



IRB Town Hall

Ramp-up of Human Subjects Research

Rascal IRB 2.1

July 30, 2020

(SLIDES UPDATED, POSTED ON AUGUST 12, 2020)

Agenda

- Brief timeline of significant directives from the HRPO in response to the COVID-19 pandemic, as it relates to human subjects research
- Useful links to University websites to help researchers navigate the landscape of conducting research in the current environment
- Ramp-up Q & A
- Research Conduct Q & A (Consent Procedures, Study Procedures)
- Rascal IRB 2.1 Presentation



Logistics

- To submit a question during the live webinar, you can:
 - Use Zoom's Q & A function. (Chat feature is disabled)
- Questions may be posted anonymously. However, if we don't get to your question during the session, we will not be able to respond to you directly afterwards.
- Participants' video and audio are by default turned off.
- Slides will be posted on the HRPO website.
- Meeting will not be recorded.



IRB operations

- The IRB has continued its routine review operations throughout the research ramp down, but some of its process were altered for rapid review of COVID-19 research.
- The IRB received approx. 400 new COVID-19 studies since March. Most of the studies were reviewed by an expedited review and about 75 new protocols required review at a convened meeting.
- All new COVID-19 research are initially processed within 3 business days of submission to ensure rapid review by the IRB. An additional 37 IRB meetings were convened since March 13, 2020.
- Each IRB rotates weekly to review greater than minimal risk COVID-19 research. The IRB “on call” has pre-scheduled meetings 3 times a week.



Timeline of HRPO/IRB Directives to Researchers

- March 2020 to July 2020 (still ongoing for Morningside): IRB surveys sent via Qualtrics for ALL active human subjects protocols (initially CUIMC, then Morningside).
 - Assess whether protocol involves in-person procedures (@CUIMC initially, then expanded to any location worldwide); PI assessment of the prospect of direct benefit, and whether in-person procedures would be paused/modified.
 - Generally, only those protocols that offered the prospect of direct benefit were permitted to continue with in-person procedures (NOTE: in-person enrollment was on hold for ALL protocols with some exceptions (e.g. COVID-19 related protocols) until the start of ramp up in June 2020.)
 - March 2020 to July 2020 (still ongoing for Morningside): Survey responses assessed by IRB/HRPO. Study specific “pause” determinations emailed to PIs.
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Timeline (continued)

- June 8, 2020: IRB communication sent PIs of CUIMC protocols describing the Priority Tier system to be used for ramp-up at CUIMC.
- June 22, 2020: Priority I and II Tier studies may resume in-person procedures (and in-person enrollment with some caveats) with departmental approval.
 - Communications sent: listserve email, study-specific emails to PIs, departmental notifications
- July 17, 2020: Remaining studies (Priority III and IV) Tier may resume in-person procedures and in-person enrollment with departmental approval.
 - Communications sent: listserve email, study-specific emails to PIs, departmental notifications



Columbia COVID-19 Related Research Websites

Ramp up of human subjects research:

https://research.columbia.edu/COVID-19_Research/Ramp-up/HS

COVID-19 and research (ramp up and ramp down):

https://research.columbia.edu/COVID-19_Research

COVID-19 resource guide for the Columbia Community

<https://covid19.columbia.edu/research-rampup>

EH&S COVID-19 guidance webpage (Biosafety tab: Handling of biospecimens for research purposes during the pandemic):

<https://research.columbia.edu/ehs-covid-19-guidance>



RAMP UP Q & A



Ramp up Q & A

1. Who determined the Priority Tier for each paused or modified CUIMC study, and how was this decision made?

The description of the four Priority Tiers, which were defined by the CUIMC Research ramp up committee, can be found in the communication sent by the HRPO on June 8, 2020. The HRPO categorized each study, to the extent possible, based on the following factors:

- Is the study a clinical trial? (This information is derived from Rascal.)
 - Does the study offer the prospect of direct benefit? (The benefit assessment was made by the IRB, taking into account the PI's responses to the IRB Qualtrics survey. This information is in Rascal but not in a discreet field for automated extraction.)
 - What is the source of funding, if any? (This information is derived from Rascal.)
 - Is this a “new” or “existing” protocol? (This information is derived from Rascal, i.e. IRB approval of 6/22 or later)
 - Do all study procedures occur at the time of a clinically indicated visit or procedure? (This information is in Rascal but not in a discreet field for automated extraction.)
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Ramp up Q & A

- 2. My PI never received an email for his study from the IRB indicating that in-person procedures or enrollment can resume. He does not remember completing a IRB Qualtrics survey, or receiving any message from the IRB to pause procedures. What should I do?**

There are several possible reasons as to why your PI either did not receive the IRB Qualtrics survey, or did not receive any subsequent study-specific messaging from the IRB. However, currently studies in ALL four Priority Tier may resume enrollment and in-person procedures with *departmental* approval. Thus, from an IRB perspective there are no current restrictions, and you should seek departmental approval to resume in-person procedures if these had been paused.



Ramp up Q & A

- 3. My PI did not receive a study specific email from the IRB indicating that in-person procedures or enrollment can resume. She does remember completing a Qualtrics survey, and subsequently received a message from the IRB indicating that the study did not involve in-person procedures. The study did not have in-person procedures at the time because we had paused procedures. We would like to resume procedures now. What should we do?**

We acknowledge that the IRB Qualtrics Survey question regarding whether or not the study involved in-person procedures was open to misinterpretation. This study was probably misclassified as one that does not involve in-person procedures. However, currently ALL four Priority Tier studies may resume enrollment and in-person procedures with departmental approval. Thus, from an IRB perspective there are no current restrictions, and you should seek departmental approval to resume procedures if these had been paused.



Ramp up Q & A

- 4. We received messages from our sponsor and the IRB that enrollment and procedures have to be put on hold. Accordingly, we paused our procedures and submitted a modification to the IRB indicating that these were on hold. We have now received notifications from the sponsor and the IRB that these can resume. Can we now bring in our participants for the study?**

Departmental approval must also be obtained to resume enrollment and in-person procedures. In general, we are not requiring that you notify the IRB (via modification or via email) when enrollment and/or in-person procedures resume. However, if the IRB-approved protocol in Rascal indicates that there is a hold, a modification must be submitted to reflect that the hold is lifted.



Ramp up Q & A

5. How do I let the IRB know that I've received departmental approval to resume in-person procedures and in-person enrollment.

We are NOT requiring that the PI or the department notify the IRB (via email or via a modification] when a study has been approved by the department to resume in-person procedures or enrollment. The PI and department should retain documentation of all approvals. If a previously submitted modification revised the study status to “enrollment on hold” because of the pandemic, a modification is needed to return the status to “open to enrollment”



Ramp up Q & A

6. What happens if there is a “second wave”? Will there be another ramp down? How will restrictions be implemented?

At this time, it is anticipated that ramp down during a second wave would begin with pausing of in-person procedures for Priority Tier III and IV studies.



Ramp up Q & A

- 7. I personally feel conflicted about bringing in healthy people for observational research to campus (needing phlebotomy, basic vitals). However, with an R01 this is being allowed at this stage (and encouraged for the sake of the study). Has anyone else raised concerns about this? My issue is bringing people into the building who don't need to be there. I thought we were working to minimize foot traffic (of both staff and community members). My director has said we should not conflate all indoor activity with being unsafe, this is also true.**

Each PI and department must assess whether the risk of bringing participants on-site is minimized to the extent possible, given the precautions that are in place (e.g., PPE for staff, face covering for participants, physical distancing to the extent possible, cleaning protocols, occupancy limits and so on). Scheduling should not proceed if there is concern that an unacceptable risk remains. Participants should be reminded, during scheduling procedures, of the precautions that are in place and that they are not required to participate in on-site visits at this time.



Ramp up Q & A

8. When will in-person procedures for human subjects research at Morningside be permitted to resume? Will the process be similar to the Priority Tier system used at CUIMC?

Discussions are continuing but a decision about timing of and process for ramp up on the Morningside and Manhattanville campuses has not been made as yet. Individuals with responsibility for managing the vast majority of the studies that have been paused are involved in the discussions. Balancing the need for important research to resume with concern about having visitors on campus is the priority.



Ramp up Q & A

9. **My research is conducted off-campus. What are the requirements for resuming in-person procedures and new enrollment?**

Off-campus research, whether in NYC, elsewhere in the United States, or in a foreign country, is broadly classified as “field research” for ramp up purposes. Refer to the [Guidelines for Planning the Resumption of Field Research](#) in the COVID-19 Resource Guide for the Columbia Community, in the Planning Tools and Guidance section. Completion of a form, and approval by the applicable dean, is required.



RESEARCH CONDUCT Q & A



Research Conduct Q & A

- 10. I am planning to transition my recruitment procedures, including consent, to complete remote procedures. Do I need to submit a modification?**

No, a modification is not required if you need to implement changes to avoid an imminent hazard to study participants. Federal regulations allow such changes without prospective IRB approval.

You may make changes to the research to reduce COVID-19 transmission risks without prior IRB approval, but you should document the changes and reasons for the contingency plan in your research records. You will need to report the changes to the IRB at the time of your next modification or renewal, or when directed to do so by the IRB, whichever comes first.



Research Conduct Q & A

- 11. I would like to obtain consent remotely to minimize the number of in-person visits. What is the recommended process to obtain the signed consent form from the subject?**

Use of REDCap in conjunction with a videoconference is recommended for remote consent processes because an electronic signature is facilitated by the system.

When this is not feasible, a copy of the consent form should first be sent by mail or email to the prospective subject prior to the scheduled telephone or videoconference consent discussion.

The remote process should be similar to an in-person process, which must include :

- An explanation of the process;
- A review of the consent form with subjects;

(continued on next slide)



Research Conduct Q & A

11. (Continued)

- The process should begin with a concise and focused presentation of the key information and the information presented should be organized.
- Subjects should be given enough time to consider the research study and ask questions.
- The entire process should provide information about the study in sufficient details.
- The process should conclude with a confirmation from the subject that their questions have been answered and, if they decide to participate, they will date and sign the consent form.

Subjects will mail, email or fax the signed consent form, or a photo of it, to the PI or person who is approved to obtain consent.

Once the signed consent is received, the PI or person who conducted the consent process must sign and date the consent. The subject must be provided with a copy of the signed consent form if the original is mailed back to the study team.



Research Conduct Q & A

12. Can I use DocuSign to obtain subjects' signatures on a consent form?

The Columbia University instance of DocuSign cannot be used to obtain electronic signature in documents that contain health information about the prospective participant (e.g., “you are eligible for this study because you have diabetes”). If a coordinating center or other collaborator provides documentation of Part 11 compliance for a version of DocuSign that will be used for enrollment of Columbia participants, it can be used for documents that contain health information.



Research Conduct Q & A

13. Will Rascal be set up with Remote e-consenting fields to fill out (incorporated with branching logic, etc, in the Consenting section)? Many studies are moving toward this; it will save all parties time if the study team does not have to write this up manually, then go back and forth with corrections.

This is an excellent suggestion for improvement of the consent process page in Rascal. We will add this suggestion to our list and will work with the Rascal team to incorporate these questions in a future Rascal version.



Research Conduct Q & A

15. What systems should I use for video interactions with subjects?

Refer to the COVID-19 Research Ramp Down FAQs. The current guidance for CUIMC on applications that can be used to contact research participants recommends the following non-public facing remote communication products: Apple FaceTime, Facebook Messenger video chat, Google Hangouts video, WhatsApp video chat, Zoom, or Skype.



Research Conduct Q & A

- 16. Our CRO keeps emailing us to determine if the study monitor can come onsite to conduct a monitoring visit. Are onsite monitoring visits permitted?**

Please consult with the Clinical Trials Office as they manage monitoring processes.



Research Conduct Q & A

17. What if the sponsor proposes to ship the drug directly to subjects?

Please consult with the Clinical Trials Office and Research Pharmacy.



TOWN HALL Q & A

This section includes responses to live questions that we were unable to respond to during the Town Hall, due to time constraints.



Town Hall Q & A

1. Are there any specific guidelines to resume in person research?

Please refer to the following links:

- Ramp up of human subjects research: https://research.columbia.edu/COVID-19_Research/Ramp-up/HS
- COVID-19 and research (ramp up and ramp down): https://research.columbia.edu/COVID-19_Research
- COVID-19 resource guide for the Columbia Community: <https://covid19.columbia.edu/research-rampup>
- EH&S COVID-19 guidance webpage (Biosafety tab: Handling of biospecimens for research purposes during the pandemic): <https://research.columbia.edu/ehs-covid-19-guidance>]



Town Hall Q & A

2. How do I go about obtaining “departmental” approval to resume in-person enrollment and procedures?

You should contact your research administrator/manager to determine what are the procedures for obtaining approval to resume in-person enrollment and procedures. If you do not have a research administrator, you should contact your division or departmental administrator. The procedures for obtaining this approval may vary across departments, divisions, and other units.



Town Hall Q & A

3. Can subjects be recruited in-person by researchers from inpatients units?

Until further notice, in-person recruitment of inpatients requires approval from the unit director as we do not know the safety precautions that are in place and necessary in each unit. Because of current safety concerns and restrictions to direct access to patients, recruitment via posted flyers, use of RecruitMe and referrals utilizing a centralized screening process through the Division of Infectious Diseases are preferred recruitment processes. In addition, for non-hospitalized patients, remote communication is supported at this time. When the study targets healthcare providers at Columbia, recruitment on site may be acceptable as long as physical access is not otherwise restricted, such as through density parameters.



Town Hall Q & A

- 4. I am submitting a renewal for my protocol, and would like to report to the IRB that certain procedures are being conducted remotely due to the COVIDd-19 pandemic. Do I need to make any modifications to the actual protocol to indicate that the interviews are being conducted remotely, or do I just indicate this in the modification summary section of the IRB datasheet?**

Yes, a modification describing the remote interviews should be included with the renewal in the procedures section in Rascal or standalone protocol



Town Hall Q & A

5. **When can we resume MRI studies at ZMBBI?**

Procedures for resuming imaging procedures at ZMBBI are being finalized. We will provide an update via the IRB listserv and on the Human Subjects Research Ramp Up FAQs page when we are notified of reopening.



Town Hall Q & A

- 6. I live with people who are high risk for COVID. My study requires me to come to work in-person. How do I go about minimizing the risk of passing COVID to those I live with?**

Please consult the COVID-19 Resource Guide for the Columbia Community, which has sections such as Preparing for Resuming On-site Research, Daily Routine before Arrival, Daily Routine at Work, Where to Go with a Concern, and Planning Tools and Guidance (<https://covid19.columbia.edu/>)



Town Hall Q & A

- 7. If the study is currently held on the Morningside campus, is it possible to transfer to field research if you have another place to hold it?**

Yes, this is possible. However, you must still obtain approval from your school/department



Town Hall Q & A

- 8. For one of my studies, Columbia is not the Single IRB. Due to the COVID-19 pandemic, the Single IRB allows for remote visits without an amendment to the protocol. Can these procedures be implemented at Columbia without a formal notification to Columbia University IRB?**

No, you will need to submit a modification in Rascal to notify the Columbia University IRB of the Single IRB's allowance for remote visits without an amendment to the protocol.



Town Hall Q & A

- 9. We are planning to resume data collection activities (one-time qualitative interviews) in our study sites in a foreign country, where the COVID epidemic is in control. In this case, would we still need departmental approval prior to the resumption?**

Yes, departmental or school approval is still needed.



Town Hall Q & A

10. Are new studies being permitted to be initiated?

There are currently no restrictions from an IRB perspective on initiating new studies. Departmental approval must still be sought, however, if the study involves in-person enrollment or in-person procedures.



Town Hall Q & A

11. As PIs consider procedures within their protocols that expose subjects to multiple study personnel, should they consider revising procedures such that only treating care team members interact in-person with participants for these procedures?

PIs should continue to minimize in-person interactions to the extent possible. If limiting the personnel to only those research team members that are part of the treating care team is possible, this should be explored as it is one way to minimize contact with multiple people.



Town Hall Q & A

12. Is verbal consent (i.e. waiver of documentation of consent) sufficient for observational research in which interviews and procedures are being conducted remotely?

Yes, a waiver of documentation of consent can be granted with the consent process being performed remotely as long as the study presents no greater than minimal risk to subjects.



Town Hall Q & A

- 13. There were several questions that we received regarding the use of REDCap in obtaining remote consent. We are in the process of gathering relevant information, and plan to post it on the HRPO website.**



HRPO Contact Information

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