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 as applicable to each study. 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 or the electronic equivalent. For individuals who have electronic system computer access 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. See SOP: IRB Member Review Expectations (HRP-045) for additional information on review expectations.  

1. **GENERAL INFORMATION FOR ALL IRB MEMBERS FOR CONVENED MEETINGS**
   - List of protocols approved using the expedited procedure via link through the agenda.
   - Information for Other Business items
   - Educational Materials

2. **FOR EACH PROTOCOL UNDERGOING INITIAL REVIEW**

   **Documents for All IRB Members and Alternate IRB Members**
   - Investigator’s application/protocol and related documents
   - HRP-401 - CHECKLIST - Pre-Review or Pre-Review stipulations
   - HRP-314 - WORKSHEET - Criteria for Approval

   Include when the protocol involves these items:
   - HRP-315 - WORKSHEET - Advertisements
   - HRP-316 - WORKSHEET - Payments
   - HRP-318 - WORKSHEET - Additional Federal Agency Criteria
   - HRP-333 - WORKSHEET - Certificate of Confidentiality
   - HRP-410 - CHECKLIST - Waiver or Alteration of Consent Process
   - HRP-411 - CHECKLIST - Waiver of Written Documentation of Consent
   - HRP-412 - CHECKLIST - Pregnant Women
   - HRP-415 - CHECKLIST - Prisoners
   - HRP-416 - CHECKLIST - Children
   - HRP-417 - CHECKLIST - Cognitively Impaired Adults
   - HRP-418 - CHECKLIST - Non-Significant Risk Device

   **Additional Items for the Scientific/Scholarly Reviewer**
   - Include:
     - HRP-320 - WORKSHEET - Scientific or Scholarly Review
     - Include when they exist:
       - Scientific evaluation

   **Items for Consultants without reviewer access to the submission**
   - Include:
     - Correspondence to consultants
     - Include as appropriate materials provided to any other reviewer.

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### FOR EACH PROTOCOL UNDERGOING CONTINUING REVIEW

<table>
<thead>
<tr>
<th>Documents for All IRB Members and Alternate IRB Members</th>
<th>Documents for Consultants and individuals without reviewer access to the submission</th>
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</thead>
<tbody>
<tr>
<td>- Investigator's application/protocol and related documents</td>
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<tr>
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<td>- HRP-314 - WORKSHEET - Criteria for Approval</td>
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Include when the protocol involves these items:

- HRP-315 - WORKSHEET - Advertisements
- HRP-316 - WORKSHEET - Payments
- HRP-318 - WORKSHEET - Additional Federal Agency Criteria
- HRP-333 - WORKSHEET - Certificate of Confidentiality
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### WORKSHEET: Review Materials

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<th>FOR EACH PROTOCOL UNDERGOING REVIEW OF MODIFICATIONS</th>
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**Documents for All IRB Members and Alternate IRB Members**

- [ ] Investigator’s application/protocol and related documents
- [ ] HRP-401 - CHECKLIST - Pre-Review or Pre-Review stipulations
- [ ] HRP-314 - WORKSHEET - Criteria for Approval

Add when modification involves these items:

- [ ] HRP-315 - WORKSHEET - Advertisements
- [ ] HRP-316 - WORKSHEET - Payments
- [ ] HRP-318 - WORKSHEET - Additional Federal Agency Criteria
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- [ ] HRP-418 - CHECKLIST - Non-Significant Risk Device

**Additional Documents for the Scientific/Scholarly Reviewer**

Include:

- [ ] HRP-320 - WORKSHEET - Scientific or Scholarly Review (if the amendments are substantive)

**Documents for Consultants and individuals without reviewer access to the submission**

Include:

- [ ] Correspondence to consultants
- [ ] Include as appropriate materials provided to any other reviewer.
**FOR EACH PROBLEM (UNANTICIPATED PROBLEM INVOLVING RISKS TO SUBJECTS OR OTHERS, OR SERIOUS OR CONTINUING NON-COMPLIANCE)**

Documents for All IRB Members, Alternate IRB Members, Primary Reviewer, Prisoner Representative, and Scientific/Scholarly Reviewer

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