

HRPO Newsletter 20

OCTOBER 2026



ANNOUNCEMENT

**A Message from
Dr. Ivana Simic,
Our New Associate Vice
President for Human
Research Protection &
IRB**

"I am delighted to serve as Columbia's Associate Vice President for Human Research Protection.

My main objective is to foster a collaborative research environment where regulatory oversight is an enabler, not an obstacle, to research.

Our team is committed to facilitating ethical research while actively reducing administrative burden and making IRB processes faster and easier for investigators across our campuses."

– Ivana Simic, PhD, CIP, Associate Vice President, HRPO & IRB.

WHAT'S NEW ON THE HRPO/IRB WEBSITE?

Reliance Agreements Processes and Webpage

We have overhauled our Reliance Agreement process to provide research teams with a streamlined workflow, clearer steps for ceding review to external IRBs, or onboarding participating sites when Columbia University serves as a single IRB.

Visit our updated [Reliance Agreements Webpage](#) to check out the new process flow, step-by-step instructions, and updated resources.

New IRB Guidance

AI-Assisted Translation in Human Subjects Research

The Columbia University IRB has published the [new guidance](#) on the use of artificial intelligence (AI)-assisted translation for study materials and informed consent documents.

This guidance establishes the IRB's position on the use of AI tools in the translation of research-related materials and supplements the University's Enrollment of Non-English Speaking Subjects Policy.

IRB Process: Repositories & Secondary Research Routing

This [guidance](#) outlines how the IRB reviews and routes protocols involving research repositories and secondary research using previously collected data or biospecimens. It provides criteria for determining the appropriate level of IRB review (Expedited or Convened, also called Full Board review) and whether a secondary use should be submitted as a new study or an amendment to an existing protocol.

RECENT CHANGES IN IRB PROCESS

Streamlining Your IRB Application -- Grant Proposals No Longer Required with IRB Applications

As part of ongoing efforts to streamline institutional oversight and support research efficiency, HRPO is updating its submission requirements regarding grant proposals. Moving forward, IRB review will center exclusively on the study protocol rather than grant documentation. Consequently, researchers are no longer required to upload grant proposals into Rascal.

Action Items for Researchers:

1. Submit study details using a **stand-alone research protocol** (preferred) or Rascal's designated protocol fields.
2. Ensuring alignment between grant awards and IRB approved protocol(s) related to the grant, as well as strictly following IRB-approved protocols only. Any protocol modifications must be approved by the IRB before implementation (even if activities are described in a grant)

Protocol templates are available on the HRPO website: [IRB Protocol & Consent Form Resources](#).

These changes don't affect the requirement to link the applicable proposal tracking(s) to the Funding page of the IRB application.

IRB Review of Protocols with Financial Conflict of Interest (FCOI) Disclosures

Research protocols with an associated FCOI disclosure may now proceed to IRB review while the disclosure is pending review and clearance by the Office of Research Compliance and Training (ORCT)/Financial COI Committee. This applies to Initial Protocols, Renewals, and Modifications. Once the disclosure is cleared, the IRB Chair will review the FCOI information and determine whether any additional IRB review is needed based on the outcome of the FCOI review.

WAIVER OF DOCUMENTATION OF CONSENT WAIVER/ALTERATION OF INFORMED CONSENT

Waiver of Documentation of Consent:

What does it Mean?

A **waiver of documentation of consent** means that participants do not need to sign a consent form.

Informed consent is still required.

Before agreeing to participate, participants must receive all required consent information and may provide consent by another method, such as verbally.

A waiver of documentation under 45 CFR 46.117 is **permissible** when **any** of the following criteria apply:

- ❖ The signature on the informed consent document would be the only record linking the subject to the research and the principal risk of harm to the subject would be a breach of confidentiality.

[Criterion not applicable to FDA-regulated research]
- ❖ The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside the research context.

[Criterion applicable to both DHHS and FDA-regulated research]
- ❖ If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.

[Criterion not applicable to FDA-regulated research]

Instances when a waiver of documentation of informed consent may be requested include:

- ❖ Research on sensitive topics where linking the collected information to participants could place them at risk (e.g., immigration status, domestic violence, or drug use).
- ❖ Research involving surveys or telephone interviews.
- ❖ A minimal-risk portion of a greater than minimal risk study in which a screening activity must be completed before written informed consent for the main study.

Waiver or Alteration of Informed Consent:

What Does It Mean?

A **waiver of consent** means that informed consent does not need to be obtained from subjects, provided that specific regulatory criteria are met.

An **alteration of consent** allows the IRB to approve a consent process that omits or modifies certain required elements.

A waiver or alteration of informed consent is **permissible** under 45 CFR 46.116, and, for applicable FDA-regulated research under 21 CFR 50.22, when all the following criteria are met, including:

1. **Minimal risk:** The research involves no more than minimal risk to subjects.
2. **Practicability:** The research could not practicably be carried out without the waiver or alteration.
3. **Use of identifiable information or biospecimens:** If the research involves identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using the information or biospecimens in an identifiable format.
4. **Rights and welfare:** The waiver or alteration will not adversely affect the rights and welfare of subjects.
5. **Additional information after participation:** Whenever appropriate, subjects or their legally authorized representatives will be provided with additional pertinent information after participation.

An Important Consideration: What Does “Practicably” Mean?

When considering whether the research could practicably be carried out without a waiver, the focus should be on whether **requiring consent would make it impracticable to conduct the research**, rather than simply whether obtaining consent would be difficult or inconvenient.

This **criterion 2** is often relevant to research *involving retrospective data*, meaning data that already exist at the time of the initial IRB submission. For research involving *prospective data* collection or review, consent will generally be required unless obtaining consent would make it impracticable to conduct the research or could threaten the scientific validity of the results. For example, in a large population-based or epidemiologic study, limiting the research to records, data, or samples from individuals from whom consent can be obtained could result in an insufficient or biased sample and affect the validity of the study's conclusions.

When Should Additional Information Be Provided to Subjects?

Criterion 5 requires the IRB to consider whether subjects should receive additional information after their participation.

This may be particularly relevant to research involving **deception or incomplete disclosure**, where certain aspects of the study are intentionally not disclosed in advance to avoid influencing subjects' responses. In these circumstances, providing information or debriefing subjects after participation may be ethically appropriate.

However, a waiver of informed consent does not automatically mean that subjects must be provided with additional information after participation. The IRB considers whether this is appropriate for each study.

Instances when a waiver of informed consent may be requested include:

- ❖ Research is limited to the collection and analysis of medical record information, with no participant interaction.
- ❖ Research involves secondary analyses of existing datasets or specimens.
- ❖ FDA-regulated research of in-vitro diagnostic devices using anonymous tissue specimens.

Instances when an alteration of consent may be granted include:

- ❖ Research that involves deception or in cases where subjects' knowledge of the purpose of the research may alter their responses. Some information is not communicated to participants in order to answer the research question.
- ❖ Research examining public benefit or service programs not regulated by the FDA that looks at or evaluates procedures for obtaining benefits or services, changes or alternatives to these programs, or changes in methods or levels of payment for these programs.

Rascal IRB Application: Steps for Requesting a Waiver of Documentation of Consent or Waiver of Consent

Complete the Informed Consent Process section within the Recruitment and Consent Page and select the appropriate waiver for your study (see the 2nd and 3rd checkboxes below).

***Informed Consent Process, Waiver or Exemption: Select all that apply**

- ☐ Informed consent with written *documentation* will be obtained from the research participant or appropriate representative.
- ☐ Informed consent will be obtained but a waiver of written documentation of consent (i.e., agreement to participate in the research without a signature on a consent document) is requested.
- ☐ A waiver of *some* or *all* elements of informed consent (45 CFR 46.116) is requested.
- ☐ Planned Emergency Research with an exception from informed consent as per 21 CFR 50.24.
- ☐ This is exempt research



RECENT CHANGES

Two new enhancements are now available in Rascal:

- **Bulk Document Upload:** A new option to upload documents in bulk has been added to the Attachments page of the IRB protocol, making it easier to add multiple documents.
- **New Researcher Dashboard:** The new Researcher Dashboard provides researchers with a centralized view of activities across the various offices/committees reviewing research, including FCOI, Human Subjects, Animal Care, Proposal Tracking, Training Center, Hazardous Materials and Contracts. The dashboard can be accessed from the Main Rascal Page.



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/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)

The upcoming MIMs will be held virtually. **To register**, please follow the link provided below for the MIM:

November MIM

Thursday, November 19, 2026, 3:30 PM - 4:30 PM

Topic: **OPEN Initiative - Consent to contact for research (CCR)** and other recruitment activities

Presented by:

- Elisabeth DiMaria, Director, Clinical Research Initiative - Irving Institute for Clinical and Translational Research
- Abigail Reed, Clinical and Translational Research Project Manager - Irving Institute for Clinical and Translational Research
- Perla Mendoza, Project Manager Research Participation - Irving Institute for Clinical and Translational Research

Location: [Microsoft Teams](#)

Rascal IRB Submission Workshops (via MS Teams)

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

Monday, November 30, 2026:
3:00 PM - 4:00 PM
[New Protocol \(Minimal Risk\)](#)

Monday, December 21, 2026
3:00 PM - 4:00 PM
[Consent Form Builder](#)

HRPO STAFF UPDATES

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

- Adrian Reyes Gloss, promoted to Manager of IRB 1
- Jason Sanchez, promoted to Manager of IRB 5

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

- Jesus Neyra, IRB EXP Specialist

Note that Yaritza Collazo, IRB Assistant Director, is no longer with the HRPO. We wish her well in her new endeavors.

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.**