HRPO Newsletter 19

JULY 2026

ANNOUNCEMENT & WHAT'S NEW ON THE HRPO/IRB WEBSITE?

Recent Announcement related to NIH-awarded Research

Make sure to review the best practices provided in the June 4, 2026 email from Sponsored Projects Administration (SPA) sent to Grant Administrators, as it contains information regarding **IRB submission timelines.**

- This is a reminder that the IRB SOPs version 6.0, effective March 6, 2025, are posted on our website. A list of the changes made to this last version was presented at the January 22, 2026 Monthly Investigators Meeting (MIM).
- As announced on April 1, 2026, **a new process for reviewing the NIH GDS Institutional Certifications** was implemented. Please refer to the announcement and the CU HRPO Standard Operating Procedure (SOP) on Submitting and Reviewing Genomic Data Sharing (GDS) Institutional Certifications to learn about this new process.

RECENT RASCAL CHANGES

New Personnel Modification Event

The new **Personnel Modification** event has been available in Rascal since early May. This new event allows for the **automatic approval of changes** that strictly involve the addition and/or removal of personnel provided all training requirements have been completed and specific criteria are met.

This event uses the algorithm that incorporates the IRB training requirements previously integrated into Rascal. This algorithm notifies initiators when any research personnel listed in the IRB protocol have not completed all required training. A red warning message is automatically generated in the **Personnel** section based on the information entered in the Rascal application and the individuals' role in the research. Any incomplete training courses identified in the warning message must be completed before a personnel modification can be submitted for automatic approval.

No other changes may be made to the protocol through a Personnel Modification event. Except for limited, defined exceptions, personnel modifications will not be routed for HRPO/IRB review.

For additional information on how to submit a personnel modification, please watch the demo of the New Rascal Personnel Modification event and review the new HRPO/IRB FAQs available under "Rascal" section.

As a reminder, the link to create a personnel-only modification is available on the **Protocol Overview** page in Rascal.

Cell Therapy Question

The "Procedures" page in Rascal has been recently updated to add the following question: "***Cell Therapy - Does this study involve transfer of living hematopoietic cells with or without genetic modification into a patient with the goal of treating a disease? This also includes transfer of a vector that genetically modifies hematopoietic cells in vivo***".

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

For any "**Yes**" responses, investigators will be guided as follows:

- *You must select "Yes" to the Drugs/Biologics question in the Procedures section and describe the cell therapy intervention.*
- *All cell therapy studies that meet the definition above will be routed to the Herbert Irving Comprehensive Cancer Center's Protocol Review and Monitoring Committee (HICCC-PRMC).*
- *Submission to the Institutional Biosafety Committee (IBC) via Appendix M is required unless otherwise determined. For questions, investigators can contact biosafety@columbia.edu.*

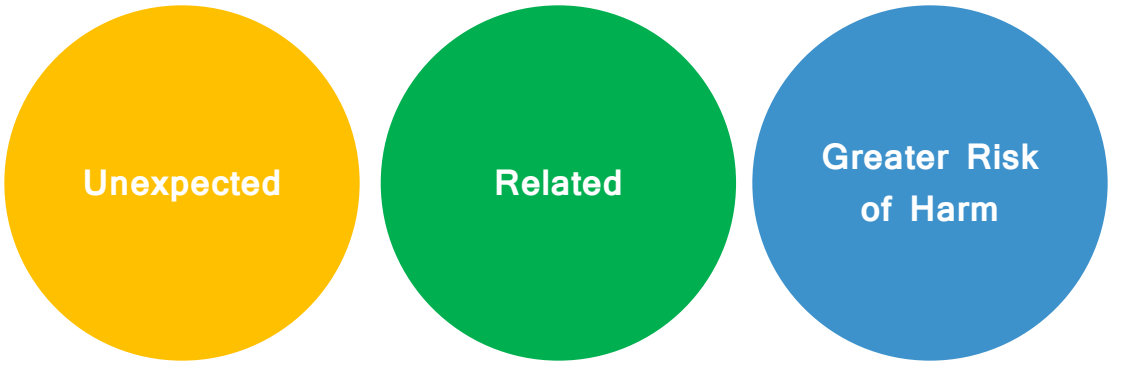
To ensure appropriate routing of protocols involving Cell Therapy to the HICCC-PRMC, these protocols will be reviewed by IRB 4, even if the studies are not cancer-related.

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

REPORTING UNANTICIPATED PROBLEMS INVOLVING RISKS TO SUBJECTS OR OTHERS TO THE COLUMBIA IRB

What Is An "Unanticipated Problem (UP)"?

An Unanticipated Problem is any incident, experience, or outcome that meets **all the following criteria**:



Unexpected	Related	Greater Risk of Harm
The event is unexpected in terms of its nature, severity, or frequency, given the research procedures described in the protocol and consent form, and the characteristics of the subject population.	The event is "related or possibly related" to participation in the research, meaning there is a reasonable possibility the incident was caused by the research procedures.	The event suggests that the research now places subjects or others at a greater risk of physical, psychological, economic, or social harm than was previously known or recognized.

Important distinctions

Reporting a UP

Report a UP only under the study in which the incident, experience, or outcome occurred. The same event should not be reported under other studies using the same drug, device, or intervention unless the event was also experienced in those studies. If the event results in new information (e.g., the identification of a new risk associated with a drug), that information may constitute a change that needs to be submitted as **a modification** for other studies using the same drug, device, or intervention.

Adverse Events vs. Unanticipated Problems

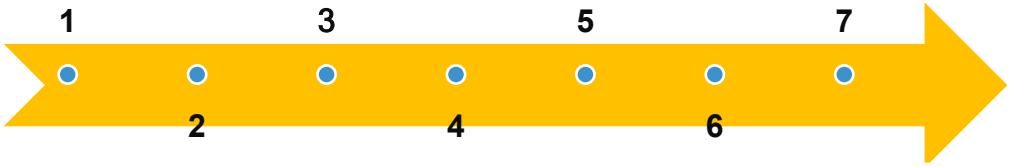
While all serious adverse events are considered to meet the "greater risk of harm" criterion, not all adverse events are reportable.

Only those that meet all three criteria for an unanticipated problem must be reported to the IRB. Conversely, some unanticipated problems (such as a breach of confidentiality or a drug dose error) may not be adverse events at all but still require reporting.

UP Reporting Timelines

- **Promptly**: Reports must be submitted as soon as possible, but no later than one week (seven calendar days) after the problem occurs or the Principal Investigator becomes aware of it.

1-Week Reporting Deadline



- **Continuing Review**: At the time of a protocol's continuing review, the investigator must provide a summary of all Unanticipated Problems that occurred during the review period and since the start of the study.

IRB Review & Determination Status

All reports must be submitted through the Rascal Unanticipated Problem Report module. For research at "Internal Sites," the Columbia investigator is responsible for determining if an incident constitutes an Unanticipated Problem; for "External Sites," this determination is typically made by a Monitoring Entity or the External Site investigator.

All UP reports are reviewed by the IRB. Once a report is submitted, it will first undergo an administrative review. It may be "Returned" with a request for the Principal Investigator (PI) to "Withdraw" the submission when the event is clearly not a UP. Otherwise, it will be routed for IRB review.

IRB Determination	Additional information required from PI	Status of UP Event in Rascal
Event reported is a UP	No, the report is complete	Approved
Event reported is a UP	Yes	Returned to PI
Event reported is NOT a UP	No, the report is complete	Approved

The IRB may require that the PI submit a modification to make changes to the protocol and/or consent document.

Events determined to be a UP that occurred at an internal site will be reported to the Compliance Oversight Team (COT) for required reporting to the regulatory and funding agencies as relevant.

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.

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TOPIC EXPERTS

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

NEWSLETTERS

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.

UPCOMING PRESENTATIONS

Monthly Investigator Meeting (MIM)

As previously announced, we are pleased to introduce a **new format for our Monthly Investigator Meetings (MIMs),** designed to improve accessibility and offer greater flexibility for investigators and research coordinators.

Moving forward, you can choose between two recurring monthly sessions:

- Virtual Sessions: Held on the 3rd Tuesday of each month at 1:30 PM
- In-Person Sessions: Held on the 3rd Thursday of each month at 3:30 PM

The topic for both **July** MIM sessions is:
Submission of Tracking Protocols when Columbia is Relying on an External IRB
Presented by: Ashley Halinski, Interim HRPO Co-Director and Tasha Smith, Senior IRB Specialist - Reliance

You may now **register** for one of the following sessions:

- In-person session: Thursday, July 16, 2026 – 3:30pm
- Virtual session: Tuesday, July 21, 2026 – 1:30 pm

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, July 27, 2026:
3:00 PM - 4:00 PM
New protocol involving minimal risk procedures

Monday, August 24, 2026:
3:00 PM - 4:00 PM
Rascal-Generated Consent Form Workshop

HRPO STAFF UPDATES

We are pleased to announce the following staff promotions that have occurred since our last update:

- Adrian Reyes Gloss, promoted to Interim Manager of IRB 1
- Shannon Strohmeyer, promoted to Assistant Manager of IRB 4
- Kipa Sherpa, promoted to Assistant Manager of IRB EXP

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

- Tommy Nuñez, Quality and Data Specialist

Note that Julissa Borbon-Marcellin, IRB Specialist, is no longer with the HRPO. We wish her well in her new endeavors.

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

- IRB Specialist Position

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

	For research originating from CUIMC
If you have not yet submitted the protocol in Rascal and/or have specific questions about how to submit a new protocol	**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	Add a protocol-specific correspondence in Rascal, or Email the IRB Specialist assigned to your protocol (see HRPO Directory) *Note that these documents are expected to be available approximately one week following approval of the event.*

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.

Columbia University appreciates your commitment towards the ethical conduct of human research.