# UMMC IRB Submission Guide

**REDCAP PROTOCOL SUBMISSIONS**

**UMMC IRB ADMINISTRATION**

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Preparing to Submit in Redcap - Initials and Continuing Reviews

Initial Submissions:

Documents required:
1. Protocol Document (on UMMC template)
2. Personnel Roster (on UMMC template)
3. Data Collection Sheet(s)
4. Informed Consents, assents, etc., if applicable.
5. Recruitment materials, if applicable.
6. Any other documents (surveys, ICD code lists, etc.) referenced within your protocol document.

Other considerations:
- Ensure that all personnel have completed the required CITI training.
- If you plan to rely on an external IRB, attach the IRB approval of the investigator/site, as well as any document(s) listed on this approval letter.

Continuing Review Submissions:

Documents required:
1. Approved Protocol Document
2. Personnel Roster (on UMMC template)
3. Most recent approval letter (either initial approval or last continuing review).
4. Study Archive PDF, if available (If your protocol was approved in IDEATE, we may have an archive document. Contact the IRB if you don’t have this document).

Other considerations:
- Ensure that all personnel have completed the required CITI course or CITI refresher course, and that the personnel roster is up-to-date.
- If you rely on an external IRB, attach the External IRB continuing review letter. Ensure this includes the new approval period dates, and that any documents listed on this approval are attached to the submission as well.
Preparing to Submit in Redcap - Initials and Continuing Reviews

Amendment Submissions:

Documents required:
1. If updating personnel, include the updated personnel roster (on UMMC template).
2. If updating/making changes to approved documents, include the following for each document you are amending:
   a. The currently-approved version
   b. A ‘track change’ or ‘marked’ copy, which clearly shows all edits that have been made.
   c. A ‘clean’ copy, with all changes accepted (i.e., this will be the new version if/when approved).
3. Current approval letter (either an initial or continuing review approval, showing the current approval period dates).
4. Study Archive PDF, if available (If your protocol was approved in IDEATE, we may have an archive document. Contact the IRB if you don’t have this document).

Other considerations:
1. If submitting a personnel modification: Ensure that all personnel have completed the required CITI course or CITI refresher course, and that the new personnel have been added to the UMMC personnel roster template and attached to your submission.
2. If you rely on an external IRB, attach the External IRB amendment approval letter. Ensure that all documents listed in this document are attached to your submission.

Final Report Submissions:

Documents required:
1. Current approval letter (either an initial or continuing review approval, showing the current approval period dates).
2. Any publications or presentations resulting from this protocol.
3. Study Archive PDF, if available (If your protocol was approved in IDEATE, we may have an archive document. Contact the IRB if you don’t have this document).
**Submission type:** Initial

**Study and Research Type:** Select the option(s) that best align with your research.

**Study Title:** Ensure this matches the title on your protocol document.

**Principal Investigator:** The PI for human subjects research under the auspices of UMMC must be a full time faculty or staff member or an affiliate faculty member with a full time faculty member identified as Co-PI.

**Study Contact:** The IRB will contact this person with any study correspondence.

**Enrollment approval -- Local site:** Enter the maximum number of participants you wish to enroll, and ensure this matches your protocol document.

**Study-Wide:** If this is a multi-site study, what is the total enrollment for all sites combined?
Note: If you are seeking UMMC IRB approval with no intent to rely on an external IRB, please select ‘no’ and move to the next section.

If you plan to rely on an external IRB:
- Select ‘yes’
- External IRB of Record: Name of reviewing IRB with whom the reliance agreement has been made.
- Study Sponsor: Include sponsor name, if applicable. List n/a if not.
- Attach External IRB Approval Letter: This letter must contain approval of the investigator and site, as well as the approval period dates. Any documents listed on this approval letter must be attached to the submission.
Initial Protocol Submissions – Completing the Redcap Submission Form – Waivers

Select all waivers you wish to apply for. Questions will appear depending on which waiver is selected – be sure to fully answer all questions.

Ensure that all waiver selections made here match the selections made on your protocol document.

Initial Protocol Submissions – Completing the Redcap Submission Form – Research Personnel

Add research personnel, beginning with Principal and Co-Investigators.

To add more than one person to the submission: Select ‘yes’ for ‘more research personnel’ and complete fields that pop up.

NOTE: You must include a personnel roster on the UMMC IRB template with your submission. List all personnel (including the 5 listed on the submission form) on the roster.
Please ensure that **at minimum**, you include the following attachments:

1. Protocol (on UMMC template).
2. Personnel roster (on UMMC template).
3. Data Collection sheet(s), if applicable.
4. Informed consent, permission, assent, if applicable (on UMMC templates).

If your protocol document references any other documents such as surveys, questionnaires, flyers, recruitment materials, etc., ensure that these documents are attached.

If your protocol document references any phone calls or interviews, a script must be attached.

If you run out of space for attachments and have additional documents, please email the additional documents to Meagan Follett (mfollett@umc.edu) and Irene Arguello (iarguello@umc.edu).
**Continuing Review Submissions – Completing the Redcap Form**

**Submission Type:** Continuing Review

**UMMC IRB Number:** The IRB number your protocol is currently approved under (xxxx-xxxx, or xxxxVxxxx).

**Study Contact:** The IRB will contact this person with any study correspondence.

**Enrollment Information**

**Enrollment to Date:** Total number of participants enrolled thus far.

**Enrollment Approvals – Local site:** Maximum enrollment approved by the IRB

**Study-wide:** If a multi-site study, what is the maximum overall enrollment for all sites combined?

**Enrollment Status:**
Is enrollment still open, or is it currently in the follow-up only or data analysis stage?
Note: If your protocol was approved by the UMMC IRB and does not rely on an external institution, please select ‘no’ and move to next section.

If your protocol relies on an external IRB:
- Select ‘yes’
- **External IRB of Record**: Name of reviewing IRB with whom the reliance agreement has been made.
- **Study Sponsor**: Include sponsor name, if applicable. List n/a if not.
- **Attach External IRB Approval Letter**: Attach the external IRB continuing review letter.
Continuing Review – Other Information

Answer all questions to the best of your ability. If you are unsure of how to answer a question, please reach out to the IRB administrative team for clarification.
Amendment Submissions – Completing the Redcap Form

Amendment Type:

1. **Personnel Change/Addition**
   Select this if you are adding, removing, or otherwise making changes to your study team.

2. **Update Study Documents**
   Select this if you are making changes to any approved documents (protocol, consents, adding new materials, etc.).

3. **Other/Notification to the IRB**
   Select this if you are submitting any other notifications to the IRB.

UMMC IRB Number: The IRB number your protocol is currently approved under (xxxx-xxxx, or xxxxVxxxx).

Submission Summary: Provide a full and complete summary of all changes being made. A ‘summary of changes’ list should be included and should match any changes made to the attached documents.

Study Contact: The IRB will contact this person with any study correspondence.
**Amendment Submissions – External IRB**

Note: If your protocol was approved by the UMMC IRB and does not rely on an external institution, please select ‘no’ and move to next section.

If your protocol relies on an external IRB:
- Select ‘yes’
- **External IRB of Record**: Name of reviewing IRB with whom the reliance agreement has been made.
- **Study Sponsor**: Include sponsor name, if applicable. List n/a if not.
- **Attach External IRB Approval Letter**: Attach the external IRB amendment letter.

Note: All documents listed on the external amendment approval letter must be attached to your submission.
Amendment Submissions – Personnel Changes

For Personnel Additions, Removals, or other Changes:

Select ‘Personnel change/addition’ for amendment type.

For each personnel addition, fill out the research personnel section. Ensure that all personnel added here have also been added to the attached UMMC Personnel Roster template.

*If you are changing the Principal Investigator on a study:*
- You must provide a short summary of the reason for the change, the new PI’s previous involvement with the study and reason why they have been chosen as the new PI.
- Any documents containing the PI name must be edited to show the change in PI, and both a ‘marked’ and ‘clean’ copy must be attached. This includes the protocol document, any informed consents, recruitment materials, etc.
- If the protocol relies on an external IRB, the external approval letter of the new investigator and updated documents must be included.

<table>
<thead>
<tr>
<th>Research Personnel 1</th>
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<tr>
<td>Name</td>
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<tr>
<th>CITI Expiration Date</th>
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<td>* must provide value</td>
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<table>
<thead>
<tr>
<th>Consenting Privileges?</th>
</tr>
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</table>
| ☐ Yes
| ☐ No
| ☐ N/A

If you have more than five research personnel to add to the study, please complete the full study roster in an Excel sheet and upload as part of the RedCap submission. Please enter the PI and study coordinator via the RedCap application as well.

<table>
<thead>
<tr>
<th>More Research Personnel</th>
</tr>
</thead>
</table>
| ☐ Yes
| ☐ No

reset
Submission Summary:
Provide a full and complete summary of all changes being made. A ‘summary of changes’ list should be included and should match any changes made to the attached documents.

Attachments:
Please include the following for each document you are amending:

1. The currently-approved version
2. A ‘track change’ or ‘marked’ copy, which clearly shows all edits that have been made.
3. A ‘clean’ copy, with all changes accepted (i.e., this will be the new version if/when approved).

Other documents to attach:
1. Current Personnel Roster
2. Current approval letter (either initial or continuing review).
Final Report Submissions – Completing the Redcap Form

Submission Type: Final Report

UMMC IRB Number: The IRB number your protocol is currently approved under (xxxx-xxxx, or xxxxVxxxx).

Study Contact: The IRB will contact this person with any study correspondence.

Enrollment Information

Completed Enrollment Number: Total number of participants enrolled.

Enrollment Approvals – Local site: Maximum enrollment approved by the IRB
Study-wide: If a multi-site study, what is the maximum overall enrollment for all sites combined?

Other Information

Answer all questions to the best of your ability. Give a thorough explanation for any questions to which you answer ‘yes.’

If there have been any publications or presentations, please attach these to your submissions.
Note: If your protocol was approved by the UMMC IRB and does not rely on an external institution, please select ‘no’ and move to next section.

If your protocol relies on an external IRB:
- Select ‘yes’
- **External IRB of Record:** Name of reviewing IRB with whom the reliance agreement has been made.
- **Study Sponsor:** Include sponsor name, if applicable. List n/a if not.
- **Attach External IRB Approval Letter:** Attach the external IRB final report/study closeout approval letter.

Note: All documents listed on the external amendment approval letter must be attached to your submission.
Please be sure to attach the following:

2. Current approval letter (either initial or continuing review).
3. Any publications or presentations resulting from this study.
4. Study Archive PDF, if available (If your protocol was approved in IDEATE, we may have an archive document. Contact the IRB if you don’t have this document).
Reportable Event Submissions – Completing the Redcap Form

Reportable Event Type:
- Adverse events
- Unanticipated Problem Reports

UMMC IRB Number: The IRB number your protocol is currently approved under (xxxx-xxxx, or xxxxVxxxx).

Study Contact: The IRB will contact this person with any study correspondence.

Submission Summary: Provide a full and complete summary of the adverse event or unanticipated problem, as well as any corrective action plans you intend to put in place, and whether or not this event is believed to be related to the study or not.

Attachments: Include any relevant problem reports or documentation, as well as any corrective action plans if applicable.
**Reportable Event Submissions – External IRB**

*Note: If your protocol was approved by the UMMC IRB and does not rely on an external institution, please select ‘no’ and move to next section.*

If your protocol relies on an external IRB:
- Select ‘yes’
- **External IRB of Record**: Name of reviewing IRB with whom the reliance agreement has been made.
- **Study Sponsor**: Include sponsor name, if applicable. List n/a if not.
- **Attach External IRB Approval Letter**: Attach the External IRB approval or acknowledgement of the reportable event, as well as any other associated documentation.

*Note: All documents listed on the external amendment approval letter must be attached to your submission.*
## Redcap Submission Link

[https://redcap.umc.edu/surveys/?s=TNT9K3FTMN](https://redcap.umc.edu/surveys/?s=TNT9K3FTMN)

## Where can I find the UMMC IRB Templates?

Human Research Office Website - Templates, Forms & Samples Page
[https://www.umc.edu/Research/Research-Offices/Human-Research-Office/Templates-Forms-and-Samples1.html](https://www.umc.edu/Research/Research-Offices/Human-Research-Office/Templates-Forms-and-Samples1.html)

## Who do I contact if I have a question?

<table>
<thead>
<tr>
<th>General IRB Questions:</th>
<th>External IRB Questions:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Meagan Follett, MS</strong></td>
<td><strong>Kyle Cardwell</strong></td>
</tr>
<tr>
<td>IRB Specialist</td>
<td>Mgr. – External IRBs</td>
</tr>
<tr>
<td><a href="mailto:mfollett@umc.edu">mfollett@umc.edu</a></td>
<td><a href="mailto:kcardwell@umc.edu">kcardwell@umc.edu</a></td>
</tr>
<tr>
<td>601-815-5016</td>
<td>601-815-4073</td>
</tr>
<tr>
<td><strong>Irene Arguello, MHS</strong></td>
<td></td>
</tr>
<tr>
<td>IRB Coordinator</td>
<td><strong>IRB Director:</strong></td>
</tr>
<tr>
<td><a href="mailto:iarquello@umc.edu">iarquello@umc.edu</a></td>
<td><strong>Chris Moore</strong></td>
</tr>
<tr>
<td>601-815-1345</td>
<td><a href="mailto:cmoore10@umc.edu">cmoore10@umc.edu</a></td>
</tr>
<tr>
<td><strong>Tenay Spann</strong></td>
<td></td>
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<tr>
<td>IRB Administrator</td>
<td></td>
</tr>
<tr>
<td><a href="mailto:tmspann@umc.edu">tmspann@umc.edu</a></td>
<td></td>
</tr>
<tr>
<td>601-984-2815</td>
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</table>

**Human Research Office Website:** [https://www.umc.edu/Research/Research-Offices/Human-Research-Office/Overview.html](https://www.umc.edu/Research/Research-Offices/Human-Research-Office/Overview.html)