Columbia University Human Research Protection Office/IRBs

Newsletter #17 – January 2026

New service available to the research community: HRPO Topic Experts

We are pleased to introduce a new service to researchers seeking guidance in specific areas. Our team members are available to provide support based on their areas of expertise, as outlined in the table below. We encourage researchers to take advantage of this new service and reach out directly to the contacts listed below.

TOPICS	HRPO STAFF MEMBERS	
AI and machine learning	Daniel Melvin dm3854@cumc.columbia.edu 212-814-3018	Janelle Ortega jo2629@cumc.columbia.edu 929-746-0498
Belmont Report	Tasha Smith ts2257@cumc.columbia.edu 929-996-1455	Pilar Borvice pb2913@cumc.columbia.edu 929-996-1457
Clinical research design	Laurence Butaud-Rebbaa lb2643@cumc.columbia.edu 917-679-3867	Tasha Smith ts2257@cumc.columbia.edu 929-996-1455
Clinical research monitoring	Carri-Ann Gay cg2618@cumc.columbia.edu 917-679-4347	Michael Minyetty mm6068@cumc.columbia.edu 646-960-2016
Community engagement and participatory research	Avi Arjune aa5406@cumc.columbia.edu 917-634-0623	Michael Sheffey ms5394@columbia.edu 917-655-0196
Compliance - best practice, scope	Grace Kim gk2477@cumc.columbia.edu 917-581-4644	

Corrective action plans	Maryanne McGinn mm4332@cumc.columbia.edu 929-746-0365	Carri-Ann Gay cg2618@cumc.columbia.edu 917-679-4347
Data use and material transfer agreements, certificates of confidentiality	Kipa Sherpa ks4231@cumc.columbia.edu 646-965-3978	Ashley Halinski ah3675@cumc.columbia.edu 929-746-0251
Deviations and violations	Maryanne McGinn mm4332@cumc.columbia.edu 929-746-0365	Julissa Borbon-Marcelin jgb15@cumc.columbia.edu 929-746-0558
Enrollment of affiliates	Rosanna Fajar rf2262@cumc.columbia.edu 917-679-3568	Stephanie Stanford ss6344@cumc.columbia.edu 929-837-1059
Enrollment of non-English speaking subjects	Mariella Hernandez mh4382@cumc.columbia.edu 917-580-2151	Katherine Greenberg kcg2123@cumc.columbia.edu 646-951-2531
Genetic/genomic research including NYS 79-l, GWAS and GDS	Julissa Borbon-Marcelin jgb15@cumc.columbia.edu 929-746-0558	Jason Sanchez js5854@cumc.columbia.edu 929-746-0526
HIPAA	Katherine Greenberg kcg2123@cumc.columbia.edu 646-951-2531	Karla Garcia kg100@cumc.columbia.edu 917-655-2489
Human subjects research (HSR) and non-HSR determinations	Annie Barry ab14@cumc.columbia.edu 929-996-1458	Michael Sheffey ms5394@columbia.edu 917-655-0196
IDE/device research including emergency use and planned emergency research	Jenilee Soto jh2716@cumc.columbia.edu 929-746-0676	Jason Sanchez js5854@cumc.columbia.edu 929-746-0526
IND/drug or biologic research including emergency use and planned emergency research	Adrian Reyes ar4370@cumc.columbia.edu 929-996-1454	Jenilee Soto jh2716@cumc.columbia.edu 929-746-0676
Informed consent - process, forms, etc.	Dixa Patel dp3364@cumc.columbia.edu 929-746-0363	Laurence Butaud-Rebbaa lb2643@cumc.columbia.edu 917-679-3867
International research	Shannon Strohmeyer ss7267@cumc.columbia.edu 929-996-1459	Janelle Ortega jo2629@cumc.columbia.edu 929-746-0498
Oral history	Karla Garcia kg100@cumc.columbia.edu 917-655-2489	Annie Barry ab14@cumc.columbia.edu 929-996-1458
PI eligibility and student research (students as researchers)	Shannon Strohmeyer ss7267@cumc.columbia.edu 929-996-1459	Diana Bae db3529@cumc.columbia.edu 929-613-1141
Radiation safety/other HazMat	Qiana Quiles qq2110@cumc.columbia.edu 929-996-1461	Avi Arjune aa5406@cumc.columbia.edu 917-634-0623
RASCAL	Yaritza Collazo yr111@cumc.columbia.edu 917-689-4636	
Recruitment including recruitment of patients, RecruitMe and ResearchMatch	Ashley Halinski ah3675@cumc.columbia.edu 929-746-0251	Mariella Hernandez mh4382@cumc.columbia.edu 917-580-2151

Requirements of federal agencies other than FDA and HHS	Grace Kim gk2477@cumc.columbia.edu 917-581-4644	Kipa Sherpa ks4231@cumc.columbia.edu 646-965-3978
Social science/behavioral research methodology	Michael Minyetty mm6068@cumc.columbia.edu 646-960-2016	Diana Bae db3529@cumc.columbia.edu 929-613-1141
SSN disclosure	Mark Leneker ml2307@cumc.columbia.edu 917-634-0625	Stephanie Stanford ss6344@cumc.columbia.edu 929-837-1059
Subpart B – Research with pregnant women, fetuses, neonates	Yaritza Collazo yr111@cumc.columbia.edu 917-689-4636	Dixa Patel dp3364@cumc.columbia.edu 929-746-0363
Subpart C - Research with prisoners	Pilar Borvice pb2913@cumc.columbia.edu 929-996-1457	Daniel Melvin dm3854@cumc.columbia.edu 212-814-3018
Subpart D - Research with children	Qiana Quiles qq2110@cumc.columbia.edu 929-996-1461	Adrian Reyes ar4370@cumc.columbia.edu 929-996-1454

Emergency use of an Investigational Drug or Device (Clinical Care)

The FDA allows the emergency use of a test article (drug, biologic or medical device) outside of a clinical trial for a patient in a life-threatening situation, when no standard acceptable treatment is available and there is not sufficient time to obtain IRB approval. This FDA pathway is referred to as emergency single-patient expanded access (emergency use). In the table **below is a summary of the FDA, CU HRPO/IRB and Clinical Trials Office (CTO) requirements for notification and reporting of emergency use applicable to the relevant test article.** Many times, the IRB will be notified in advance of the emergency use, particularly if the manufacturer of the test article requires a letter from the IRB that it is aware of the proposed use. In all cases, the FDA requires that the IRB must be notified within five working days of use. None of these situations will be considered research.

FDA regulations (21 CFR 56.104(c)) allow for **one emergency use** of a test article per institution. However, when prior IRB review and approval is not feasible for a subsequent expanded access emergency use at a particular institution, the FDA will not deny the subsequent request for emergency use based on the lack of time to obtain prospective IRB review, as long as that use will be reported to the IRB within five (5) working days of initiation of treatment.

All other expanded access categories (i.e., non-emergency, single patient requests and small/intermediate group expanded access protocols) do require prospective IRB approval. For more information, please see the following references:

- CU IRB SOPs (Section III – Preparation of submissions)
- CU Clinical Research Handbook (Section II – The ABCs of FDA regulated research),
- CTO website: Emergency Use and Expanded Access Use of Investigational Products Information

Emergency Use	Single-patient Emergency Use Drug	Single-patient Emergency Use Medical Device
Criteria	• The patient is in a life-threatening situation*. • No standard acceptable treatment is available. • There is not sufficient time to obtain IRB approval. • The physician who is proposing the emergency use must determine that the probable risk to the person from the investigational drug is not greater than the probable risk from the disease or condition.	• The patient is in a life-threatening situation*. • No generally acceptable alternative treatment for the condition exists. • There is no time to obtain FDA approval for the use. • The physician who is proposing the emergency use is expected to make the determination that the patient's circumstances meet the above criteria, to assess the potential for benefit from the use of the unapproved device, and to have substantial reason to believe that benefits will exist.
	***Life-threatening** means diseases or conditions where the likelihood of death is high unless the course of the disease is interrupted and diseases or conditions with potentially fatal outcomes, where the end point of clinical trial analysis is survival. The criteria for life-threatening do not require the condition to be immediately life-threatening or to immediately result in death. Rather, the subjects must be in a life-threatening situation requiring intervention before review at a convened meeting of the IRB is feasible.*	
FDA approval	Call the FDA to obtain an emergency Investigational New Drug (IND), which is an exemption to use the test article, and/or written approval to ship the drug. Treatment may start immediately upon FDA authorization. The physician or	Prospective FDA approval is not required. Follow-up reports to the FDA are required within 5 days: • **If an Investigational Device Exemption (IDE), which is**

	sponsor must agree to submit a written IND submission within 15 working days of the initial authorization. FDA must determine that the patient cannot obtain the drug under another IND or protocol.	**an exemption to use the test article, already exists:** The IDE sponsor must notify the FDA through the submission of an IDE report. • **If no IDE exists:** The physician should submit to the FDA a follow-up report.
IRB approval	Prospective IRB approval is not required. The use should be reported to the IRB within 5 working days of treatment.	Prospective IRB Chair concurrence is required (*this is not an IRB approval*). The use should be reported to the IRB within 5 working days of treatment.
Notification to the HRPO/IRB & CTO	Send notification to IRBoffice@columbia.edu and INDhelp@columbia.edu in advance of the proposed use. Documentation to be included if available at the time of the notification, or within 5 working days of use: • A description of the test article, including name or other unique identifier, and IND, BB-IND, or IDE number, as applicable. • A written explanation of the life-threatening situation necessitating the use of the test article and the patient's initials, and confirmation that there is no effective alternative treatment available. • Concurrence by a physician who is not otherwise involved in the use of the investigational product. • For drugs only: The completed form FDA 3926 (if available) submitted to the FDA and/or FDA approval. • A copy of the consent document that will be or was used or an explanation of why it will not be or was not possible to obtain informed consent. One of the purposes of informed consent is to ensure that patients are informed that they will be treated with an investigational product and that there may be uncertainty about the safety and effectiveness of the product. A consent form template for individual patient access to a drug is available on the FDA website: refer to Appendix B of the FDA guidance "Expanded Access to Investigational Drugs for Treatment Use Questions and Answers". • An indication of whether additional uses are anticipated, in which case a protocol and consent form should be submitted for IRB approval. • In addition, the following information needs to be provided/considered for CTO review:	

	○ The test article manufacturer's letter of authorization (LoA). ○ Potential requirement to execute an agreement for the use. ○ Research Pharmacy Cost Estimate Form. • If required by the manufacturer, a letter from the HRPO can be provided to indicate that the IRB is aware of the proposed use.

What's new on the HRPO/IRB Website?

Our website has been updated. Researchers can now find revised information on IRB submissions, protocol templates, IRB levels of review, tips for an efficient IRB review process, an overview of the IRB protocol life cycle (including a process diagram), and the pre-review checklists used by the IRB specialists. **This updated information is available on the IRB Protocol Resources Page.**

We have issued new information that addresses the potential impact on research procedures of clinical disruptions such as a reduction in clinical resources, including how and when potential resultant violations should be reported to the IRB. **This information is available on the Clinical Disruption Information 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.

Upcoming Presentations

Monthly IRB Investigator Meeting (via MS Teams):

- **IRB Updates** presented by **Brenda Ruotolo, Associate Vice President for Human Research Protection**

  Thursday, January 22, 2026: 3:30 – 4:30 PM
  Click here to register

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, January 27, 2026: 3:00 PM – 4:00 PM
New protocol involving more than minimal risk procedures

Monday, February 23, 2026: 3:00 PM – 4:00 PM
Renewal/Annual Report/Modification 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.