# Study-Specific Checklist for Rampdown of Human Participant Research

This checklist is provided to assist your study in ramping down and does not need to be submitted.

*Visit the UMOR website for the most recent information on human research during COVID-19*

Use the following checklists and action items as a guide for research rampdown and/or adjustment of research activities due to COVID-19 related impacts on human participant research. For each Action, indicate Y/N as to whether the Action is applicable to the study. In the Notes field, include any information pertaining to the Actions, including the outcome. See Sections I to V for general items and Sections V to IX for special circumstances.

## STUDY INFORMATION & STATUS

| | |
|---|---|
| **HUM ID:** | |
| **Study Title:** | |
| **PI Name:** | |
| **Study Sponsor:** | |
| **UMOR Reactivation Tier level:** | |

## STUDY STATUS

Research rampdown plans will vary based on the status and the risk profile of individual studies and whether participants are still being recruited as distinct from previously-enrolled participants. The emphasis of any rampdown plans will focus on the potential risks and benefits for participants and the risk of viral transmission.

All human participant-related at U-M will be categorized into one of the options outlined below:

**OPTION A:** Research rampdown plans **will NOT impact** my study as **ALL** of the following options are true for my current study:

- ☐ The study is conducted completely remotely without any in-person interactions between participants and/or study team members or is approved to transition to remote procedures.
- ☐ The U-M study team does not need to be on U-M premises or leave their remote work settings for study purposes
- ☐ Research activities will continue with no changes to the study procedures
- ☐ Additional justification: _____

**OPTION B:** Research rampdown plans **will impact** my study as Option A does not apply:

- ☐ For new (to be enrolled) participants *(select one of the options below)*
  - ☐ Research activities will be paused until the rampdown restrictions are lifted
  - ☐ Research activities will continue with some changes to the study procedures
- ☐ For previously-enrolled participants *(select one of the options below)*
  - ☐ Research activities will be fully paused until the rampdown restrictions are lifted
  - ☐ Research activities will continue with some changes to the study procedures

 If Option A is selected, no additional action is needed.

 If Option B is selected, use the checklist below to assist in ramping down this study.

# Study-Specific Checklist for Rampdown of Human Participant Research

## I. PREPARATION

| Also review UMOR, IRBMED, or IRB-HSBS websites, as applicable, for assistance with study-specific planning. | | |
|---|---|---|
| **Action** | **Yes/No** | **Notes** |
| 1. Create a contact list (e.g., email, cell, pagers) of study team members/critical study resources:<br>● PI<br>● Co-I<br>● Study coordinators/project managers<br>● Lab personnel<br>● Department administrators<br>● Sponsor representatives<br>● Coordinating center/CRO | | |
| a. Post the contact list where it is locally accessible (within an office space) and/or remotely accessible (e.g., M-Box, Google docs). | | |
| b. Identify key study team members (e.g., PI, study coordinators, research pharmacy, sponsor monitors) and ensure that back-up is available. | | |
| c. Re-evaluate the study procedures to identify study-specific activities that can be done remotely, delayed, or suspended. | | |
| 2. Create a list of *active* study participants that would need to be contacted in the event of a rampdown | | |
| a. Record their preferred contact information | | |
| b. Maintain the list in a secure location | | |

## II. COMMUNICATION

| Communicating current and accurate information is critical. Always refer to UMOR and/or corresponding IRB websites for the most recent information about the status of any rampdown requirements. | | |
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| **Action** | **Yes/No** | **Notes** |
| 1. Assure the U-M study team has been alerted and made aware of the rampdown plans. | | |
| 2. Assess the impact of rampdown on the current study and develop a communication plan. | | |

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| 3. Once the changes to the current study are determined, as appropriate and applicable, notify the following entities or individuals and document the notification:<br>● Other U-M offices (research pharmacy, labs, etc.)<br>● The sponsor(s) and/or coordinating center<br>● Federal Agencies (FDA, OHRP, etc.)<br>● Participants | | |

## III. REMOTE RESEARCH ACTIVITIES

Certain research activities may be modified or shifted to fully remote in order to provide for continuity of the study and decrease the risk of viral transmission.

| Action | Yes/No | Notes |
|---|---|---|
| UMOR guidance (link provided here) provides information regarding possible modifications to certain study activities and how to apply remote approaches to human participants research/fieldwork during the COVID-19 pandemic. | | |

## IV. MODIFICATIONS TO STUDY VISITS/SCHEDULE/PROCEDURES

If research activities will be *fully paused* for both new participants and previously enrolled participants until the rampdown restrictions are lifted, no changes may be needed to the study and/or the IRB application (*although notifications are likely necessary per the Communication Plan*). If the research is not fully paused, the study team should carefully evaluate how the study will be updated to ensure the continuity of the study and its operations. This usually starts with assessing the study visits so they can be modified to minimize or remove in-person interactions.

**NOTES:**

⇨ If the study procedures will be modified either for new participants or previously enrolled participants, the changes must be submitted to and approved by the IRB. This is done by submitting an Amendment in eResearch.

⇨ If the research activities will be paused or modified for previously-enrolled participants, also establish a plan to communicate the change(s) to participants. See Section II Communication. Examples: cancellation and/or rescheduling of appointments, modification of study timelines, new procedures for continuing to receive research interventions or interactions including shipments of drugs from the research pharmacy.

| Action | Yes/No | Notes |
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| 1. There will be no changes to the study procedures or visits/interactions with participants *(if "no" is selected, the remainder of this section need not be completed*). | | |

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| 2. The study visits/procedures need to be modified to ensure continuity of the study under the rampdown restrictions *(if "yes" is selected, complete all that apply below and submit an Amendment in eResearch for review and approval.* | | |
| 3. Convert some/all visits/interactions to remote visits/interactions as permitted. | | |
| 4. Modify or remove study procedures that cannot be done remotely as long as they do not compromise participant safety and data integrity (check with any study sponsors). | | |
| 5. Conduct recruitment and informed consent procedures remotely. | | |
| 6. If collecting specimens (e.g., blood, urine, saliva) determine if:<br>a. participants will be provided with at-home-collection kits to self-collect the specimens (as appropriate) and ship them directly to sponsors or study teams<br>b. collection will occur at a non-U-M location (e.g., a sponsor authorized commercial laboratory) | | |
| 7. Consider any changes to previously scheduled Data and Safety Monitoring Board (DSMB) meetings and/or sponsor monitoring visits. | | |
| 8. Address the timing for study procedures to align with clinical care visits as possible. | | |
| 9. Modify study drug administration procedures as necessary (see Special Scenarios: FDA Regulated Research). | | |

## V. STUDY DOCUMENTS

It is important to keep IRB applications and/or the supporting materials accurate with study-specific information. The subject-facing materials (e.g., recruitment, informed consent, letters, emails, phone scripts, etc.) and the procedures associated with them should be updated to ensure that the information is accurate and current. Study teams may be able to utilize an addendum to the materials instead of revising the main study materials (e.g., an addendum to the previously approved consent). Procedures associated with these documents will also need to be adapted to address the current remote working conditions as well as the subject population.

| Action | Yes/No | Notes |
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| 1. The study protocol will be revised or an addendum will be developed to address COVID-19 related study-specific planning. | | |

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| 2. The recruitment and/or informed consent process will be conducted remotely and therefore the corresponding documents will be updated as appropriate. | | |
| 3. Participant-facing materials (scripts, emails, consent documents, etc.) that will address changes to the research will be developed and provided to the IRB for review. | | |
| 4. Technology-related challenges may occur with certain participant populations; plan accordingly.<br>● If electronic consent and/or email is not an option to communicate with the participants, consider mailing the written documents to the participants | | |

## VI. SPECIAL SCENARIOS: FDA Regulated Studies

| FDA regulated studies require additional actions to assure protocol and sponsor compliance with regulatory requirements. | | |
|---|---|---|
| **Action** | **Yes/No** | **Notes** |
| 1. Changes to the study protocol, study procedures, or study conduct must be provided to the IRB for review and approval. | | |
| 2. Study drug shipped to a participant's home requires prior approval from the Sponsor and the Research Pharmacy. | | |
| 3. If a U-M PI holds the IND or IDE from FDA, notify MIAP regarding any changes in study procedures to permit notification to FDA. | | |
| 4. To utilize the option of visiting nurses or other home-healthcare-agency assure the following are in place and update the IRB application and consent form as necessary:<br>● The clinical trial agreement/contract (contact ORSP)<br>● Protocol<br>● Informed Consent | | |

## VII. SPECIAL SCENARIOS: Multi-center Studies

A. U-M as single IRB (accepting oversight for non-U-M sites)

| Rampdown activities at U-M may impact overall study activities depending on U-M's role in providing study-related services. | | |
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| **Action** | **Yes/No** | **Notes** |

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| 1. Ensure that the master protocol or any addendum outlines changes to the study procedures or study conduct. This must be provided to the IRB for review and approval. | | |
| 2. Notify the external sites, using the "Post Correspondence to Participating Site Application" activity in the HUM workspace, (as applicable) providing the necessary documentation and notification of the research rampdown or any change in procedures or study conduct. | | |
| 3. Require the external sites to complete the COVID Checkpoint Survey for their own site activity: https://research.medicine.umich.edu/our-units/institutional-review-boards-irbmed (IRBMED KeyLinks-> Single IRB and Multi-site Research Information for Research Reactivation) | | |

B. U-M is Ceding oversight to non-U-M sites

| Rampdown activities at U-M may require notification to external IRBs serving as the IRB of Record. | | |
|---|---|---|
| **Action** | **Yes/No** | **Notes** |
| 1. Ensure that the protocol or a site-specific addendum will outline any changes to the study procedures or study conduct during the rampdown. This must be provided to the external IRB. If needed, contact the external IRB for proper reporting timelines/requirements. | | |
| 2. Open an eResearch amendment to report the above changes to the U-M IRB and include external IRB's outcome/approval. | | |

C. U-M is a Coordinating Center

| Rampdown activities at U-M may impact overall study activities depending on U-M's role in providing study-related services. | | |
|---|---|---|
| **Action** | **Yes/No** | **Notes** |
| 1. Ensure that the protocol or any addendum will outline any changes to the study procedures or study conduct during the rampdown. This must be provided to the U-M IRB for approval via an amendment. | | |
| 2. Provide new information to the external sites regarding the status of the U-M coordinating center activities/procedures. | | |
| 3. Include proof of communication with the external sites as posted correspondence in the HUM workspace. | | |

## VIII. SPECIAL SCENARIOS: External Collaborators

| An external collaborator conducting research activities on behalf of a U-M research project is expected to work within the rampdown guidelines of U-M and to follow the same rampdown procedures of the U-M study team. | | |
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| **Action** | **Yes/No** | **Notes** |
| 1. Communicate with the external collaborator in eResearch via posted correspondence so that their understanding of the rampdown procedures is well-documented. | | |

## IX. SPECIAL SCENARIOS: International Studies

| Investigators with projects in international settings or outside of Michigan should have a rampdown plan if COVID-19 circumstances in the research location change.<br><br>Most international projects work with a collaborating institution and Research Ethics Board or IRB in-country. Individual researchers in an international site are responsible for monitoring the COVID-19 situation at their research site and for changing procedures as necessary. Study teams must be in frequent contact with their in-country partners and should develop a rampdown plan together. The plan should include the key elements as outlined in this Rampdown Checklist guidance document.<br><br>[Similar procedures should be implemented for research projects being conducted domestically but outside of Michigan. Study teams should notify the U-M IRB if conditions change at the research site.] | | |
|---|---|---|
| **Action** | **Yes/No** | **Notes** |
| 1. Develop communication plans between U-M and study teams located in-country. Include a plan to notify U-M study team of any required changes from the in-country IRB and amend the U-M IRB application if required. | | |
| 2. Notify the U-M IRB if research activities must be ramped down because of local conditions. | | |
| 3. Identify study procedures that can be conducted remotely or revert to approved remote data collection procedures for the study. | | |
| 4. Identify provisions to securely store or transfer research data, biospecimens, informed consent documents, and other study records during the rampdown. | | |
| 5. Notify the sponsor, if any, of COVID-19-related delays or project changes. | | |