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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

- ☐ Information items
- ☐ List of protocols approved using the expedited procedure
- ☐ List of protocols granted exemption determinations
- ☐ List of protocols approved after verification of Modifications Required to Secure Approval
- ☐ Information for Other Business items
- ☐ Educational Materials

2 GENERAL INFORMATION FOR ALL DESIGNATED REVIEWERS FOR NON-COMMITTEE REVIEW

- ☐ Completed TEMPLATE LETTER: Designated Reviewer Materials (HRP-540)

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3 **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: ☐ 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 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) ☐ CHECKLIST: Waiver of Consent for Emergency Research (HRP-419)	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.

4 FOR EACH PROTOCOL 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) ☐ 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 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) ☐ CHECKLIST: Waiver of Consent for Emergency Research (HRP-419)	Include: ☐ Cover letter to consultants Include as appropriate materials provided to any other reviewer.

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5 **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) ☐ CHECKLIST: Waiver of Consent for Emergency Research (HRP-419)	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.

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6 **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) CHECKLIST: Waiver of Consent for Emergency Research (HRP-419)	Include: ☐ Cover letter to consultants Include as appropriate materials provided to any other reviewer.

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Documents for All IRB Members and Alternate IRB Members	Documents for Consultants
7 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.
8 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.
9 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.