HRPO 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:

Policy/guidance

Guidance on Risk to Subjects from Skin Biopsies has been posted on our website: Skin Biopsies.

> The guidance describes how the risks associated with skin biopsies will be assessed by the IRB.
>
> When research involves such biopsies, sufficient information such as: description of the procedure, number of biopsies to be performed, the site and size of biopsies, the collection method, and the subject's underlying condition, should be included in the protocol so that the IRB can evaluate its risk for the targeted population. The consent form should provide enough details about the procedures, its risks, discomforts, and post-biopsy care instructions.
>
> If you have any questions about this new guidance, please email IRBoffice@columbia.edu.

Did you know the following resources are available in Rascal (main page of the Human Subjects Module)?

- Our **statement of compliance with ICH GCP,** which can be downloaded to share with sponsors.
- A **Rascal 2.1 tutorial (video)** on the following functionalities: correspondence, researcher tasks and determination letter

  URL: https://www.rascal.columbia.edu/courses/irb/videos/investigatorTutorial.mp4

Current Review Process of Events

HRPO staff are processing items in the order they are received and with consideration of the level of review, however the following events are prioritized:

- Submission of a COVID-19 treatment or vaccine protocol
- Request for a time-sensitive protocol deviation
- Submission of a protocol associated with a NIH Just-in-Time (JIT) request
- Renewal of a treatment protocol about to expire
  - Reminder: these should be submitted 60-90 days in advance of the expiration date of IRB approval

Please alert the manager of the team processing your protocol if an event falls into one of these categories.

Upcoming Rascal Workshops

Rascal workshops are being scheduled monthly for the rest of the calendar year, generally to occur on the last Monday or each month. A separate announcement and link to registration will be sent soon.

HRPO Staff Promotions

We are pleased to announce the following staff promotions and team changes that have occurred in recent months:

- Grace Kim, promoted to Director for Compliance Oversight
- Yaritza Collazo, now Senior IRB Specialist-Senior Manager for IRB 5 (previously IRB 3)
- Stephanie Pena, promoted to Senior IRB Specialist-Manager, IRB 3
- Oskar Neyra, promoted to Senior IRB Specialist-Manager, IRB 2
- Ashley Halinski, promoted to Senior IRB Specialist-Manager, IRB Exp
- Maryanne McGinn, promoted to Research Compliance Manager
- Jenilee Henriquez, promoted to Assistant Manager, IRB 4

New IRB Specialists who have joined the HRPO

The following IRB Specialists have joined our team within the last 6 months and, as are the rest of the team, are working remotely most of the time:

- Elaine Baulsir, IRB 4
- Julissa Borbon-Marcelin, IRB 3
- Emily Capak, IRB 2
- Rosanna Fajar, IRB Exp
- Matthew Neky, IRB Exp
- Adrian Reyes, IRB 4
- Catherine Singer, IRB 1
- Kristin Williams, IRB 5

Their contact information is available in the HRPO directory.
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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