Columbia University Medical Center

Monthly IRB-Investigator Meeting (MIM)

HRPO Response to January 2021 MIM Focus Group Feedback

April 15, 2021

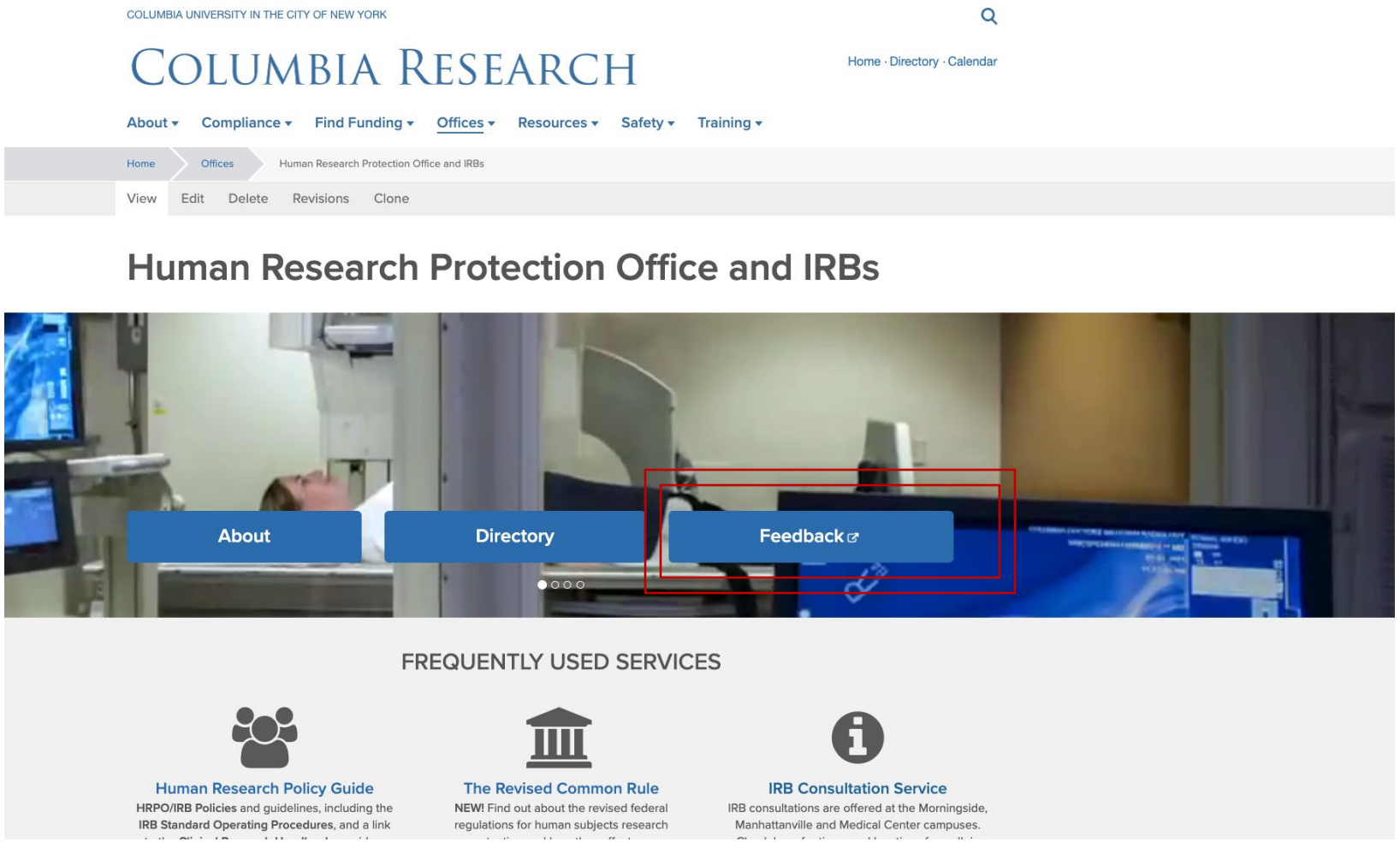
Agenda

- Meeting background
- Description of items and HRPO responses
- Questions and feedback

Zoom Meeting Logistics

- Participants' video and audio are by default turned off.
- To submit a question, use the chat feature, or you can unmute yourself at the end of the presentation and ask the question.
- Slides will be posted on the HRPO website.
- An evaluation survey will be sent via the chat at the end of the presentation.

Anonymous Feedback to HRPO



Background

- Focus group meetings held on 01/21/2021
  - 2PM meeting
  - 3PM meeting
- Diversity in role and departmental affiliation among attendees
- Objectives of the focus groups were to gain valuable feedback for HRPO operational planning
- 11 items were identified

HRPO Response Plan

- Respond to items identified in the focus groups
- Share measures taken to resolve minor items
- Describe new processes or planned initiatives to address major items

ITEM #1

Policy changes are not communicated effectively

- HRPO acknowledges that there is room for improvement in the way policy or procedural changes are communicated to the research community.
- Commitment to improve communications by consistently using email blasts, the HRPO website, and announcements at MIMs.
- Project: IRB newsletter to be distributed on a regular schedule
  - Include summary of policy updates, significant Rascal system updates, staffing changes, and other relevant information.

ITEM #2

Researchers are not involved in policy change/process discussions

- HRPO acknowledges that the input of researchers and research staff members for certain policy/process discussions is important.
- Current process includes seeking input from the research community at MIMs.
- Project: Working group
  - Establish an engaged group of investigators and research staff from various backgrounds and departments who would serve as consultants when warranted.

ITEM #3

Better communication with researchers during study pre-review

- Our current process is for HRPO staff to reach out to the study team via phone/email during the pre-review process for clarification/documentation if a protocol return can be avoided.
- This additional procedural step can lead to longer review times for some submissions while shortening others.
- Researchers and members of the study team must respond timely to such communications for the process to be effective.
- HRPO will explore ways to measure occurrences where the process did not work and resulted in a return.
- HRPO is seeking specific examples of this, please send to Sean Hobson.

ITEM #4

Extensive work required when study requires sIRB

- HRPO senior staff are working on an electronic intake process to make this process more efficient.
- Researchers must notify the HRPO as soon as it appears or is proposed that reliance may be involved (contact Tasha Smith).
- The intake form to be completed and (currently) to be sent by email to Tasha Smith is on the HRPO website (sIRB Webpage).

ITEM #5

Resources for new research staff

- HRPO offers several education courses for research staff including quarterly IRB 101 and monthly Rascal workshops.
  - HRPO can make additional efforts to advertise the availability of these courses on the HRPO education webpage.
- An IRB consultation service is offered at no cost to the research community (Consultation service webpage).
- Implementation of other courses for new research personnel is under discussion.

ITEM #6

Rascal fields are sometimes duplicative or unnecessary

- HRPO works with the Rascal team to make the Rascal system user friendly and efficient.
- Please send examples of Rascal fields that are thought to be duplicative or unnecessary to the Rascal Team and Amanda Fox.
- Our goal is to work with the Rascal technical team to eliminate any unanimously unnecessary fields within a reasonable time frame of receiving the feedback.

ITEM #7

Submission of Non-English and English ICFs at the same time

- Our current process requires the approval of the English documents before submission of the translated documents.
- It is advised that researchers planning to do this keep in mind that all IRB requested changes to the English ICF will also need to be implemented onto the second language ICF before approval is given.
  - This could lead to increased costs for translations and confusion about which consent form version is approved.

ITEM #8

IRB create educational documents for non-research community

- HRPO is in the process of revising its patient facing materials. Other offices at CU will need or want to be involved as well (e.g., community outreach).
- In the interim the HRPO recommends use of documents by OHRP and FDA that have both English and Spanish options.
- HRPO is also considering developing a video in both English and Spanish languages.
  - Link to OHRP videos (here)

ITEM #9A

IRB provide guidance on dealing with difficult research participants

- Refer to the HRPO:
  - Complaints by participants that cannot be resolved by the PI.
  - Concerns about compliance or integrity of data as a result of actions of participants.
- Safeguards should be in place to facilitate safety and resolve most situations
  - A PI may consider, for staff, HR training courses on managing difficult situations.
  - Study visits should be planned with safety in mind (e.g., location, multiple personnel)
  - Coordinators should contact the study PI immediately if a participant is uncooperative.
  - The participant should be reminded that study participation requires cooperation.
  - If a participant is uncooperative, the PI can remove him/her from the study.
  - **Research staff should immediately seek assistance if a situation becomes unsafe (e.g., PI or other investigator, colleague, Public Safety)**

ITEM #9B

Dealing with hostile or unsafe incidents

- Resources for when situations with participants escalate:
  - Report the *discrimination, harassment, gender-based misconduct* incident to the office of Equal Opportunity and Affirmative Action

    a. Contact Seth Marnin J.D. to discuss policies and specific issues pre-investigation

    b. You are encouraged to report the incident even if you resolve it.

  - Report *criminal* incidents to Public Safety
  - Counseling: Sexual Violence Response and Employee Assistance Program

ITEM #10

Can a PI contact the IRB to have a review prioritized

- HRPO is supportive of the research team reaching out to specific IRB staff members for assistance in the prioritization of events.
- If you know which IRB/team has processed your protocol, you can then use the HRPO directory to find the contact information of the IRB member.
- If you do not know which IRB/team has processed your protocol, please reach out to Laurence Rebbaa-Butaud for assistance.
    - Note, the contact person may change in the future as additional staff are onboarded in the IRB office.

ITEM #11

Request option to place all ICFs in the same section in Rascal

- Reminders:
  - Rascal generated consent forms, and HIPAA forms, are already in their own section.
  - Rascal technical team can create new document types (e.g. Non-English ICFs)
- The HRPO discussed this issue with the Rascal team. While all consent forms cannot be placed in one section, the document types can be sorted.
- Demo: Walkthrough of how the documents in the Print menu can be sorted.

Questions?
Don’t forget to complete the evaluations

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