This guide has been developed to help researchers complete IRB continuing review applications. The review questions are listed and text in bold provides guidance/information to answer the renewal question.

If you require further assistance, please contact the IRB at 792-4148 or SUCCESS Center research support services at success@musc.edu or 792-8300.

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Study Details

The information below appears at the top of the renewal and will be automatically populated based on the initial application or amendments.

If any of the information is not accurate, submit the appropriate documents with the renewal that lists the requested changes.

1. HR #: This number is assigned by IRB and cannot be changed.
2. PI/Dept/Div: A change in PI requires an amendment to be sent to IRB.
3. Email/Phone/Bldg/MSC:
   This is the contact information of the personnel who is approved as the IRB contact (or the PI if no contact is identified). Revisions to this information require an amendment to be sent to IRB.
4. MUSC/VAMC/GCRC/Charleston Memorial/Georgetown Hospital/CRCC/HCC/IDS/Other
   Changes to any of the study facilities above require an amendment to be sent to IRB.
   VAMC = Veterans Administration Medical Center
   GCRC = General Clinical Research Center. This has been re-named to CTRC (Clinical & Translational Research Center)
   CCRC = Coastal Carolina Regional Center
   HCC = Hollings Cancer Center
   IDS = Investigational Drug Services
5. Agency/Sponsor:
   A change in the sponsor of the study requires an amendment to be sent to IRB.
6. Title:
   A change in the study title requires an amendment to be sent to IRB.

Study and Subject Status

This section requests information on the current statuses of the study and subjects. A definition of ‘Enrolled’ is include to assist with determining subject statuses

**Enrolled = the point at which a subject is approved for study treatment, intervention, registration or procedures OR when study screening procedures have been applied and the subject has met screening criteria to have data collected and included in support of the research objective

1. Enrolling Subjects - No accrual to date
   Study is actively recruiting subjects and no subjects have been enrolled** to date

2. Enrolling Subjects and Collecting Data
Study is actively recruiting subjects, subjects have been enrolled** and data are being collected on these subjects

*If the study did not involve interaction with living individuals (i.e., retrospective chart review/existing biological specimen analysis), this option can be selected until all data are collected.*

3. Accrual Closed - On-going Research and Treatment/Intervention

Study is no longer actively recruiting subjects, subjects have been enrolled** and are still receiving study defined treatment/intervention and procedures

4. Accrual Closed - Follow-up or Data Collection only

Study is no longer actively recruiting subjects, subjects have been enrolled*, are no longer receiving study defined treatment/intervention and are only receiving follow-up or study data collection

5. Accrual Closed - Data Analysis Only

Study is no longer actively recruiting subjects, subjects have been enrolled**, are no longer receiving study defined treatment/intervention, follow-up or study data collection; data are only being analyzed

*If the study did not involve interaction with living individuals (i.e., retrospective chart review/existing biological specimen analysis), this option can be selected for subsequent reviews until study termination conditions are met.*

6. Termination Requested

Study is no longer actively recruiting subjects, subjects have been enrolled**, are no longer receiving study defined treatment/intervention, follow-up or data collection is complete.

**AND**

Data has been analyzed and study is complete OR investigator has chosen to terminate the study (investigator decision or an external sponsor has given MUSC permission to terminate the study [rationale and/or correspondence with sponsor must be included in either case]

*If the study did not involve interaction with living individuals (i.e., retrospective chart review/existing biological specimen analysis) this option can be selected as specified above*

**OR**

Study did not enroll subjects and is being closed to enrollment.

**Date subject accrual completed (mm/dd/yyyy):**

The date subject accrual was completed, whether the target enrollment was achieved, or it was an MUSC or external sponsor decision to cease study accrual.
**Personnel**

List of current study personnel:

| The system will list all currently IRB approved personnel with their approved roles. |

Is this list current?

| Indicate 'Yes' if all personnel are up to date. Indicate 'No' if old personnel should be deleted and/or new personnel should be added. |

*Note: if changes are required, an electronic amendment to change personnel must be completed and sent to IRB at the time the renewal is completed. If changes are not submitted at the time of study continuing review, the continuing review approval will be held until an amendment to revise the personnel list has been submitted to IRB.|

Is research education current for all investigators and research staff?

| Indicate if all personnel have completed the required CITI training. To complete online training go to http://www.musc.edu/citi. For an explanation of training requirements go to http://research.musc.edu/ori/irb/ed_citi.html. |

*Note: If all personnel have not completed the required training, study continuing review approval will be held until all training has been completed.|

**Type Study**

This section requests information regarding the activity and locations of the study

1. Does this study involve record chart/review only?

   | A ‘Yes’ answer indicates the study is not prospectively recruiting subjects and involves reviewing previously collected medical information/samples. |

2. Is this multi-center trial?

   | A ‘Yes’ answer indicates the study is conducted at MUSC and at least one additional location off MUSC’s campus (a location not operated by MUSC or that are not considered in the MUSC family of organizations) at the time of the renewal. |

3. If this is a multi-center trial, are you the lead investigator?

   | The lead investigator is the principal investigator responsible for the overall conduct of the study at all sites and has access to and control of the data. |

4. Are you conducting any study procedures at one or more off site campus facilities other than MUSC? This includes screening, testing, enrollment, etc.
A ‘Yes’ answer indicates the listed procedures are occurring at facilities not operated by MUSC or that are not considered in the MUSC family of organizations.

*Note: this answer is usually answered ‘Yes’ if an amendment or an off campus form to add additional facilities has been required for this study. In addition, study data from all sites is normally included on one renewal.

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**Data Safety Monitoring Board Reports or Other Reports**

**Note, only one option should be selected in this section**

The DSMB has not sent any reports

<table>
<thead>
<tr>
<th>A DSMB exists for this study, but has not sent any new reports since the last continuing review.</th>
</tr>
</thead>
<tbody>
<tr>
<td>DSMB report(s) were previously submitted to the IRB.</td>
</tr>
<tr>
<td>A DSMB exists for this study and updated report(s) was(were) already sent to IRB since the last continuing review.</td>
</tr>
<tr>
<td>No electronic DSMB report. It will be sent via campus mail or fax.</td>
</tr>
<tr>
<td>A DSMB exists for this study and there have been updates since the last continuing review. However, the report is a hard copy that will not be attached to this electronic renewal and will be sent separately to IRB.</td>
</tr>
<tr>
<td>DSMB report will be attached electronically.</td>
</tr>
<tr>
<td>A DSMB exists for this study and there have been updates since the last continuing review. This information will be attached to this electronic renewal.</td>
</tr>
<tr>
<td>NA</td>
</tr>
<tr>
<td>A DSMB does not exist for this study (therefore a DSMB report is not relevant to this study).</td>
</tr>
</tbody>
</table>

**Other Reports**

| A DSMB does not exist for this study; however there are other study related reports that will be attached to this electronic renewal. |

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**Upload Reports**

- Upload any DSMB Reports or Reports that have been completed since the last IRB review.

This will be permitted at the end of completing the renewal application. Upload any DSMB reports or other study related reports/documents, such as Conflict of Interest forms, auditing/monitoring reports, study progress reports, annual reports, memos, etc. *Note: be sure that any items noted within reports as requiring IRB submission have been sent to IRB.*
Enrollment and demographic information

1. TOTAL number of subjects since activation of this study: If an extension study, record only those involved in the extension portion.

These numbers should reflect total number of subjects encountered for each category since the study was activated to enroll subjects.

Extension study: subjects previously enrolled in the initial portion of the study are allowed to enroll in the extended portion of the same study that extends the intervention/procedures.

<table>
<thead>
<tr>
<th>Ethnic Origin</th>
<th>Consented* Males/Females</th>
<th>Enrolled** Males/Females</th>
<th>Completed*** Males/Females</th>
</tr>
</thead>
<tbody>
<tr>
<td>Caucasian</td>
<td>0/0</td>
<td>0/0</td>
<td>0/0</td>
</tr>
<tr>
<td>African American</td>
<td>0/0</td>
<td>0/0</td>
<td>0/0</td>
</tr>
<tr>
<td>Hispanic/Latino</td>
<td>0/0</td>
<td>0/0</td>
<td>0/0</td>
</tr>
<tr>
<td>Asian</td>
<td>0/0</td>
<td>0/0</td>
<td>0/0</td>
</tr>
<tr>
<td>American Indian/Alaska Native</td>
<td>0/0</td>
<td>0/0</td>
<td>0/0</td>
</tr>
<tr>
<td>Native Hawaiian</td>
<td>0/0</td>
<td>0/0</td>
<td>0/0</td>
</tr>
<tr>
<td>Other</td>
<td>0/0</td>
<td>0/0</td>
<td>0/0</td>
</tr>
<tr>
<td>Totals (click on &quot;Calculate&quot; button)</td>
<td>0/0</td>
<td>0/0</td>
<td>0/0</td>
</tr>
</tbody>
</table>

*Consented = subject has signed consent to be considered for entry on the study

**Enrolled = the point at which a subject is approved for study defined treatment, intervention, registration or procedures OR when study screening procedures have been applied and the subject has met screening criteria to have data collected and included in support of the research objective

***Completed = subject is finished with study requirements and is no longer receiving study defined treatment/intervention, follow-up or study data collection. For example, subject status terms such as off study, deceased & completed would be eligible as a completed status.

A withdrawn status (subject or investigator/sponsor decision to withdraw) may be considered ‘completed’ when the subjects’ follow up data are no longer being collected for research purposes. Subject status terms such as in follow-up, lost to follow-up and withdrawn would not be eligible for a status of ‘completed’ if data from subjects are still being collected or could potentially be collected.

2. The demographics of the subject population should not reflect a disproportionate representation of one gender or ethnic group unless the IRB originally approved the study for that specific population.
If your demographics do not represent appropriate distribution, explain:

*Include a response that reflects the study objective (i.e., if only females or minorities are to be enrolled, include a statement to that effect). Otherwise, an acceptable response may include “All eligible subjects willing to participate were consented & considered for enrollment into the study.”*

3. If your study is recruiting from populations which may be considered vulnerable (Item III of the initial application, which includes but is not limited to, children, prisoners, pregnant women, neonates, cognitively impaired individuals, or, depending upon study specifics, students and/or employees), indicate the vulnerable populations from which you are recruiting and the number of subjects enrolled from each type.

*Indicate whether the study includes vulnerable populations and the number of subjects enrolled from each of those populations. *Note: if the study is not recruiting specifically from these populations but does not exclude them, an acceptable response to this question may include language to that effect.*

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**Current Assessment of Risk/Benefit Ratio**

When continuation of a study is requested, the IRB must make a determination as to whether or not the study should continue. This review is based on any changes that might affect the safety of the study or risks to subjects.

Please provide a summary for each section below. Type "N/A", if there is no response.

1. Any unanticipated problems or adverse events involving risks to participants or increased incidence of expected events.

   **Rationale:** to document risks of internal (on-site) or external (off-site) safety events reported to IRB or pending submission to IRB, per policy

2. Are you aware of any breach in confidentiality of privacy?

   **Rationale:** to document risks associated with subjects’ privacy rights.

3. Reasons for any participant withdrawals and any complaints about the research since the last IRB review.

   **Rationale:** to document subject withdrawals or complaints to assess any risks associated with subjects' rights.

4. Any relevant literature, interim findings or other relevant information affecting the risk/benefit ratio of this study. Include any new findings that may relate to the participant willingness to continue in this research project.
Rationale: to document information that may increase risk for subjects to participate in the study.

5. Any other relevant information, especially information about safety or risks associated with the research. Include a summary of any relevant multi-center trial reports. Enter here or upload on the last page.

Rationale: to document information that may address safety or risk of the study or provide a summary of current study information

6. Based on all available information, provide a current assessment of risks/benefits ratio for this study.

Rationale: to summarize the information provided in this section and draw a conclusion about the changes in the risk to benefit for subjects to participate in the study.

Conflict of Interest

1. If this is an industry-sponsored study, attach a completed copy of the Human Research Conflict of Interest Disclosure Form. Upload on the last page.

Rationale: to provide continuing disclosure of associated conflicts of financial interest investigators may have with the industry sponsor for the study.

Note: the renewal application will not be considered complete if a conflict of interest is required and is not included with the application.

2. Do you or any member of your family or other study personnel have any financial interest or relationship with a sponsor or agency that would appear to be a conflict of interest with your participation in this study?

If yes, attach a completed copy of the Human Research Conflict of Interest Disclosure Form.

Rationale: to provide continuing disclosure of associated conflicts of financial interest investigators may have with any sponsor or agency that may affect participation in this study

*Note: If this answer is ‘Yes’, even for a non-industry sponsored study (i.e. federal sponsorship), a conflict of interest form must be completed & included with the renewal application to document the interest disclosure. The renewal application will not be considered complete if a conflict of interest is required and is not included with the application.

Amendments
Have any amendments been submitted since the last continuing review?

If any amendments have been sent to IRB since the SUBMISSION (not approval) of the last renewal, indicate 'Yes'. Otherwise, indicate 'No'.

If yes, please summarize:

Include a brief description of amendments sent to IRB since the last renewal submission. Be sure to list all electronic and hard copy submissions (i.e., Investigator's Brochures). *Protocol deviations do not need to be included here.*

**Informed Consent and HIPAA**

Do not include 'Obsolete' consents.

Indicate the number of currently used consents/HIPAAs that were approved by IRB. Include all types of currently used and approved informed consents and HIPAA authorization documents (main, genetic/DNA, tissue, VAMC, additional parent/minor consents, decision capacity, etc.). *If documents were previously approved for the study but are no longer used (IRB approved), do not include those documents.*

If waivers were not used, indicate 'N/A' in the waiver sections.

If waivers were requested but not approved, indicate 'No'.

If a waiver of consent/HIPAA was approved, indicate '0' in the # of currently approved consent/HIPAA documents section and indicate 'Yes' in the waiver or consent approved by IRB section.

| # of Currently approved Consents Document(s): | Waiver of consent approved by IRB: |
| # of Currently approved HIPAA Document(s): | Waiver of HIPAA approved by IRB: |

HIPAA and Consent Form approval date(s) (List active consents by name and date of approval):

List the IRB stamped approval dates for all currently used and approved consents/HIPAAs and waivers as indicated in the counts above. *Note: the number of consents/HIPAAs listed here should equal the amount listed above.*

**PI Statement of Assurance**

✓

By checking this box I assure that all serious or unexpected adverse events have been reported as required.

This box must be checked in order for the renewal to be complete & ready for submission to IRB.