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| **Version** | **Date** | **Revisions** |
| R00 | 3/14 | Original issue |
| R01 | 12/18 | Update to Toolkit 4.0 and 4.1 |
| R01 | 11/26/19 | Annual review, updated logo  |
| R01 | 12/16/2020 | Annual review, no changes |
| R01 | 1/14/22 | Annual review, no changes |
| R01 | 11/17/22 | Annual review, no changes |
| R02 | 11/15/23 | Annual review, reformat tables |

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| 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**
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| * List of protocols approved using the expedited procedure (For Veterans Administration (VA) Research, include the review category.)
* List of protocols approved after verification of Modifications Required to Secure Approval (VA)
* For Veterans Administration (VA) research, determinations for internal unanticipated serious adverse events reported to the IRB regardless of outcome.
* Information for Other Business items
* Educational Materials
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| **2. FOR EACH PROTOCOL UNDERGOING INITIAL REVIEW** |
| **Documents for All IRB Members and Alternate IRB Members** | **Additional Items for the Scientific/Scholarly Reviewer** | **Items for Consultants** |
| 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: Non-Viable Neonates (HRP-413)
* CHECKLIST: Neonates of Uncertain Viability (HRP-414)
* 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)
* CHECKLIST: HIPAA Waiver of Authorization (HRP-441)
* CHECKLIST: Criteria for Approval (HRP-314)
 | Include:* WORKSHEET: Scientific or Scholarly Review (HRP-320)
* Include when they exist:

Scientific evaluation | Include:* Cover letter to consultants
* Include as appropriate materials provided to any other reviewer.
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| **3. FOR EACH PROTOCOL UNDERGOING CONTINUING REVIEW** |
| **Documents for All IRB Members and Alternate IRB Members** | **Documents for Consultants** |
| 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: Non-Viable Neonates (HRP-413)
* CHECKLIST: Neonates of Uncertain Viability (HRP-414)
* 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)
* CHECKLIST: HIPAA Waiver of Authorization (HRP-441)
* CHECKLIST: Criteria for Approval (HRP-314)
 | Include:* Cover letter to consultants
* Include as appropriate materials provided to any other reviewer.
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| **4. FOR EACH PROTOCOL UNDERGOING REVIEW OF MODIFICATIONS** |
| **Documents for All IRB Members and Alternate IRB Members** | **Additional Items for the Primary Reviewer and Prisoner Representative** | **Additional Documents for the Scientific/Scholarly Reviewer** | **Documents for Consultants** |
| Include:* 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: Non-Viable Neonates (HRP-413)
* CHECKLIST: Neonates of Uncertain Viability (HRP-414)
* 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)
* CHECKLIST: HIPAA Waiver of Authorization (HRP-441)
* CHECKLIST: Criteria for Approval (HRP-314)
 | * Documents for Consultants
 | Include:* WORKSHEET: Scientific or Scholarly Review (HRP-320) (if the amendments are substantive)
 | Include:* Cover letter to consultants
* Include as appropriate materials provided to any other reviewer.
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| **5. 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** | **Documents for Consultants** |
| 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: Non-Viable Neonates (HRP-413)
* CHECKLIST: Neonates of Uncertain Viability (HRP-414)
* 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)
* CHECKLIST: HIPAA Waiver of Authorization (HRP-441)
* CHECKLIST: Criteria for Approval (HRP-314)
 | Include:* Cover letter to consultants
* Include as appropriate materials provided to any other reviewer.
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| **6. FOR USE OF A HUMANITARIAN USE DEVICE (HUD) UNDERGOING INITIAL REVIEW** |
| **Documents for All IRB Members and Alternate IRB Members** | **Documents for Consultants** |
| Include:* FORM: Initial Review (HRP-211)
* CHECKLIST: Pre-Review (HRP-401)
* All submitted materials
* WORKSHEET: Criteria for Approval for HUD (HRP-323)
 | Include:* Cover letter to consultants
* Include as appropriate materials provided to any other reviewer.
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| **7. FOR USE OF A HUMANITARIAN USE DEVICE (HUD) UNDERGOING CONTINUING REVIEW** |
| **Documents for All IRB Members and Alternate IRB Members** | **Documents for Consultants** |
| 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)
 | Include:* Cover letter to consultants
* Include as appropriate materials provided to any other reviewer.
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| **8. FOR USE OF A HUMANITARIAN USE DEVICE (HUD) UNDERGOING REVIEW OF MODIFICATIONS** |
| **Documents for All IRB Members and Alternate IRB Members** | **Documents for Consultants** |
| 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
* Include as appropriate materials provided to any other reviewer.
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