Columbia University Human Research Protection Office/IRBs

Newsletter #10 – September 2024

Policy/Guidance

- **Policy on Resolution of Queries after Study Closure**: This new policy effective 08/20/2024 has been posted on our website. It clarifies which information can be accessed in response to queries from Sponsors and auditors without IRB approval following closure of a research study.

- **This newsletter** and all HRPO Newsletters previously released are now available on our website with a list of topics addressed in each newsletter.

- **New information about Renewals and Annual/Progress Reports (AR)**, including regulatory and institutional requirements, the IRB and HRPO review process, the calculation of the expiration or due date, the recommended timeline for submission of renewals, and instructions on how to submit renewals and ARs has been posted on the Maintain IRB Approval page of the HRPO website.

- **Reimbursement and Compensation to Participants**: An updated version of the TruCentive Instructions to participants (English and Spanish) is available here. The update consisted of adding page 11 "*Physical Card Instructions*".

Protocol Deviations and Protocol Violations

Protocol Deviation

***Columbia University (CU) IRB Definition*:**

A divergence from the approved protocol, IRB determinations or IRB policies for one subject or to address a temporary situation that is identified by the research team and approved by the IRB before implementation.

Sponsors of research may have a different definition for a deviation from the protocol. Terms such as protocol exceptions or protocol waivers are used. Other sponsors will specify in the protocol that such divergence from the protocol will not be allowed. It is therefore important to review the IRB-approved protocol and, in the absence of specific information about deviations in the protocol, consult with the

Sponsor to ensure appropriate adherence to the protocol before submission of a request for a protocol deviation to the IRB.

Examples of protocol deviation requests are:

- Request to deviate from one of the eligibility criteria, e.g. enroll a subject even though a certain laboratory test value is not met, but there is already an amendment in preparation to update the value range of the specific eligibility criteria.
- Request to use a recent test/procedure results available in a subject' s medical record instead of re-testing or re-performing the procedure per protocol.
- Request to schedule an out-of-window study visit for one subject.
- Request to change the drug dosing schedule for one subject.

Submission of a request for a protocol deviation

A request for deviation should be submitted as a Modification in Rascal.

- The description of the request should be included in the modification summary or in a document attached in Rascal
- Be specific, citing the specific criteria and/or procedure to be deviated from in the approved protocol, and explaining why the deviation is necessary for the specific subject (the subject ID should be included in the request).
- The PI should indicate whether the deviation affects the risk/benefit ratio for subjects, integrity of the research data, and/or subjects' willingness to continue study participation.
- A plan to inform the subject if the deviation may change the subject's willingness to participate in the research study should be included.
- Documentation of approval of the request by the Sponsor should be attached to the modification.
- If the deviation involves an Investigational New Drug (IND), documentation that the FDA has been notified should be submitted to the IRB at the time of renewal.
- If the Deviation involves an Investigational Device under an Investigational Device Exemption (IDE), FDA approval is required prior to submission for Columbia IRB approval.

Repeated requests for similar deviation will require submission of an amendment to the protocol.

If the deviation is time sensitive and/or another submitted modification is pending review, please alert the Manager of the IRB reviewing your protocol as soon as the need to deviate is known.

Protocol Violation

Columbia University (CU) IRB definition:

A divergence from the approved protocol, IRB determinations or IRB policies that was implemented without prospective approval by the IRB and was not implemented to avoid or minimize imminent harm.

Protocol violations should be assessed by the study team and the assessment will guide the timing for reporting the violations to the IRB.

Timing for reporting protocol violations to the IRB

- Protocol violations should be reported *within one week (5 business days)* if they constitute an *Unanticipated Problem Involving Risks to Subject or Others (UP)**. They should be reported via the Unanticipated Problem Module.

- Major Violations are those that:
  - violate the rights or welfare of subjects,
  - negatively affect the integrity of the study or,
  - result in the need for a change to the protocol or consent document(s).

  Major violations should be reported promptly via a *Modification, within one week* (5 business days) of occurrence or, if it is not known to the PI at that time, of discovery by the PI.

*UP Criteria

- unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;
- related or possibly related to participation in the research (in this guidance document, *possibly related* means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and
- suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

- Minor violations (violations that are not UPs or major violations) should be reported *at the time of renewal.* For studies eligible for elimination of continuing review (*Annual Report*), these violations must be submitted as a *modification*.

Examples of protocol violations are:

- Due to personal circumstances, subject (ID#) could not complete one of the visits' assessments within window.
- A subject's clinical examination was performed by a physician who was not listed in the study datasheet.
- A subject was not reconsented with the IRB approved updated consent form during their next scheduled clinic visit
- The pharmacokinetic (PK) samples freezer temperature log was not maintained daily.

Submission of protocol violations

- The protocol violation's description should be included in the modification summary or in a log that includes all Ups, deviations and violations. The log should reflect when individual submissions of each UP, deviation, or major violation were made.
- Include an explanation of why the violation occurred
- The PI should indicate whether the violation affected the risk/benefit ratio for subjects, integrity of the research data, and/or subjects' willingness to continue study participation.
- Describe the measures that will be taken to correct or mitigate the situation and measures that will be taken to prevent a recurrence of the same or similar violations must also be submitted.

HRPO Staff Updates

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

- Senior IRB Specialist-Manager (2)

Upcoming Presentations

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

- Monday, October 28, 2024, 3:00 PM-4:00 PM
IRB Rascal Workshop: Renewal/Annual Report/Modification

- 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

Recent Presentations

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

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: Please contact IRB Liaison, Tasha Smith, at ts2257@cumc.columbia.edu or 929-996-1455. 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.