The purpose of this worksheet is to provide support for IRB staff who prepare review materials for convened IRB meetings or prepare materials for Non-Committee Review. This worksheet lists the information that each IRB member/Designated Reviewer, scientific/scholarly reviewer, or consultant needs to review and the worksheets or checklist to be used. For individuals who have electronic (computer) access to or provided all information, this document describes the subset of materials the IRB member is expected to access and review. For individuals who are provided a subset of the information, this document describes the subset of materials the IRB staff are to provide to each individual.

1 **GENERAL INFORMATION FOR ALL IRB MEMBERS FOR CONVENED MEETINGS**
- Information for Other Business Items
- Educational Materials

2 **FOR EACH PROTOCOL UNDERGOING INITIAL REVIEW**

<table>
<thead>
<tr>
<th>Documents for All IRB Members and Alternate IRB Members</th>
<th>Additional Items for the Scientific/Scholarly Reviewer</th>
<th>Items for Consultants</th>
</tr>
</thead>
<tbody>
<tr>
<td>Documents to review:</td>
<td>Include:</td>
<td>Include:</td>
</tr>
<tr>
<td>☐ Application for Human Research</td>
<td>☐ WORKSHEET: Scientific or Scholarly Review (HRP-320)</td>
<td>☐ Cover letter to consultants</td>
</tr>
<tr>
<td>☐ Research Protocol</td>
<td>☐ Include when they exist:</td>
<td>Include as appropriate materials provided to any other reviewer.</td>
</tr>
<tr>
<td>☐ Pre-Review (HRP-401)</td>
<td>☐ Scientific evaluation</td>
<td>Documents to review:</td>
</tr>
<tr>
<td>Documents to review when they exist:</td>
<td></td>
<td>☐ Application for Human Research</td>
</tr>
<tr>
<td>☐ Consent document</td>
<td></td>
<td>☐ Investigator’s Protocol</td>
</tr>
<tr>
<td>☐ Recruitment materials</td>
<td></td>
<td>Documents to review when they exist:</td>
</tr>
<tr>
<td>☐ Any relevant grant applications</td>
<td></td>
<td>☐ Proposed consent document</td>
</tr>
<tr>
<td>☐ Investigator’s brochure</td>
<td></td>
<td>Recruitment materials</td>
</tr>
<tr>
<td>☐ The DHHS-approved sample informed consent document</td>
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<td></td>
</tr>
<tr>
<td>☐ All other materials provided by the investigator</td>
<td></td>
<td></td>
</tr>
<tr>
<td>☐ Scientific Review</td>
<td></td>
<td></td>
</tr>
<tr>
<td>☐ Copy of the investigator’s current curriculum vita or</td>
<td></td>
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<tr>
<td>other documentation evidencing qualifications.</td>
<td></td>
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</tbody>
</table>

Include when the protocol involves these items:
- ☐ WORKSHEET: Criteria for Approval (HRP-314)
- ☐ WORKSHEET: Advertisements (HRP-315)
- ☐ WORKSHEET: Payments (HRP-316)
- ☐ WORKSHEET: Short Form of Consent Documentation (HRP-317)
- ☐ WORKSHEET: Additional Federal Agency Criteria (HRP-318)
- ☐ CHECKLIST: Waiver or Alteration of Consent Process (HRP-410)
- ☐ CHECKLIST: Waiver of Written Documentation of Consent (HRP-411)
### WORKSHEET: Review Materials

<table>
<thead>
<tr>
<th>NUMBER</th>
<th>DATE</th>
<th>PAGE</th>
</tr>
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<tbody>
<tr>
<td>HRP-301</td>
<td>8/15/2017</td>
<td>2 of 5</td>
</tr>
</tbody>
</table>

☐ CHECKLIST: Pregnant Women (HRP-412)
☐ CHECKLIST: Prisoners (HRP-415)
☐ CHECKLIST: Children (HRP-416)
☐ CHECKLIST: Cognitively Impaired Adults (HRP-417)
☐ CHECKLIST: Non-Significant Risk Device (FDA) (HRP-418)

### 3 FOR EACH PROTOCOL UNDERGOING CONTINUING REVIEW

**Documents for All IRB Members and Alternate IRB Members**
- Application for Human Research
- Continuing Review Progress Report
- Pre-Review
- Research Protocol
- Any modifications to the sponsor protocol previously approved by the IRB

Include when the protocol involves these items:
- WORKSHEET: Short Form of Consent Documentation (HRP-317)
- WORKSHEET: Additional Federal Agency Criteria (HRP-318)
- CHECKLIST: Waiver or Alteration of Consent Process (HRP-410)
- CHECKLIST: Waiver of Written Documentation of Consent (HRP-411)
- CHECKLIST: Pregnant Women (HRP-412)
- CHECKLIST: Prisoners (HRP-415)
- CHECKLIST: Children (HRP-416)
- CHECKLIST: Cognitively Impaired Adults (HRP-417)
- CHECKLIST: Non-Significant Risk Device (FDA) (HRP-418)

**Documents for Consultants**
- Cover letter to consultants

### 4 FOR EACH PROTOCOL UNDERGOING REVIEW OF MODIFICATIONS

**Documents for All IRB Members and Alternate IRB Members**
- Modification of Approved Human Research

**Additional Items for the Primary Reviewer and Prisoner Representative**
- Documents for Consultants

**Additional Documents for the Scientific/Scholarly Reviewer**
- WORKSHEET: Scientific or Scholarly Review (HRP-320) (if applicable)

**Documents for Consultants**
- Cover letter to consultants

Documents to review when modified:
**WORKSHEET: Review Materials**

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<td>8/15/2017</td>
<td>3 of 5</td>
</tr>
</tbody>
</table>

Documents to review when modified:
- [ ] Application for Human Research
- [ ] Pre-Review
- [ ] Investigator’s Protocol
- [ ] Consent document
- [ ] Recruitment materials
- [ ] Advertisements
- [ ] Payments
- [ ] WORKSHEET: Criteria for Approval (HRP-314)

Add when modification involves these items:
- [ ] WORKSHEET: Short Form of Consent Documentation (HRP-317)
- [ ] WORKSHEET: Additional Federal Agency Criteria (HRP-318)
- [ ] CHECKLIST: Waiver or Alteration of Consent Process (HRP-410)
- [ ] CHECKLIST: Waiver of Written Documentation of Consent (HRP-411)
- [ ] CHECKLIST: Pregnant Women (HRP-412)
- [ ] CHECKLIST: Prisoners (HRP-415)
- [ ] CHECKLIST: Children (HRP-416)
- [ ] CHECKLIST: Cognitively Impaired Adults (HRP-417)
- [ ] CHECKLIST: Non-Significant Risk Device (FDA) (HRP-418)
- [ ] CHECKLIST: Waiver of Consent for Emergency Research (HRP-419)

5 FOR EACH PROBLEM (UNANTICIPATED PROBLEM INVOLVING RISKS TO SUBJECTS OR OTHERS, OR SERIOUS OR CONTINUING NON-COMPLIANCE)

<table>
<thead>
<tr>
<th>Documents for All IRB Members, Alternate IRB Members, Primary Reviewer, Prisoner Representative, and Scientific/Scholarly Reviewer</th>
<th>Documents for Consultants</th>
</tr>
</thead>
</table>

**Document to review:**
- [ ] Report of New Information

**Documents to review when they exist:**
- [ ] Investigation report
- [ ] Other supporting documents

**Documents to review when the problem involves a protocol:**

- [ ] Application for Human Research
- [ ] Investigator’s Protocol
- [ ] Consent document
- [ ] Recruitment materials

Include as appropriate materials provided to any other reviewer.
### WORKSHEET: Review Materials

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<td>HRP-301</td>
<td>8/15/2017</td>
<td>4</td>
</tr>
</tbody>
</table>

- [ ] Investigator’s Protocol
- [ ] Consent document

**Include:**
- [ ] WORKSHEET: Review of Information Items (HRP-321)
- [ ] WORKSHEET: Criteria for Approval (HRP-314)

Add when the problem involves a protocol and the new information affects these items:
- [ ] WORKSHEET: Short Form of Consent Documentation (HRP-317)
- [ ] WORKSHEET: Additional Federal Agency Criteria (HRP-318)
- [ ] CHECKLIST: Waiver or Alteration of Consent Process (HRP-410)
- [ ] CHECKLIST: Waiver of Written Documentation of Consent (HRP-411)
- [ ] CHECKLIST: Pregnant Women (HRP-412)
- [ ] CHECKLIST: Prisoners (HRP-415)
- [ ] CHECKLIST: Children (HRP-416)
- [ ] CHECKLIST: Cognitively Impaired Adults (HRP-417)
- [ ] CHECKLIST: Non-Significant Risk Device (FDA) (HRP-418)

**Documents for All IRB Members and Alternate IRB Members**

#### 6 FOR USE OF A HUMANITARIAN USE DEVICE (HUD) UNDERGOING INITIAL REVIEW

**Documents to review:**
- [ ] Application for Humanitarian Use Device (HUD)
- [ ] Pre-Review
- [ ] Investigator’s Protocol
- [ ] Investigator’s Brochure
- [ ] Consent document

**Include:**
- [ ] Cover letter to consultants

**Documents:**
- [ ] Application for Humanitarian Use Device (HUD)
- [ ] Investigator’s Protocol
- [ ] Consent document

Include as appropriate materials provided to any other reviewer.

#### 7 FOR USE OF A HUMANITARIAN USE DEVICE (HUD) UNDERGOING CONTINUING REVIEW

**Documents to review:**
- [ ] Application for Humanitarian Use Device (HUD)

**Include:**
- [ ] Cover letter to consultants
### WORKSHEET: Review Materials

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<td>8/15/2017</td>
<td>5</td>
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</table>

- Continuing Review Progress Report for Humanitarian Use Device (HUD)
- Pre-Review
- Investigator’s Protocol
- Current and proposed consent document

Include:
- FORM: Initial Review (HRP-211)
- FORM: Continuing Review (HRP-212)
- CHECKLIST: Pre-Review (HRP-401)
- All submitted materials
- WORKSHEET: Criteria for Approval for HUD (HRP-323)

#### Documents:
- Application for Humanitarian Use Device (HUD)
- Continuing Review Progress Report for Humanitarian Use Device (HUD)
- Investigator’s Protocol
- Current and proposed consent document

Include as appropriate materials provided to any other reviewer.

### 8 FOR USE OF A HUMANITARIAN USE DEVICE (HUD) UNDERGOING REVIEW OF MODIFICATIONS

Documents to review when modified:
- Application for Humanitarian Use Device (HUD)
- Pre-Review
- Investigator’s Protocol
- Consent document
- All other materials provided by the investigator

Include when modified:
- FORM: Initial Review (HRP-211)
- FORM: Modification (HRP-213)
- CHECKLIST: Pre-Review (HRP-401)
- All submitted materials
- WORKSHEET: Criteria for Approval for HUD (HRP-323)

Include:
- Cover letter to consultants

Document to review:
- Modification of Approved Humanitarian Use Device (HUD)

Documents to review when modified:
- Application for Humanitarian Use Device (HUD)
- Investigator’s Protocol
- Consent document

Include as appropriate materials provided to any other reviewer.

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1. This assumes use of an “Investigator’s Protocol” as described in these SOPs which is a document that includes all information required for the IRB to determine whether the regulatory criteria for approval are met. If such a document is not provided, then this list will need to be modified.
2. See 1.
3. See ii.
4. See iii.