



HRP-301 | 2/2/2024

WORKSHEET: Review Materials

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

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 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

2. FOR EACH PROTOCOL UNDERGOING INITIAL REVIEW

Documents for All IRB Members and Alternate IRB Members

Include when the protocol involves these items:

- | | |
|---|---|
| <input type="checkbox"/> HRP-315 - WORKSHEET - Advertisements | <input type="checkbox"/> HRP-412 - CHECKLIST - Pregnant Women |
| <input type="checkbox"/> HRP-316 - WORKSHEET - Payments | <input type="checkbox"/> HRP-413 - CHECKLIST - Non-Viable Neonates |
| <input type="checkbox"/> HRP-317 - WORKSHEET - Short Form of Consent Documentation | <input type="checkbox"/> HRP-414 - CHECKLIST - Neonates of Uncertain Viability |
| <input type="checkbox"/> HRP-318 - WORKSHEET - Additional Federal Agency Criteria | <input type="checkbox"/> HRP-415 - CHECKLIST - Prisoners |
| <input type="checkbox"/> HRP-333 - WORKSHEET - Certificate of Confidentiality | <input type="checkbox"/> HRP-416 - CHECKLIST - Children |
| <input type="checkbox"/> HRP-410 - CHECKLIST - Waiver or Alteration of Consent Process | <input type="checkbox"/> HRP-417 - CHECKLIST - Cognitively Impaired Adults |
| <input type="checkbox"/> HRP-411 - CHECKLIST - Waiver of Written Documentation of Consent | <input type="checkbox"/> HRP-418 - CHECKLIST - Non-Significant Risk Device |
| | <input type="checkbox"/> HRP-419 - CHECKLIST - Waiver of Consent Process for Emergency Research |

Additional Items for the Scientific/Scholarly Reviewer

Include:

- ☐ HRP-320 - WORKSHEET - Scientific or Scholarly Review

Include when they exist:

- ☐ Scientific evaluation

Items for Consultants and individuals without reviewer access to the submission

Include:

- ☐ Cover letter to consultants

Include as appropriate materials provided to any other reviewer.

3. FOR EACH PROTOCOL UNDERGOING CONTINUING REVIEW

Documents for All IRB Members and Alternate IRB Members

Include when the protocol involves these items:

- | | |
|---|---|
| <input type="checkbox"/> HRP-315 - WORKSHEET - Advertisements | <input type="checkbox"/> HRP-412 - CHECKLIST - Pregnant Women |
| <input type="checkbox"/> HRP-316 - WORKSHEET - Payments | <input type="checkbox"/> HRP-413 - CHECKLIST - Non-Viable Neonates |
| <input type="checkbox"/> HRP-317 - WORKSHEET - Short Form of Consent Documentation | <input type="checkbox"/> HRP-414 - CHECKLIST - Neonates of Uncertain Viability |
| <input type="checkbox"/> HRP-318 - WORKSHEET - Additional Federal Agency Criteria | <input type="checkbox"/> HRP-415 - CHECKLIST - Prisoners |
| <input type="checkbox"/> HRP-333 - WORKSHEET - Certificate of Confidentiality | <input type="checkbox"/> HRP-416 - CHECKLIST - Children |
| <input type="checkbox"/> HRP-410 - CHECKLIST - Waiver or Alteration of Consent Process | <input type="checkbox"/> HRP-417 - CHECKLIST - Cognitively Impaired Adults |
| <input type="checkbox"/> HRP-411 - CHECKLIST - Waiver of Written Documentation of Consent | <input type="checkbox"/> HRP-418 - CHECKLIST - Non-Significant Risk Device |
| | <input type="checkbox"/> HRP-419 - CHECKLIST - Waiver of Consent Process for Emergency Research |

Documents for Consultants and individuals without reviewer access to the submission

Include:

- ☐ Cover letter to consultants

Include as appropriate materials provided to any other reviewer.

4. FOR EACH PROTOCOL UNDERGOING REVIEW OF MODIFICATIONS

Documents for All IRB Members and Alternate IRB Members

Include:

HRP-314 - WORKSHEET - Criteria for Approval

Add when modification involves these items:

- | | |
|---|---|
| <input type="checkbox"/> HRP-315 - WORKSHEET - Advertisements | <input type="checkbox"/> HRP-316 - WORKSHEET - Payments |
|---|---|

- ☐ HRP-317 - WORKSHEET - Short Form of Consent Documentation
- ☐ HRP-318 - WORKSHEET - Additional Federal Agency Criteria
- ☐ HRP-333 - WORKSHEET - Certificate of Confidentiality
- ☐ 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

Additional Documents for the Scientific/Scholarly Reviewer

Include:

- ☐ HRP-320 - WORKSHEET - Scientific or Scholarly Review (if the amendments are substantive)

Documents for Consultants and individuals without reviewer access to the submission

Include:

- ☐ Cover letter to consultants

Include as appropriate materials provided to any other reviewer.

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

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-315 - WORKSHEET - Advertisements
- ☐ HRP-316 - WORKSHEET - Payments

- ☐ HRP-317 - WORKSHEET - Short Form of Consent Documentation
- ☐ HRP-318 - WORKSHEET - Additional Federal Agency Criteria
- ☐ HRP-333 - WORKSHEET - Certificate of Confidentiality
- ☐ 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 and individuals without reviewer access to the submission

Include:

- ☐ Cover letter to consultants

Include as appropriate materials provided to any other reviewer.

6. FOR USE OF A HUMANITARIAN USE DEVICE (HUD) UNDERGOING INITIAL REVIEW

Documents for All IRB Members and Alternate IRB Members

Include:

- ☐ HRP-323 - WORKSHEET - Criteria for Approval HUD

Documents for Consultants and individuals without reviewer access to the submission

Include:

- ☐ Cover letter to consultants

Include as appropriate materials provided to any other reviewer.

7. FOR USE OF A HUMANITARIAN USE DEVICE (HUD) UNDERGOING CONTINUING REVIEW

Documents for All IRB Members and Alternate IRB Members

Include:

☐ HRP-323 - WORKSHEET - Criteria for Approval HUD

Documents for Consultants and individuals without reviewer access to the submission

Include:

☐ Cover letter to consultants

Include as appropriate materials provided to any other reviewer.

8. FOR USE OF A HUMANITARIAN USE DEVICE (HUD) UNDERGOING REVIEW OF MODIFICATIONS

Documents for All IRB Members and Alternate IRB Members

Include when modified:

☐ HRP-323 - WORKSHEET - Criteria for Approval HUD

Documents for Consultants and individuals without reviewer access to the submission

Include:

☐ Cover letter to consultants

Include as appropriate materials provided to any other reviewer.