|  |
| --- |
| 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
 |
| * Completed TEMPLATE LETTER: IRB Member Review Materials (HRP-541)
* Information items
* List of protocols approved using the expedited procedure
* List of protocols approved after verification of Modifications Required to Secure Approval
* Information for Other Business items
* Educational Materials
 |
| 1. GENERAL INFORMATION FOR ALL DESIGNATED REVIEWERS FOR NON-COMMITTEE REVIEW
 |
| * Completed TEMPLATE LETTER: Designated Reviewer Materials (HRP-540)
 |
| 1. FOR EACH PROTOCOL UNDERGOING INITIAL REVIEW
 |
| Documents for All IRB Members and Alternate IRB Members | Additional Items for the Primary Reviewer and Prisoner Representative | Additional Items for the Scientific/Scholarly Reviewer | Items for Consultants |
| Include:* FORM: Initial Review (HRP-211)
* CHECKLIST: Pre-Review (HRP-401)
* Investigator’s Protocol and documents referenced by the Investigator’s Protocol
* WORKSHEET: Criteria for Approval (HRP-314)

Include when they exist:* Consent document
* Recruitment materials
* Participating site materials

Add 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)
 | Include when they exist:* Sponsor protocol
* Investigator’s brochure
* The DHHS-approved sample informed consent document
* The complete DHHS-approved protocol
* All other materials provided by the investigator
* Scientific Review
* Copy of the investigator’s current curriculum vita or other documentation evidencing qualifications.

Add when the protocol involves these items:* WORKSHEET: Advertisements (HRP-315)
* WORKSHEET: Payments (HRP-316)
 | 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. |
| 1. FOR EACH PROTOCOL UNDERGOING CONTINUING REVIEW
 |
| 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:* FORM: Initial Review (HRP-211)
* FORM: Continuing Review (HRP-212)
* CHECKLIST: Pre-Review (HRP-401)
* Investigator’s Protocol and documents referenced by the Investigator’s Protocol
* WORKSHEET: Criteria for Approval (HRP-314)

Include when they exist:* Current and proposed consent document(s)

Add 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)
 | Include:* Sponsor protocol
* Any modifications to the sponsor protocol previously approved by the IRB
 |  | Include:* Cover letter to consultants

Include as appropriate materials provided to any other reviewer. |
| 1. 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:* FORM: Modification (HRP-213)
* WORKSHEET: Criteria for Approval (HRP-314)

Include all modified documents.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)
 | Include:* All other materials provided by the investigator

Add when modification involves these items:* WORKSHEET: Advertisements (HRP-315)
* WORKSHEET: Payments (HRP-316)
 | 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. |
| 1. 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:* FORM: Reportable New Information (HRP-214)
* WORKSHEET: Review of Information Items (HRP-321)
* WORKSHEET: Criteria for Approval (HRP-314)

Include when they exist or are relevant:* Investigation report
* Other supporting documents
* Investigator’s Protocol and modified documents referenced by the Investigator’s Protocol
* Consent document

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)
 | Include:* Cover letter to consultants

Include as appropriate materials provided to any other reviewer. |
| Documents for All IRB Members and Alternate IRB Members | Documents for Consultants |
| 1. FOR USE OF A HUMANITARIAN USE DEVICE (HUD) UNDERGOING INITIAL REVIEW
 |
| 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. |
| 1. FOR USE OF A HUMANITARIAN USE DEVICE (HUD) UNDERGOING CONTINUING REVIEW
 |
| * 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.
 |
| 1. FOR USE OF A HUMANITARIAN USE DEVICE (HUD) UNDERGOING REVIEW OF MODIFICATIONS
 |
| 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. |