Columbia University Human Research Protection Office/IRBs

Newsletter #18 – March 2026

Celebrating the Remarkable Career of Brenda Ruotolo, Associate Vice President, Human Research Protection

After 23 years of exceptional leadership and dedication to the protection of human research participants, Brenda retired from Columbia University on February 28, 2026. Please join us in thanking Brenda for her incredible contributions and wishing her the very best in her retirement!

Effective March 1, 2026, Grace Kim, Director, Compliance Oversight, and Ashley Halinski, Assistant Director, IRB Management for Expedited Review, are serving as Interim Co-Directors of the Human Research Protection Office (HRPO)/IRB.

Policy/Guidance

- The **CU IRB** Policy on Informed Consent has been updated, and the changes are effective February 1, 2026. The main changes include:
    - Aligning the policy to reflect the general requirements for informed consent, the elements of consent per the current DHHS regulations, and the waiver criteria under current DHHS and FDA regulations.
    - Adding methods for documenting the consent process in certain circumstances.
    - Adding institutional consent requirements and references to the NIH Data Sharing & Genomic Data Sharing Policies, which require that consent forms include specific information regarding the future use and sharing of data.
    - Referring to existing requirements for special populations.

  It is important that all research personnel review this updated, comprehensive policy.

- The **CU IRB** Policy on Research with Prisoners, effective February 1, 2026, has been released and is now available for review. This policy outlines the additional safeguards required to protect prisoners who participate as subjects in biomedical and behavioral research. These regulatory protections, defined in 45 CFR 46, subpart C, mandate that

IRBs reviewing protocols involving this vulnerable population include at least one member who is a prisoner or a prisoner representative with the appropriate background and experience to serve in that capacity.

CU IRBs 1-3 and IRB EXP meet this membership requirement, and research involving prisoners, as defined in the policy, is being routed to one of these IRBs for review. Please review the policy to learn more about the other additional protections under subpart C.

Important note: If a research participant becomes a prisoner after enrollment in a research study that does not target the enrollment of prisoners, the Principal Investigator must notify the IRB immediately by submitting a modification in Rascal. Unless there is an immediate risk of harm to the incarcerated research participant, all study interactions with that individual must be paused until IRB review is completed.

- The **CU IRB Policy on Research Repositories,** effective February 28, 2026, has been released. This policy applies to Repositories established at or on behalf of Columbia University (Columbia or the University), including Columbia University Irving Medical Center (CUIMC), for the purpose of storing Materials for current or future research.

  As we implement this new policy, we also want to take this opportunity to remind you of the resources available to CUIMC researchers. Those seeking to build new or unique biobanks should contact the Columbia University Biobank (CUB) staff (dp2657@cumc.columbia.edu) to determine how CUB resources can best advance their research efforts. CUB is a CUIMC-wide effort to enroll all patients of CUIMC-NYP into a unified, longitudinal biobank research protocol with broad future use and data sharing allowances. CUB can partner with departments, centers, and other groups to perform start-to-finish enrollment, collection, processing, and storage for specific patient groups under the CUB protocol. You may also visit **here** to find out more about CUB and what services they may provide.

What's new on the HRPO/IRB Website?

- ### User's Guide to the Rascal IRB Module

  This Guide provides Columbia researchers with general guidance on how to create a Protocol in Rascal, the University's research administration and compliance IT system. Its purpose is to help researchers avoid common mistakes, particularly those made by researchers who are not familiar with Rascal and/or are new to submitting a research

study to the IRB for review and approval. This new resource is available on the **IRB Protocol Resources Page**.

- **Consent Form Templates**

  Please review the new CU Consent Form for All Research template which may be used to prepare a consent form and/or parental permission for:
  - minimal risk or greater than minimal risk studies, and
  - biomedical, pharmaceutical or social and behavioral science studies.

  This template replaces the previous consent form templates for minimal risk and for genetic/genomic research. It incorporates language from earlier versions along with new options and is designed to streamline IRB review. Its use is encouraged but not required.

  Additional updates to the template include moving the HIPAA authorization section to the end of the form and adding two new elements to the Key Information section, as recommended by OHRP/FDA guidance.

Recent Rascal Changes

- The link to the new **Rascal IRB User's Guide** is now available in Rascal. You can find it on the **main page of the Human Subject Module**. Please consult this guide as you are preparing your IRB application.

- A new section listing the **status of each ancillary review** applicable to the protocol has been added in Rascal. For each ancillary review, this section provides the current review status (approved or Not Yet Approved) and the contact information for the committee or office handling the review. This enhancement can be found under the "**View History**" page of each event.

  For additional information about ancillary review, please consult our previous HRPO Newsletter#8

Submission of a Research Proposal involving Drugs or Biologics

The IRB SOPs list the information to be provided in the Rascal IRB application when a clinical investigation involves **drugs or biologics.** 21 CFR part 312 "Investigational New Drug Application" defines a clinical investigation as any experiment in which a drug is administered or dispensed to, or used involving, one or more human subjects. For the purposes of this part, an experiment is any use of a drug except for the use of a marketed drug in the course of medical practice.

Definitions:

The definition of the term "**drug**" in Section 201(g)(1) of the Food, Drug & Cosmetic (FD&C) Act includes:

- "*articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease*" and
- "*articles (other than food) intended to affect the structure or any function of the body of man or other animals*."

Biological products are also considered **drugs** as defined in Section 351(i)(1) of the Public Health Service Act.

A biological product is: "*a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein (except any chemically synthesized polypeptide), or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings.*"

Information to provide in the Rascal application:

- Ensure the appropriate completion of the Drugs/Biologics page in Rascal, including:
  - Listing all drugs, and all requested information, **that are being studied and administered specifically per the research treatment protocol**, whether investigational or already approved. Guidance on how to complete this page is available on page 71 of the User's Guide to the Rascal IRB Module.
  - Providing the appropriate regulatory status of the drug as used in the research and, when not clear, confirming the status with the sponsor. If there is no plan to submit an IND application to the FDA, the applicable exemption should be selected in the Drugs/Biologics page.
    Important note: Exemption criterion (1) *[see list of Exemption criteria at 21 CFR 312.2(b)]* applies only to clinical investigations of **drugs** that are **lawfully**

marketed in the U.S. For additional questions regarding IND submissions or exemptions, you may contact the IND/IDE Assistance Program (IAP) at the Clinical Trials Office.

- Providing special attention to clinical investigations that involve dietary supplements. Although dietary supplements--intended to supplement the diet and may include vitamins, minerals, herbs, amino acids, or probiotics--are regulated as foods, not drugs, under the Dietary Supplement Health and Education Act (DSHEA), **a product that is intended to diagnose, cure, mitigate, treat, or prevent disease, is considered a drug, regardless of labeling. Its use in the study will require an IND. Additional information about dietary supplements is available on the FDA website.**

- Documentation of the current Investigational New Drug (IND) application status, if one is required. A recent communication from the FDA or from the IND holder confirming the IND status, is acceptable documentation if the IND number is not included in the sponsor's protocol. If the FDA issues a clinical hold on an IND, the IRB will not approve the research until the hold has been lifted.
- Confirmation in Rascal that the investigational drug will be dispensed by Research Pharmacy or that a waiver has been obtained from Research Pharmacy. If the latter, please provide documentation of the waiver.
- The standalone sponsor's protocol, if industry sponsored.
- The current Investigator's Drug Brochure (IB) for each investigational drug, or package insert for FDA-approved drugs.
- A data and safety monitoring plan.
- Form FDA 1572 (Statement of Investigator).

Additional requirements when the **IND holder is a CU Faculty member and the PI is acting as the Sponsor-Investigator (S-I):**

- The PI must complete the S-I training (TC0096) prior to IRB approval.
- Documents to be attached to the Rascal application: Form FDA 1571 (IND Application), the signed Form of Notice (commitment from the Department Chair and the S-I that adequate resources will be provided that will permit the conduct of the study in compliance with FDA regulatory requirements) and the FDA's "Safe to Proceed" letter.

These requirements are fully described on page 64 of the IRB SOPs (version 5.2)

Recent Reminder from the National Institutes of Health (NIH) regarding Documentation of IRB Approval.

On February 23, 2026, NIH released the notice NOT-OD-26-043 regarding the required certification of IRB approval (also known as the IRB determination/approval letter).

Key points include:

Applicants for NIH funding of non-exempt human subjects research must have final IRB approval before NIH funds can be used.

- Applicants must submit the final IRB approval date, which is defined as the date that all protocols in the grant application received IRB review and approval (i.e., the date of the last protocol approval).
- Pending, conditional, interim, or expired IRB approvals are not acceptable.

It is important that Principal Investigators request IRB review and approval of research proposed in NIH applications that are in a fundable range in a timely manner.

For additional questions about submission of documents before award, please contact the Project Officer assigned to the review of your grant application or Sponsored Project Administration.

For additional questions about IRB review, please email IRBOffice@columbia.edu.

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@columbia.edu.

Topic Experts

The list of HRPO Topic Experts can be accessed from the HRPO/IRB website home page.

Upcoming Presentations

- **Rascal Submission Workshops (via MS Teams):**

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

Monday, March 23, 2026: 3:00 PM - 4:00 PM
New protocol involving minimal risk procedures

Monday, April 27, 2026: 3:00 PM – 4:00 PM
Rascal-Generated Consent Form Workshop

Recent Presentations/Announcement

- All HRPO newsletters are available on our website with a list of topics that are addressed in each newsletter. To receive the newsletter and other announcements sent via the IRB listserv, please send an email to IRBoffice@columbia.edu to subscribe.

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:** **In-person consultations** are available weekly, on **Thursdays (1-2pm).** No registration is required. Regular Location: Hammer Health Sciences Building, Room 314

	Virtual consultations may be scheduled on demand between the in-person consultations. To schedule a virtual consultation, please contact one of the staff members listed on the full schedule for that week. **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.