# Worksheet 311 – Reviewer Worksheet for Continuing Review, Modification or Study Closure

<table>
<thead>
<tr>
<th>File Number:</th>
<th>IRB Reviewer:</th>
<th>Date of Review:</th>
</tr>
</thead>
</table>

P.I. Name:

Study Title or Short Title:

<table>
<thead>
<tr>
<th>Initial IRB Approval Date:</th>
<th>Current Expiration Date:</th>
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</table>

**Type of Application (check one):**
- [ ] Continuing Review
- [ ] Modification
- [ ] Study Closure (may be administratively processed)

**Reviewer Recommendations:**

### Continuing Review:
- [ ] Approve for one year
- [ ] Approve for less than one year:
- [ ] Approve with stipulations for one year
- [ ] Approve with stipulations for less than one year:
- [ ] Defer decision making pending receipt of additional information and/or documents
- [ ] Disapprove (for full-board review only)

**Modification:**
- [ ] Approve modification
- [ ] Approve modification with stipulations
- [ ] Defer decision making pending receipt of additional information and/or documents
- [ ] Disapprove (for full-board review only)

**Study Closure:**
- [ ] Acknowledge study closure
- [ ] Acknowledge study closure with stipulations
- [ ] Defer decision making pending receipt of additional information and/or documents
- [ ] Disapprove (for full-board review only)

Recommended stipulations:

For deferred applications, additional information and/or documents to be provided prior to continued IRB review:

**Approval (Check one – for office use):**
- [ ] Expedited
- [ ] Full Board

Review category for expedited review:
Instructions:
1. Complete only **one** of the following boxes below:
   a. Continuing Review
   b. Modification
   c. Study Closure
2. For a Modification or Continuing Review application, re-evaluate the three principles of the Belmont Report as a requirement for approval.
3. Return to page 1 to make your recommendation.

### Continuing Review

<table>
<thead>
<tr>
<th>Enrollment status:</th>
<th>open</th>
<th>closed</th>
<th>not applicable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Most recent IRB - approved enrollment target:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of participants screened: during this review period =  ; total screened to date =</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of participants enrolled: during this review period =  ; total enrolled to date =</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Note - in most cases, the number screened should be larger than the number enrolled

Current Enrollment Status:
- [ ] Review of this study was performed under expedited review category number: , NA: [ ]
- [ ] This research is permanently closed to enrollment; all participants have completed research-related interventions and the research remains active only for long-term follow-up of participants (expedited category 8a).
- [ ] No participants have been enrolled and no additional risks have been identified (8b).
- [ ] Remaining research activities are limited to data analysis (8c). *Note - categories 8a, 8b, and 8c are expedited review categories only. See below for expedited review categories key.

Check all that apply for the review period:
- [ ] Report of problems that have delayed the progress of this study (i.e., study participants, staffing, funding, etc...). If so, specify:
- [ ] Received complaints from participants. If so, briefly summarize:
- [ ] Participant withdrawal. Explain:
- [ ] New literature has been published or findings have been produced that were previously unknown. How do these new findings change the risk/benefit ratio of the study?
- [ ] Changes were made to this study or its study documents and approved by the IRB during the review period.
- [ ] Report of major and/or minor protocol violations. Summarize protocol violations:
- [ ] Report of unanticipated problems (UPs)(and those that are adverse events). Summarize UPs and adverse events:

### Expedited Review Categories Key for Continuing Review & Modification Applications:

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>8a</td>
<td>Research permanently closed to enrollment of new subjects, all subjects have completed all interventions, and research remains active only for long term follow up of subjects.</td>
</tr>
<tr>
<td>8b</td>
<td>Where no subjects have been enrolled and no additional risks have been identified.</td>
</tr>
<tr>
<td>8c</td>
<td>Where remaining research activities are limited to data analysis.</td>
</tr>
<tr>
<td>9</td>
<td>Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two through eight do not apply but the IRB has previously determined that the research involves no greater than minimal risk and no additional risks have been identified.</td>
</tr>
<tr>
<td>110b</td>
<td>Changes or revisions to previously approved research provided: The research is eligible for expedited review under one of the other categories on this list. Or The changes / revisions qualify as minor changes in previously approved research.</td>
</tr>
</tbody>
</table>
### Modification

Summarize the modification(s) and reason(s) why they are proposed:

Check all study documents to be modified/added, if applicable:
- [ ] Consent form(s), and assent forms
- [ ] Recruitment material
- [ ] Study instruments (including interview questions)
- [ ] Other, specify:

How do the changes affect the level of risk to participants?

**Modification Plan:**
- [ ] Currently enrolled participants will be notified of this modification
- [ ] This modification is related to an unanticipated problem or protocol violation
- [ ] This modification is being initiated by the sponsor
- [ ] This modification has already been implemented to remove an apparent immediate hazard(s) to study participants
  
  **Briefly explain:**

Does the research need verification from sources other than the P.I. that no material changes have occurred since the last IRB review?

- [ ] Yes, because: 
- [ ] No

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**For Continuing Review and Modification applications, re-address the following:**

- [ ] **Respect for Persons**
  - Informed consent will be sought from prospective participant or the participant's legally authorized representative
  - Informed consent will be appropriately documented
  - Adequate mechanisms are in place to monitor the collected data to ensure the safety of participants
  - Adequate mechanisms are in place to protect the privacy of participants and confidentiality of data
  - Additional safeguards are in place, as necessary, to protect vulnerable research participants

- [ ] **Beneficence**
  - Risks to participants are minimized:
    - By using procedures consistent with sound research design and that do not unnecessarily expose participants to risk;
    - If appropriate, by using procedures already being performed for diagnostic or treatment purposes
  - Study risks are reasonable in relation to anticipated benefits and the importance of the knowledge that may be expected to result

- [ ] **Justice**
  - Selection of participants is equitable
### Study Closure

**Last IRB Approval Date:**

**Last Approved Total Target Enrollment Number:**
- Number of potential participants screened (this should be larger than the number enrolled) to date:

- Number of locally enrolled participants to date (this should be equal to or smaller than the total target enrollment number):

**To qualify for study closure, the following four criteria must be met (check all that apply):**

1. □ The research is permanently closed to enrollment.
2. □ All participants have completed all research-related interventions and/or procedures.
3. □ Collection of private identifiable information has been completed.
4. □ Analysis of private identifiable information has been completed.

**Check all that apply:**

- □ Report of problems that have delayed the progress of this study (i.e., study participants, staffing, funding, etc...). If so, specify:
- □ Received complaints from participants. If so, briefly summarize:
- □ Participant withdrawal. Explain:
- □ New literature has been published or findings have been produced that were previously unknown. How do these new findings change the risk/benefit ratio of the study?
- □ Changes were made to this study or its study documents and approved by the IRB during the review period.
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Thank you for your review!