# IRB Continuation Review

## Primary Reviewer Checklist

<table>
<thead>
<tr>
<th>Primary Reviewer:</th>
<th>Date:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Principal Investigator:</td>
<td>IRB #:</td>
</tr>
</tbody>
</table>

### Type of Review:  
- [ ] Expedited  
- [ ] Full  

#### Level of risk as currently approved (circle category):  
- [ ] 1  
- [ ] 2  
- [ ] 3  
- [ ] 4

---

**REQUIRED**

Please check the applicable boxes:

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>[ ] 1. The research meets the criteria for IRB approval (refer to attached Criteria for IRB Approval checklist(s) if necessary).</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>[ ] 2. The risk/benefit ratio has changed.</td>
<td></td>
</tr>
</tbody>
</table>

- [ ] Category 1 Not greater than minimal risk;  
- [ ] Expedited Category 8: The IRB agreed that this research, previously reviewed by the convened IRB, meets the Expedited criteria set forth in 45 CFR 46.110(a)(8); therefore an Expedited review was conducted.  
- [ ] Expedited Category 9: Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.  
- [ ] Category 2 Greater than minimal risk, but presenting the prospect of direct benefit to individual subjects;  
- [ ] Category 3 Greater than minimal risk, no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition;  
- [ ] Category 4 Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of subjects.  

Please describe why the risk/benefit ratio has changed:

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>[ ] 3. Significant new findings (e.g., from scientific literature; a procedural change; PI disclosure of financial interest; privacy/confidentiality issues, etc…) that might relate to the subject's willingness to continue participation need to be relayed to the subject.</td>
<td></td>
</tr>
</tbody>
</table>

If “yes”, describe what should be relayed to the subjects and how the subjects should be informed (e.g., revise consent document & re-consent subjects; send letter to subjects):

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>[ ] 4. The consent document(s) are complete and accurately describe the research. (The consent form(s) include the required elements of informed consent (see attached guidance document “Federally Required Elements of Informed Consent”).)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

If "No", provide related comments in space provided on page 2.
1. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result (achieved from research interventions).
   - When possible, risks to subjects are minimized by using procedures that are consistent with sound research design and which do not unnecessarily expose subjects to risk.

2. Subject selection is equitable (in relation to:)
   - Objectives of the research;
   - The setting in which the research is to take place;
   - The special problems of research involving special populations;
   - Recruitment methods;
   - Inclusion/exclusion criteria

3. Adequate provisions are in place for seeking informed consent from each prospective subject ("subject"); or the prospective subject’s legally authorized representative ("subject’s LAR").
   - The proposed consent process provides the subject/subject’s LAR with sufficient opportunity to consider whether to participate.
   - The proposed consent process minimizes the possibility of coercion or undue influence.
   - The information to be relayed during the consent process is in a language understandable to the subject/subject’s LAR.
   - The information being communicated during the consent process does not include exculpatory language through which the subject/subject’s LAR waives or appears to waive any of the subject’s legal rights.
   - The information being communicated during the consent process does not include exculpatory language through which the subject/subject’s LAR releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

4. The provisions for documenting informed consent/assent are appropriate.

5. The research proposal describes adequate provisions for protecting the privacy of subjects.

6. The research proposal describes adequate provisions for maintaining confidentiality of the data.

7. The credentials and/or described qualifications of the research staff/investigators are representative of the appropriate expertise needed to perform their responsibilities in the study.

8. The research setting (e.g., location of research, facilities, drug/device controls & accounting) supports adequate safeguards for protection of human subjects.

9. Additional safeguards have been included in the study to protect the rights and welfare of subjects vulnerable to coercion or undue influence (e.g., children, prisoners, adults with impaired consent capacity).

10. For greater than minimal risk research or NIH funded/FDA regulated clinical investigations, adequate provisions are in place for monitoring the data collected to ensure safety of subjects. Where applicable, the following may be considered in evaluating the data and safety monitoring is adequate:
   - If the proposal is a multicenter study in which the lead PI or UK is the coordinating institution, the plans for communication among sites are adequate to protect the participant (e.g., consider communication of protocol modifications, data and safety monitoring reports, and unanticipated problems).
   - Proposed payment to participants and/or cost to subjects for participation is appropriate.
   - If PI/research staff conflict of interest is identified, the conflict of interest in relation to human research protections is appropriately minimized or managed (e.g., limit who obtains informed consent; add disclosure(s) in informed consent)
   - Review and approval by other committees/units, as applicable for medical research (e.g., RDRC, IBC, RSC, MCC PRC), has been conducted.
   - Approval from external institutions has been obtained from an authorized official.

16. A signature assurance sheet signed by the Principal Investigator and his/her Department Chairperson (or appropriate equivalent) is on file.
IRB Continuation Review
Primary Reviewer Checklist

Primary Reviewer: _____________________________ Date: _____________________________

Principal Investigator: _____________________________ IRB #: _____________________________

Reviewer’s Recommendations

☐ Approve

☐ Approve pending minor revisions/additional information (you review)

☐ Withhold approval for major revisions/additional information (committee reviews response at meeting)

☐ PI does not need to attend meeting

☐ PI needs to attend meeting

☐ The protocol needs verification from sources other than the investigators that no material changes have occurred since the previous IRB review.

☐ Disapproved: Determination made at a convened meeting.

Recommended Interval for Continuation Review:  ☐ 12 months ☐ 6 months ☐ Other

I am not aware of any conflict of interest that would prohibit me from reviewing and/or making a determination about the attached materials.

Reviewer’s Printed Name

Reviewer’s Signature (Date)

Some of the following may or may not apply to the research. You only need to provide comments/recommendations for items deemed to involve controverted issues.

[MINOR concerns include, but are not limited to: typographical errors, grammar, pagination, headers/footers, template language, signatures; MAJOR concerns include, but are not limited to: risk/benefit ratio, ethical concerns, cognitive ability, failure to obtain consent, waiver of consent, etc.]

<table>
<thead>
<tr>
<th>Area to Address</th>
<th>Page</th>
<th>Specific Requests/Questions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consent Document(s)/Process</td>
<td></td>
<td>For Minor concerns regarding the consent document submitted for approval, you may write the corrections on your copy of the consent document(s) and return it to the ORI staff person. For other minor or major concerns about the consent document(s)/process, please describe in the space to the right.</td>
</tr>
<tr>
<td>Study Personnel Changes:</td>
<td></td>
<td>☐ Human subject protections training for each new (or existing) study personnel (SP) has not been completed.</td>
</tr>
<tr>
<td>Unanticipated problem(s)/Adverse Event(s) or other New Safety Information (e.g., data and safety monitoring report, new relative literature, etc.)</td>
<td></td>
<td>☐ Other (e.g., expertise not appropriate). Please describe:</td>
</tr>
<tr>
<td>Subject Withdrawals</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Deviations/Exceptions/Violations</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other (e.g. unanswered question, form missing):</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Federally Required Elements of Informed Consent
45 CFR Part 46.116(a)
21 CFR Part 50.25(a)

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
</table>
| 1. | - Statement that study involves research  
    - Explanation of purposes of research and expected duration of subject's participation  
    - Description of procedures to be followed  
    - Identification of any procedures which are experimental  |
| 2. | - Description of risks or discomforts to subject.                                           |
| 3. | - Description of benefits to subject or to others.                                          |
| 4. | - Disclosure of alternative procedures, if appropriate.                                    |
| 5. | - Description of the extent to which confidentiality will be maintained. [If FDA regulated: statement that FDA may inspect records.] |
| 6. | - For research involving more than minimal risk, explanation as to whether compensation and medical treatments are available if injury occurs. |
| 7. | - Explanation of whom to contact if the subject has questions, concerns, suggestions, or input about:  
    1. the research;  
    2. the subjects' rights; or  
    3. whom to contact if research-related injury occurs. |
| 8. | - Statement that participation is voluntary, that refusal to participate involves no penalty or loss of benefits, and that subject may discontinue at any time. |

The UK IRB requires additional elements of informed consent unless the item(s) does not apply given the nature of the research or the proposed procedures. The additional elements of informed consent are:

- Information concerning payment;
- Statement that procedure may involve unforeseeable risks;
- Description of circumstances under which subject's participation may be terminated by the investigator without subject's consent;
- Description of additional costs to subject resulting from participation in research;
- Description of consequences of subject's decision to withdraw from research;
- Statement that significant new findings developed during research which may relate to subject's willingness to continue will be provided to subject;
- Approximate number of subjects involved in study.
- For applicable FDA-regulated clinical trials, a statement to inform subjects the clinical trial will be registered with a national clinical trial registry data bank (clinicaltrials.gov).
- For FDA-regulated clinical trials, a statement to inform subjects that if he/she should choose to withdraw early from the study, the data collected to the point of withdrawal remains in the study database and may not be removed.