HRPO Monthly Updates

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To:cuhs-irb@LISTS.CUMC.COLUMBIA.EDU <cuhs-irb@LISTS.CUMC.COLUMBIA.EDU>

Dear Colleagues,

The Human Research Protection Office (HRPO) is excited to provide the following updates:

Recent updates made to the Human Subjects Module in Rascal

- Under the procedures page, the question related to stem cell research was updated to "**Human embryos or human pluripotent stem cells**". In addition, this link to the Stem Cell Research webpage was added. Please visit this new page for information on how to obtain approval from the Stem Cell Research Committee and when approval is needed.

- Drug and Device pages: The link to the Form of Notice that is required to be submitted when a CU Faculty member is the IND/IDE Holder is now available on these pages.

Process for IRB Review of Events

- IRB-approved documents: All consent documents, recruitment materials and study instruments that are attached in Rascal are stamped with the IRB approval stamp after IRB approval. The electronic stamp can only be applied on pdf-formatted documents. Please ensure pdf documents are attached in Rascal before submission to avoid delay in approval and stamping.

- Resubmissions: A correspondence addressing researcher tasks should be added via the correspondence menu or attached to the print menu when changes were not made and/or to provide the clarifications requested. In addition, a tracked-change version, or a detailed list of corrections should be provided for each updated document.

- Recruitment of CU/NYPH Employees/Residents/Fellows/Interns/Students: As a reminder, Institutional Official (IO) approval is required when CU and/or NYP affiliates will be targeted for recruitment. The IO approval is obtained by HRPO staff. A letter of support from the Department from which CU affiliates will be recruited should be attached by the study team in Rascal before submission.

- Change in Principal Investigator (PI): A modification should be submitted to list the new PI and attach the updated documents affected by this change (e.g. consent form, protocol, recruitment materials). In addition, if the former PI will no longer be involved in the conduct of the study and will be removed from the personnel list, a letter from the former PI supporting the transition is needed. If the former PI is not available to provide such letter, documentation from the Department Chair or other appropriate unit head should be attached to the modification. If research subjects are still participating in the research study, a plan to inform them promptly of the change in PI and provide them with the new contact information should be included with the modification. Depending on the study, the plan may include written or verbal communication.

Upcoming presentations

- Monthly-IRB Investigator's meeting (MIM) **- May 19th at 3:30pm**
  Topic: Columbia Biobank (CUB) and Biobank Resource for Investigating Disease, Genes, and the Environment (BRIDGE)
  Link to MIM registration

- New Protocol Rascal Workshop **– May 23rd at 3pm**
  Link to workshop registration

Recent presentations

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

HRPO Staff Changes

- Carri-Ann Gay, who was previously working with the IRB Exp team, has transitioned to the Research Compliance Specialist position on the Compliance Oversight Team.

Please contact us with any questions and/or feel free to provide us with feedback to irboffice@columbia.edu.

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This message has been sent by the Columbia University Human Research Protection Office.

If you have questions, please contact us:
Medical Center: phone: 212.305.5883; e-mail: irboffice@columbia.edu
Morningside: phone: 212.851.7040; e-mail: askirb@columbia.edu

In addition, please visit our website for additional information: https://research.columbia.edu/irb

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