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| The purpose of this worksheet is to provide support for IRB Office 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 use. 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 Office staff are to provide to each individual. This worksheet should be used for guidance. |
| 1. GENERAL INFORMATION FOR ALL IRB MEMBERS FOR CONVENED MEETINGS
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| * 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 |
| Reference:* WORKSHEET: Criteria for Approval (HRP-314)

Reference when the protocol involves these items:* WORKSHEET: Advertisements (HRP-315)
* WORKSHEET: Payments (HRP-316)
* WORKSHEET: Additional Federal Agency Criteria (HRP-318)
* WORKSHEET: Certificate of Confidentiality (HRP-333)
* 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: Adults with Impaired Decision-Making Capacity (HRP-417)
* CHECKLIST: Non-Significant Risk Device (USFDA) (HRP-418)
* CHECKLIST: Waiver of Consent for Emergency Research (HRP-419)
 | Reference:* WORKSHEET: Scientific or Scholarly Review (HRP-320)

Reference when they exist:* Scientific evaluation
 | Include:* Email correspondence 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 |
| Reference:* WORKSHEET: Criteria for Approval (HRP-314)

Reference when the protocol involves these items:* WORKSHEET: Short Form of Consent Documentation (HRP-317)
* WORKSHEET: Advertisements (HRP-315)
* WORKSHEET: Payments (HRP-316)
* WORKSHEET: Additional Federal Agency Criteria (HRP-318)
* WORKSHEET - Certificate of Confidentiality (HRP-333)
* 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: Adults with Impaired Decision-Making Capacity (HRP-417)
* CHECKLIST: Non-Significant Risk Device (USFDA) (HRP-418)
* CHECKLIST: Waiver of Consent for Emergency Research (HRP-419)
 | Include:* Email correspondence to consultants

Include as appropriate materials provided to any other reviewer. |

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| 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 |
| Reference:* WORKSHEET: Criteria for Approval (HRP-314)

Add when modification involves these items:* WORKSHEET: Advertisements (HRP-315)
* WORKSHEET: Payments (HRP-316)
* WORKSHEET: Short Form of Consent Documentation (HRP-317)
* WORKSHEET: Additional Federal Agency Criteria (HRP-318)
* WORKSHEET - Certificate of Confidentiality (HRP-333)
* 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: Adults with Impaired Decision-Making Capacity (HRP-417)
* CHECKLIST: Non-Significant Risk Device (USFDA) (HRP-418)
* CHECKLIST: Waiver of Consent for Emergency Research (HRP-419)
 | * Documents forConsultants
 | Reference:* WORKSHEET: Scientific or Scholarly Review (HRP-320) (if the amendments are substantive)
 | Include:* Email correspondence to consultants

Include as appropriate materials provided to any other reviewer. |

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| 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 |
| Reference:* 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: Advertisements (HRP-315)
* WORKSHEET: Payments (HRP-316)
* WORKSHEET: Short Form of Consent Documentation (HRP-317)
* WORKSHEET: Additional Federal Agency Criteria (HRP-318)
* WORKSHEET - Certificate of Confidentiality (HRP-333)
* 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: Adults with Impaired Decision-Making Capacity (HRP-417)
* CHECKLIST: Non-Significant Risk Device (USFDA) (HRP-418)
* CHECKLIST: Waiver of Consent for Emergency Research (HRP-419)
 | Include:* Email correspondence 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
 |
| Reference:* FORM: Initial Review (HRP-211)
* CHECKLIST: Pre-Review (HRP-401)
* All submitted materials
* WORKSHEET: Criteria for Approval for HUD (HRP-323)
 | Include:* Email correspondence to consultants: Include as appropriate materials provided to any other reviewer.
 |
| 1. FOR USE OF A HUMANITARIAN USE DEVICE (HUD) UNDERGOING CONTINUING REVIEW
 |
| Reference:* 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:* Email correspondence to consultants: Include as appropriate materials provided to any other reviewer.
 |
| 1. FOR USE OF A HUMANITARIAN USE DEVICE (HUD) UNDERGOING REVIEW OF MODIFICATIONS
 |
| Reference 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:* Email correspondence to consultants: Include as appropriate materials provided to any other reviewer.
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