected in response to the question, "*Data will be obtained from (select all that apply)*", the prompt, "***Provide the specific patient information that will be extracted or requested in a TRAC report, i.e., each data variable***" appears.

This new question should be addressed as relevant when submitting a new protocol, or a renewal or modification of a previously approved protocol

- If enrollment is closed or data has already been obtained when this section is updated, it is acceptable to provide one of the following responses: "*N/A – closed to enrollment*" or *"Data abstraction/collection is complete*"
- If the list of specific eligibility criteria is included in the attached standalone protocol, you may refer to the specific protocol page number.

Note: Please refer to the Rascal **help text** provided for this question, as it offers additional guidance and clarification.

Follow-up on Recent Rascal Server Changes

As a result of one of the software changes recently implemented by Rascal, the IRB protocol numbers were advanced for technical reasons. The protocol numbers, which include a combination of letters and numbers based on a numeric value, jumped from protocol #AAAW0184 (ID=220184) to protocol ACYY0001 (ID=20000001). This change did not otherwise affect the Rascal database.

Update regarding the list of certified systems (RSAM)

The link to "Log in to RSAM" referenced in the Rascal Application, under the *Privacy & Data Security* page, is currently unavailable. If you need to verify the system ID of an electronic certified server, you may access the list of certified systems below. Please note that this list can only be accessed by researchers from the Medical Campus. Morningside researchers should contact itsecurityrisk@cumc.columbia.edu for verification.

CUIMC Certified Systems List (SharePoint)

For additional information about RSAM and/or questions about the electronic system certification process, please email: **itsecurityrisk@cumc.columbia.edu**.

Documents recently posted on the HRPO website

New TruCentive Instructions

Research participants will soon be able to receive **multiple gift cards** totaling the compensation or reimbursement amount. For example, participants scheduled to receive a total of $100 for their participation in a study, may opt to receive four (4) $25 gift cards from different vendors.

This new multi-select feature is only available to projects where the payment cards (Venmo, PayPal, Direct Deposit, Deposit to Debit, Physical Cards) are not an option. There are no fees associated with using the multi-select feature.

Additional instructions for research participants for selecting multiple gift cards in TruCentive (in English & Spanish) are available **here**. Note that this method of payment is currently only available for CUIMC. Please consult the Reimbursement and Compensation of Research Participants - Payment Options Guidance for additional information. For additional information, please contact Raquel Marin, Associate Vice President (AVP) Internal Controls and Compliance, Deputy Controller, CUIMC Office of the Controller (rm2698@cumc.columbia.edu) or cumcinternalcontrols@cumc.columbia.edu.

Below is the **recommended consent form sample language** to be used when the research involves payment of research participants via gift cards (TruCentive).

"Compensation for this study will be provided in the form of an electronic Gift Card in the amount of $[amount], via TruCentive.com. You may choose to receive this electronic gift card by email, SMS text message or both methods. Based on your preference, we will provide your email and/or SMS text number to TruCentive.com. You may also select that a physical card be sent. ***Some gift cards may use a 3rd party for activation and may require you to provide personal information.*** *Additional instructions on how to receive compensation through TruCentive will be provided to you."*

Addendum to Consent Template

This form can be used to update the previously signed consent form. An addendum to consent requires IRB review and approval and must have an IRB approval stamp.

Check out the HRPO FAQs page, where you will find answers to many common questions received from researchers. If you don't see your question addressed, please don't hesitate to contact us directly at: 212-305-5883 or email: IRBoffice@cumc.columbia.edu.

Incoming Presentations

Rascal Submission Workshops (via Teams):

Below is the list of upcoming workshops. To register, please follow the link provided below for each workshop:

Monday, November 24, 2025: 3:00 PM - 4:00 PM
IRB Rascal Workshop: New Protocols involving minimal risk procedures

Monday, December 15, 2025: 3:00 PM - 4:00 PM
IRB Rascal Workshop: Rascal-Generated Consent Form

Recent Presentations/Announcement

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

- Monthly Investigator Meetings (MIM):
  Slides of past MIM presentations are available on the HRPO website (Informational Materials)

HRPO Staff Updates

Note that Meenakshi Seetharaman, IRB Specialist, and Justin Vargas, Quality and Data Specialist are no longer with the HRPO. We wish them well in their new endeavors.

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. *Coming soon:* Weekly in-person consultations - Details will be provided in an upcoming announcement 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 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 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.