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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]](#footnote-2) | | | | | |
| 1. GENERAL INFORMATION FOR ALL IRB MEMBERS FOR CONVENED MEETINGS | | | | | |
| List of protocols approved using the expedited procedure.  Information for Other Business items  Educational Materials | | | | | |
| 1. 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:  HRP-317 - WORKSHEET - Short Form of Consent Documentation  HRP-318 - WORKSHEET - Additional Federal Agency Criteria  HRP-410 - CHECKLIST - Waiver or Alteration of Consent Process  HRP-411 - CHECKLIST - Waiver of Written Documentation of Consent  HRP-412 - CHECKLIST - Pregnant Women  HRP-413 - CHECKLIST - Non-Viable Neonates  HRP-414 - CHECKLIST - Neonates of Uncertain Viability  HRP-415 - CHECKLIST - Prisoners  HRP-416 - CHECKLIST - Children  HRP-417 - CHECKLIST - Cognitively Impaired Adults  HRP-418 - CHECKLIST - Non-Significant Risk Device  HRP-419 - CHECKLIST - Waiver of Consent Process for Emergency Research | Include:  HRP-320 - WORKSHEET - Scientific or Scholarly Review  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 | Documents for Consultants | | | |
| Include when the protocol involves these items:  HRP-317 - WORKSHEET - Short Form of Consent Documentation  HRP-318 - WORKSHEET - Additional Federal Agency Criteria  HRP-410 - CHECKLIST - Waiver or Alteration of Consent Process  HRP-411 - CHECKLIST - Waiver of Written Documentation of Consent  HRP-412 - CHECKLIST - Pregnant Women  HRP-413 - CHECKLIST - Non-Viable Neonates  HRP-414 - CHECKLIST - Neonates of Uncertain Viability  HRP-415 - CHECKLIST - Prisoners  HRP-416 - CHECKLIST - Children  HRP-417 - CHECKLIST - Cognitively Impaired Adults  HRP-418 - CHECKLIST - Non-Significant Risk Device  HRP-419 - CHECKLIST - Waiver of Consent Process for Emergency Research | 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:  HRP-314 - WORKSHEET - Criteria for Approval  Add when modification involves these items:  HRP-317 - WORKSHEET - Short Form of Consent Documentation  HRP-318 - WORKSHEET - Additional Federal Agency Criteria  HRP-410 - CHECKLIST - Waiver or Alteration of Consent Process  HRP-411 - CHECKLIST - Waiver of Written Documentation of Consent  HRP-412 - CHECKLIST - Pregnant Women  HRP-413 - CHECKLIST - Non-Viable Neonates  HRP-414 - CHECKLIST - Neonates of Uncertain Viability  HRP-415 - CHECKLIST - Prisoners  HRP-416 - CHECKLIST - Children  HRP-417 - CHECKLIST - Cognitively Impaired Adults  HRP-418 - CHECKLIST - Non-Significant Risk Device  HRP-419 - CHECKLIST - Waiver of Consent Process for Emergency Research | Documents for Consultants | Include:  HRP-320 - WORKSHEET - Scientific or Scholarly Review (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:  HRP-321 - WORKSHEET - Review of Information Items  HRP-314 - WORKSHEET - Criteria for Approval  Add when the problem involves a protocol and the new information affects these items:  HRP-317 - WORKSHEET - Short Form of Consent Documentation  HRP-318 - WORKSHEET - Additional Federal Agency Criteria  HRP-410 - CHECKLIST - Waiver or Alteration of Consent Process  HRP-411 - CHECKLIST - Waiver of Written Documentation of Consent  HRP-412 - CHECKLIST - Pregnant Women  HRP-413 - CHECKLIST - Non-Viable Neonates  HRP-414 - CHECKLIST - Neonates of Uncertain Viability)  HRP-415 - CHECKLIST - Prisoners  HRP-416 - CHECKLIST - Children  HRP-417 - CHECKLIST - Cognitively Impaired Adults  HRP-418 - CHECKLIST - Non-Significant Risk Device  HRP-419 - CHECKLIST - Waiver of Consent Process for Emergency Research | | 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:  HRP-211 - FORM - Basic Study Information  HRP-401 - CHECKLIST - Pre-Review  All submitted materials  HRP-323 - WORKSHEET - Criteria for Approval HUD | | | 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:  HRP-211 - FORM - Basic Study Information  HRP-212 - FORM - Continuing Review  HRP-401 - CHECKLIST - Pre-Review  All submitted materials  HRP-323 - WORKSHEET - Criteria for Approval HUD | | | 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:  HRP-211 - FORM - Basic Study Information  HRP-213 - FORM - Modification  HRP-401 - CHECKLIST - Pre-Review  All submitted materials  HRP-323 - WORKSHEET - Criteria for Approval HUD | | | Include:  Cover letter to consultants  Include as appropriate materials provided to any other reviewer. | | |

1. This document satisfies AAHRPP elements I.1.F, I.5.D, I-9, II.1.B, II.2.D, II.2.G, II.2.E-II.2.E.2, II.2.F-II.2.F.3 [↑](#footnote-ref-2)