|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| 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 worksheets and checklists each IRB member/Designated Reviewer, scientific/scholarly reviewer, or consultant is expected to review and use, as applicable to the research, in addition to reviewing all forms completed by the investigator in e-IRB or uploaded to the submission, such as the protocol, consent documents, recruitment materials, sponsor documents, forms completed when conducting International Research, participating site materials, and other documents referenced in the protocol. This document lists the subset of materials the IRB staff are to provide to each individual. [NOTE: Worksheets are to be used as guides, but do not need to be completed or uploaded to e-IRB. Checklists must be completed by the reviewer(s) and uploaded to e-IRB.] | | | | | | |
| 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:  HRP-314 - WORKSHEET - Criteria for Approval  Include when the protocol involves these items:  HRP-307 - WORKSHEET – Devices  HRP-315 – WORKSHEET – Advertisements  HRP-316 – WORKSHEET - Payments  HRP-317 - WORKSHEET - Short Form of Consent Documentation  HRP-318 - WORKSHEET - Additional Federal Agency Criteria  HRP-322 – WORKSHEET – Emergency Use  HRP-325 – WORKSHEET – Device Compassionate Use  HRP-335 – WORKSHEET – GDPR Compliance  HRP-332 – CHECKLIST – NIH GDS Institutional Certificate  HRP-333 – CHECKLIST – Certificates 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 – Decisionally-Impaired Adults  HRP-418 - CHECKLIST - Non-Significant Risk Device  HRP-419 - CHECKLIST - Waiver of Consent Process for Emergency Research  HRP-441 – CHECKLIST – HIPAA Waiver of Authorization | 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:  HRP-314 - WORKSHEET - Criteria for Approval  Include when the protocol involves these items:  HRP-307 - WORKSHEET – Devices  HRP-315 – WORKSHEET – Advertisements  HRP-316 – WORKSHEET - Payments  HRP-317 - WORKSHEET - Short Form of Consent Documentation  HRP-318 - WORKSHEET - Additional Federal Agency Criteria  HRP-322 – WORKSHEET – Emergency Use  HRP-325 – WORKSHEET – Device Compassionate Use  HRP-335 – WORKSHEET – GDPR Compliance  HRP-332 – CHECKLIST – NIH GDS Institutional Certificate  HRP-333 – CHECKLIST – Certificates 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 – Decisionally-Impaired Adults  HRP-418 - CHECKLIST - Non-Significant Risk Device  HRP-419 - CHECKLIST - Waiver of Consent Process for Emergency Research  HRP-441 – CHECKLIST – HIPAA Waiver of Authorization | 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 Documents for the Scientific/Scholarly Reviewer | | | | Documents for Consultants | |
| Include:  HRP-314 - WORKSHEET - Criteria for Approval  Add when modification involves these items:  HRP-307 - WORKSHEET – Devices  HRP-315 – WORKSHEET – Advertisements  HRP-316 – WORKSHEET - Payments  HRP-317 - WORKSHEET - Short Form of Consent Documentation  HRP-318 - WORKSHEET - Additional Federal Agency Criteria  HRP-322 – WORKSHEET – Emergency Use  HRP-325 – WORKSHEET – Device Compassionate Use  HRP-335 – WORKSHEET – GDPR Compliance  HRP-332 – CHECKLIST – NIH GDS Institutional Certificate  HRP-333 – CHECKLIST – Certificates 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 – Decisionally-Impaired Adults  HRP-418 - CHECKLIST - Non-Significant Risk Device  HRP-419 - CHECKLIST - Waiver of Consent Process for Emergency Research  HRP-441 – CHECKLIST – HIPAA Waiver of Authorization | 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 REPORTABLE NEW INFORMATION (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 Reportable New Information (Events)  HRP-314 - WORKSHEET - Criteria for Approval  N**OTE #1:** If the reportable new information necessitates a modification, see also Section 3 FOR EACH PROTOCOL UNDERGOING REVIEW OF MODIFICATIONS.  **NOTE #2**: If the reportable new information necessitates a modification to a HUD, see also Section 5 HUMANITARIAN USE DEVICES. | |  | | | | |
| Documents for All IRB Members and Alternate IRB Members | | | Documents for Consultants | | | |
| 1. FOR USE OF A HUMANITARIAN USE DEVICE (HUD) UNDERGOING INITIAL REVIEW, CONTINUING REVIEW OR MODIFICATIONS | | | | | | |
| Include:  All submitted materials  HRP-323 - WORKSHEET - Criteria for Approval HUD | | | Include:  Cover letter to consultants  Include as appropriate materials provided to any other reviewer. | | | |