# Columbia University Human Research Protection Office/IRBs

## Newsletter #11 – November 2024

## Policy/Guidance

> **Process for requesting a Certificate of Confidentiality**
> A Certificate of Confidentiality (CoC) from the National Institutes of Health (NIH) is required for certain federally funded research involving identifiable, sensitive data as defined in the NIH Policy for Issuing Certificates of Confidentiality, version effective Oct. 1, 2017, and may be requested for specific projects that are not funded by NIH, including projects for which NIH funding has ended. A CoC protects the privacy of research participants by prohibiting disclosure of identifiable, sensitive research information to anyone not connected to the research except when the participant consents.
>
> The process for requesting a CoC is initiated by the Principal Investigator through the online NIH CoC system and requires institutional verification.
>
> The HRPO standard operating procedure for submitting and verifying the CoC request has been posted on our website.

## Recent Enhancements made to the Rascal Human Subject Module

1. **Protocols reviewed by the convened IRBs (IRBs 1-5):**
   The Principal Investigator (PI) now receives a correspondence in Rascal when a new protocol requiring convened review is added to the IRB Meeting agenda. The correspondence provides the anticipated time of IRB review and requires confirmation of the PI or designee's best phone number to be contacted, should any key questions or clarifications arise during IRB review. You can expect to receive the correspondence 5-6 days before the meeting.

2. **Rascal Consent form Builder:**
   A new option to print the consent form with a designated space to document the time of consent was added to the Signature section of the consent builder.

As a reminder the Columbia University IRB policy on Informed Consent requires that the date of consent be documented on the consent form for all studies. The policy also requires that the time of consent be documented if the study enrolls patients who are hospitalized at the time of enrollment. Selecting the option to "*Print signature lines with "Date and Time*" will add a line for this information for each signature line needed on your document.

3. **Attachments of documents to the IRB protocol:**
   The order of fields presented under the "Add Attachment" page was changed. The option "Choose File" is now presented first and the name of the selected file will be automatically displayed in the "Document Identifier" text field that appears once the file is chosen.

4. **Rascal application:**
   The following question "*Is this project associated with, or an extension of, an existing Rascal protocol?*" available on the Procedure Page was updated to allow the listing of up to 3 Rascal Protocol numbers.



**Upcoming Presentations**

**Rascal Submission Workshops (via Zoom):**
**To register, please follow the link provided below for each workshop:**



| **2024 Workshops** | **2025 Workshops** |
| --- | --- |

**2024 Workshops**

- Monday, November 18, 2024, 3:00 PM-4:00 PM
  IRB Rascal Workshop: New Protocol involving Minimal Risk procedures

- Monday, December 16, 2024, 3:00 PM-4:00 PM
  IRB Rascal Workshop: Consent Form Builder

**2025 Workshops**

- Monday, January 27, 2025, 3:00 PM - 4:00 PM
  IRB Rascal Workshop: New Protocol involving More than Minimal Risk Procedures

- Monday, February 24, 2025, 3:00 PM - 4:00 PM
  IRB Rascal Workshop: Renewal - Annual Report - Modification

- Monday, March 24, 2025, 3:00 PM - 4:00 PM
  IRB Rascal Workshop: New Protocol involving Minimal Risk Procedures

- Monday, April 28, 2025, 3:00 PM - 4:00 PM
  IRB Rascal Workshop: Consent Form Builder

## Recent Presentations/Announcement

- Monthly Investigator Meetings (MIM):
  Slides of recent MIM presentations are available on the HRPO website (Informational Materials) at https://research.columbia.edu/human-subjects-protection-training-program-educational-resources

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


## HRPO Staff Updates

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

- Senior IRB Specialist-Manager (2)                    - IRB Specialist Position (1)

Note that Madeline Parra, IRB EXP Specialist is no longer with the HRPO. We wish her well in her 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

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|---|---|
| **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.<br><br>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 protocol-specific 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 |
| **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.