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 eIRB+ 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 eIRB+. Checklists must be completed by the reviewer(s) and uploaded to eIRB+.]

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: ☐ 4.201 (HRP-314) - WORKSHEET - Criteria for Approval Include when the protocol involves these items: ☐ 8.203 (HRP-307) - WORKSHEET – Devices ☐ 9.202 (HRP-315) – WORKSHEET – Advertisements ☐ 9.203 (HRP-316) – WORKSHEET - Payments ☐ 6.202 (HRP-317) - WORKSHEET - Short Form of Consent Documentation ☐ 4.203 (HRP-318) - WORKSHEET - Additional Federal Agency Criteria ☐ 8.206 (HRP-322) – WORKSHEET – Emergency Use ☐ 8.205 (HRP-325) – WORKSHEET – Device Compassionate Use ☐ 11.201 (HRP-335) – WORKSHEET – GDPR Compliance ☐ 3.214 (HRP-332) – WORKSHEET – NIH GDS Institutional Certificate ☐ 4.206 (HRP-333) – WORKSHEET – Certificates of Confidentiality ☐ 6.208 (HRP-410) - WORKSHEET - Waiver or Alteration of Consent Process ☐ 6.207 (HRP-411) - WORKSHEET - Waiver of Written Documentation of Consent ☐ 7.201 (HRP-412) - WORKSHEET - Pregnant Women ☐ 7.202 (HRP-413) - WORKSHEET - Non-Viable Neonates ☐ 7.203 (HRP-414) - WORKSHEET - Neonates of Uncertain Viability ☐ 7.204 (HRP-415) - WORKSHEET - Prisoners ☐ 7.205 (HRP-416) - WORKSHEET - Children ☐ 7.101 (HRP-417) - CHECKLIST – Adults with Impaired Decision-Making Capacity ☐ 8.201 (HRP-418) - WORKSHEET - Non-Significant Risk Device ☐ 6.101 (HRP-419) - CHECKLIST - Waiver of Consent Process for Emergency Research ☐ 6.201 (HRP-441) – WORKSHEET – HIPAA Waiver of Authorization	Include: ☐ 4.204 (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.

2 FOR EACH PROTOCOL UNDERGOING CONTINUING REVIEW

Documents for All IRB Members and Alternate IRB Members	Documents for Consultants
Include: ☐ 4.202 (HRP-314) - WORKSHEET - Criteria for Approval Include when the protocol involves these items: ☐ 8.203 (HRP-307) - WORKSHEET – Devices ☐ 9.202 (HRP-315) – WORKSHEET – Advertisements ☐ 9.203 (HRP-316) – WORKSHEET - Payments ☐ 6.202 (HRP-317) - WORKSHEET - Short Form of Consent Documentation ☐ 4.203 (HRP-318) - WORKSHEET - Additional Federal Agency Criteria ☐ 8.206 (HRP-322) – WORKSHEET – Emergency Use ☐ 8.205 (HRP-325) – WORKSHEET – Device Compassionate Use ☐ 11.201 (HRP-335) – WORKSHEET – GDPR Compliance ☐ 3.214 (HRP-332) – WORKSHEET – NIH GDS Institutional Certificate ☐ 4.206 (HRP-333) – WORKSHEET – Certificates of Confidentiality ☐ 6.208 (HRP-410) - WORKSHEET - Waiver or Alteration of Consent Process ☐ 6.207 (HRP-411) - WORKSHEET - Waiver of Written Documentation of Consent ☐ 7.201 (HRP-412) - WORKSHEET - Pregnant Women ☐ 7.202 (HRP-413) - WORKSHEET - Non-Viable Neonates ☐ 7.203 (HRP-414) - WORKSHEET - Neonates of Uncertain Viability ☐ 7.204 (HRP-415) - WORKSHEET - Prisoners ☐ 7.205 (HRP-416) - WORKSHEET - Children ☐ 7.101 (HRP-417) - CHECKLIST – Adults with Impaired Decision-Making Capacity ☐ 8.201 (HRP-418) - WORKSHEET - Non-Significant Risk Device ☐ 6.101 (HRP-419) - CHECKLIST - Waiver of Consent Process for Emergency Research ☐ 6.201 (HRP-441) – WORKSHEET – HIPAA Waiver of Authorization	Include: ☐ Cover letter to consultants Include as appropriate materials provided to any other reviewer.

3 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: ☐ 4.202 (HRP-314) - WORKSHEET - Criteria for Approval Add when modification involves these items: ☐ 8.203 (HRP-307) - WORKSHEET – Devices ☐ 9.202 (HRP-315) – WORKSHEET – Advertisements ☐ 9.203 (HRP-316) – WORKSHEET - Payments ☐ 6.202 (HRP-317) - WORKSHEET - Short Form of Consent Documentation ☐ 4.203 (HRP-318) - WORKSHEET - Additional Federal Agency Criteria ☐ 8.206 (HRP-322) – WORKSHEET – Emergency Use ☐ 8.205 (HRP-325) – WORKSHEET – Device Compassionate Use ☐ 11.201 (HRP-335) – WORKSHEET – GDPR Compliance ☐ 3.214 (HRP-332) – WORKSHEET – NIH GDS Institutional Certificate ☐ 4.206 (HRP-333) – WORKSHEET – Certificates of Confidentiality ☐ 6.208 (HRP-410) - WORKSHEET - Waiver or Alteration of Consent Process ☐ 6.207 (HRP-411) - WORKSHEET - Waiver of Written Documentation of Consent ☐ 7.201 (HRP-412) - WORKSHEET - Pregnant Women ☐ 7.202 (HRP-413) - WORKSHEET - Non-Viable Neonates ☐ 7.203 (HRP-414) - WORKSHEET - Neonates of Uncertain Viability ☐ 7.204 (HRP-415) - WORKSHEET - Prisoners ☐ 7.205 (HRP-416) - WORKSHEET - Children ☐ 7.101 (HRP-417) - CHECKLIST – Adults with Impaired Decision-Making Capacity ☐ 8.201 (HRP-418) - WORKSHEET - Non-Significant Risk Device ☐ 6.101 (HRP-419) - CHECKLIST - Waiver of Consent Process for Emergency Research ☐ 6.201 (HRP-441) – WORKSHEET – HIPAA Waiver of Authorization	Include: ☐ 4.204 (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.

4 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: ☐ 10.201 (HRP-321) - WORKSHEET - Review of Reportable New Information (Events) ☐ 4.202 (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
5 FOR USE OF A HUMANITARIAN USE DEVICE (HUD) UNDERGOING INITIAL REVIEW, CONTINUING REVIEW OR MODIFICATIONS	
Include: ☐ All submitted materials ☐ 8.204 (HRP-323) - WORKSHEET - Criteria for Approval HUD	Include: ☐ Cover letter to consultants Include as appropriate materials provided to any other reviewer.