The purpose of this worksheet is to provide support for Office of IRB Administration (OIA) staff who prepare review materials for convened IRB meetings or non-committee review. This worksheet lists the information that each IRB member, scientific/scholarly reviewer, non-committee reviewer, or consultant needs to review and the worksheets or checklists, or equivalent, to be used. All IRB members will have electronic (computer) access to and/or will be provided all information and will have all previously submitted documents available for review. This document describes the subset of materials the IRB members are expected to access and review. This worksheet, or equivalent, is to be used. It does not need to be completed or retained.

GENERAL INFORMATION FOR ALL IRB MEMBERS FOR CONVENED MEETINGS

☐Agenda prepared for the meeting

☐List of protocols that were approved using the expedited procedure, granted exemption determinations, and approved after verification of modifications required to secure approval

☐List of guests who will be present at the convened meeting

☐List of IRB member conflicting interests associated with any agenda items

☐Information for other business items

☐Educational materials

FOR EACH PROTOCOL UNDERGOING INITIAL REVIEW

Documents for All IRB Members, Alternate IRB Members and Non-Committee Reviewers	**Additional Items for the Primary Reviewer, Non-Committee Reviewer and Prisoner Representative**	**Additional Items for the Scientific/Scholarly Reviewer**
Include: • Electronic submission system initial application • *OIA-401 CHECKLIST: Pre-Review*, or equivalent • Investigator's protocol or master protocol provided by sponsor • Relevant documents referenced by the investigator's protocol/master protocol • *OIA-314 WORKSHEET: Criteria for Approval and Additional Considerations*, or equivalent Include when they exist: • Consent document(s) • Recruitment materials • Consultant review comments • *OIA-508 TEMPLATE: Multi-Site Communication Plan*, or equivalent • *OIA-509 TEMPLATE QUESTIONNAIRE: UCSD Local Context Questionnaire*, or equivalent Add when the protocol involves these items: • *OIA-317 WORKSHEET: Short Form of Consent Documentation*, or equivalent • *OIA-318 WORKSHEET: Additional Federal Criteria*, or equivalent • *OIA-410 CHECKLIST: Waiver or Alteration of the Consent Process*, or equivalent • *OIA-411 CHECKLIST: Waiver of Written Documentation of Consent*, or equivalent • *OIA-412 CHECKLIST: Pregnant Subjects*, or equivalent • *OIA-413 CHECKLIST: Non-Viable Neonates*, or equivalent • *OIA-414 CHECKLIST: Neonates of Uncertain Viability*, or equivalent • *OIA-415 CHECKLIST: Prisoners*, or equivalent • *OIA-416 CHECKLIST: Children*, or equivalent • *OIA-417 CHECKLIST: Cognitively Impaired Adults*, or equivalent • *OIA-418 CHECKLIST: Non-Significant Risk Device*, or equivalent • *OIA-419 CHECKLIST: Waiver of the Consent Process for Emergency Research*, or equivalent • *OIA-441 CHECKLIST: HIPAA Waiver of Authorization*, or equivalent	Include when they exist: • Investigator's brochure(s) • Package insert(s) • Device instructions for use • All other relevant materials provided by the investigator • Ancillary reviews • Evidence of principal investigator qualifications Add when the protocol involves these items: • *OIA-306 WORKSHEET: Drugs*, or equivalent • *OIA-307 WORKSHEET: Devices*, or equivalent • *OIA-315 WORKSHEET: Advertisements*, or equivalent • *OIA-316 WORKSHEET: Payments*, or equivalent	Include: • *OIA-320 WORKSHEET: Scientific or Scholarly Review*, or equivalent Include when they exist: • Scientific evaluation

FOR EACH PROTOCOL UNDERGOING CONTINUING REVIEW		
Documents for All IRB Members, Alternate IRB Members and Non-Committee Reviewers	**Additional Items for the Primary Reviewer, Non-Committee Reviewer and Prisoner Representative**	**Additional Documents for the Scientific/Scholarly Reviewer**
Include: • Electronic submission system renewal application • *OIA-401 CHECKLIST: Pre-Review*, or equivalent • Investigator's protocol or master protocol provided by sponsor • Relevant documents referenced by the investigator's research plan or master protocol • *OIA-314 WORKSHEET: Criteria for Approval and Additional Considerations*, or equivalent Include when they exist: • Current and proposed consent document(s) • Consultant review comments Add when the protocol involves these items: • *OIA-317 WORKSHEET: Short Form of Consent Documentation*, or equivalent • *OIA-318 WORKSHEET: Additional Federal Criteria*, or equivalent • *OIA-410 CHECKLIST: Waiver or Alteration of the Consent Process*, or equivalent • *OIA-411 CHECKLIST: Waiver of Written Documentation of Consent*, or equivalent • *OIA-412 CHECKLIST: Pregnant Subjects*, or equivalent • *OIA-413 CHECKLIST: Non-Viable Neonates*, or equivalent • *OIA-414 CHECKLIST: Neonates of Uncertain Viability*, or equivalent • *OIA-415 CHECKLIST: Prisoners*, or equivalent • *OIA-416 CHECKLIST: Children*, or equivalent • *OIA-417 CHECKLIST: Cognitively Impaired Adults*, or equivalent • *OIA-418 CHECKLIST: Non-Significant Risk Device*, or equivalent • *OIA-419 CHECKLIST: Waiver of the Consent Process for Emergency Research*, or equivalent • *OIA-441 CHECKLIST: HIPAA Waiver of Authorization*, or equivalent	Include: • Any modifications to the sponsor protocol previously approved by the IRB	None

FOR EACH PROTOCOL UNDERGOING REVIEW OF AMENDMENTS		
Documents for All IRB Members, Alternate IRB Members And Non-Committee Reviewers	**Additional Items for the Primary Reviewer, Non-Committee Reviewer and Prisoner Representative**	**Additional Documents for the Scientific/Scholarly Reviewer**
Include: • Electronic submission system amendment application • *OIA-314 WORKSHEET: Criteria for Approval and Additional Considerations*, or equivalent Include tracked and clean copies of all modified documents. Include when they exist: • Summary of changes documents • Consultant review comments • *OIA-508 TEMPLATE: Multi-Site Communication Plan, or equivalent* • *OIA-509 TEMPLATE QUESTIONNAIRE: UCSD Local Context Questionnaire*, or equivalent Add when modification involves these items: • *OIA-317 WORKSHEET: Short Form of Consent Documentation*, or equivalent • *OIA-318 WORKSHEET: Additional Federal Criteria*, or equivalent • *OIA-410 CHECKLIST: Waiver or Alteration of the Consent Process*, or equivalent • *OIA-411 CHECKLIST: Waiver of Written Documentation of Consent*, or equivalent • *OIA-412 CHECKLIST: Pregnant Subjects*, or equivalent • *OIA-413 CHECKLIST: Non-Viable Neonates*, or equivalent • *OIA-414 CHECKLIST: Neonates of Uncertain Viability*, or equivalent • *OIA-415 CHECKLIST: Prisoners*, or equivalent • *OIA-416 CHECKLIST: Children*, or equivalent • *OIA-417 CHECKLIST: Cognitively Impaired Adults*, or equivalent • *OIA-418 CHECKLIST: Non-Significant Risk Device*, or equivalent • *OIA-419 CHECKLIST: Waiver of the Consent Process for Emergency Research*, or equivalent • *OIA-441 CHECKLIST: HIPAA Waiver of Authorization*, or equivalent	Include: • All other materials provided by the investigator Add when modification involves these items: • *OIA-315 WORKSHEET: Advertisements*, or equivalent • *OIA-316 WORKSHEET: Payments*, or equivalent	Include: • *OIA-320 WORKSHEET: Scientific or Scholarly Review*, or equivalent (if the amendments are substantive)

FOR EACH REPORTABLE EVENT (UNANTICIPATED PROBLEM INVOLVING RISKS TO SUBJECTS OR OTHERS/UNANTICIPATED PROBLEM REPORT, 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: • Electronic submission system report application • *OIA-321 WORKSHEET: Review of Reportable Events*, or equivalent • *OIA-314 WORKSHEET: Criteria for Approval and Additional Considerations*, or equivalent Include when they exist or are relevant: • Investigation report • Other supporting documents • Investigator's protocol and modified documents referenced by the investigator's protocol • Consent document Add when the problem involves a protocol and the reportable event affects these items: • *OIA-317 WORKSHEET: Short Form of Consent Documentation*, or equivalent • *OIA-318 WORKSHEET: Additional Federal Criteria*, or equivalent • *OIA-410 CHECKLIST: Waiver or Alteration of the Consent Process*, or equivalent • *OIA-411 CHECKLIST: Waiver of Written Documentation of Consent*, or equivalent • *OIA-412 CHECKLIST: Pregnant Subjects*, or equivalent • *OIA-413 CHECKLIST: Non-Viable Neonates*, or equivalent • *OIA-414 CHECKLIST: Neonates of Uncertain Viability*, or equivalent • *OIA-415 CHECKLIST: Prisoners*, or equivalent • *OIA-416 CHECKLIST: Children*, or equivalent • *OIA-417 CHECKLIST: Cognitively Impaired Adults*, or equivalent • *OIA-418 CHECKLIST: Non-Significant Risk Device*, or equivalent • *OIA-419 CHECKLIST: Waiver of the Consent Process for Emergency Research*, or equivalent • *OIA-441 CHECKLIST: HIPAA Waiver of Authorization*, or equivalent	Include: • Cover letter to consultants • Include as appropriate materials provided to any other reviewer.

FOR USE OF A HUMANITARIAN USE DEVICE (HUD) UNDERGOING INITIAL REVIEW	
Documents for All IRB Members and Alternate IRB Members	**Documents for Consultants**

Include:
• Electronic submission system initial application
• *OIA-401 CHECKLIST: Pre-Review*, or equivalent
• All submitted materials to include:
  ○ A copy of the humanitarian device exemption (HDE) approval order
  ○ A description of the device
  ○ The product labelling
  ○ The patient information packet that may accompany the HUD
  ○ A summary of how the physician proposes to use the device, including a description of any screening procedures, the HUD procedure, and any patient follow-up visits, tests or procedures
• *OIA-323 WORKSHEET: Criteria for Approval and Additional Considerations HUD*, or equivalent
	Include:
	• Cover letter to consultants
	• Include as appropriate materials provided to any other reviewer.

FOR USE OF AN HUD UNDERGOING CONTINUING REVIEW	

Include:
• Electronic submission system renewal application
• *OIA-401 CHECKLIST: Pre-Review*, or equivalent
• All submitted materials to include:
  ○ Any new risk/benefit information of which the physician has become aware [e.g., publications, Food and Drug Administration (FDA) notifications, or manufacturer communications]
  ○ Any medical device reports (obtain from manufacturer)
  ○ A copy of the safety information submitted by the manufacturer to FDA in the periodic reports required by 21 CFR 814.126(b)(1)
• *OIA-323 WORKSHEET: Criteria for Approval and Additional Considerations HUD*, or equivalent
	Include:
	• Cover letter to consultants
	• Include as appropriate materials provided to any other reviewer.

FOR USE OF AN HUD UNDERGOING REVIEW OF AMENDMENTS	
Include when modified: • Electronic submission system amendment application • *OIA-401 CHECKLIST: Pre-Review*, or equivalent • All submitted materials • *OIA-323 WORKSHEET: Criteria for Approval and Additional Considerations HUD*, or equivalent	Include: • Cover letter to consultants • Include as appropriate materials provided to any other reviewer.

FOR EMERGENCY USE UNDERGOING INITIAL REVIEW

Documents for All IRB Members, Alternate IRB Members, and Non-Committee Reviewers	**Documents for Consultants**

Include:
• Electronic submission system initial application
• *OIA-401 CHECKLIST: Pre-Review*, or equivalent
• All submitted materials to include:
  ○ For all types of investigational products:
  ○ The expanded access consent document that will be/was signed by the patient/LAR
  ○ Documentation of FDA authorization including the eIND or IDE number (may be an email)
  ○ All correspondence with FDA
  ○ For drugs/biologics:
  ○ FDA Form 3926, if the use will be/was under a new IND (most common) rather than existing IND (less common)
  ○ Letter of Authorization allowing FDA to reference manufacturer's existing IND in FDA's review of the treating physician's IND (unless the drug will be/was given under the manufacturer's existing IND, which is uncommon)
  ○ Investigator's Brochure/equivalent
  ○ Treatment Plan if not sufficiently documented on FDA Form 3926
  ○ For devices:
  ○ Authorization from the device manufacturer
  ○ A description of the device/equivalent
  ○ Independent assessment from an uninvolved physician
• *OIA-322 WORKSHEET: Emergency Use*, or equivalent
	Include:
	• Cover letter to consultants
	• Include as appropriate materials provided to any other reviewer.

FOR EXPANDED ACCESS UNDERGOING INITIAL REVIEW	
Documents for All IRB Members, Alternate IRB Members, and Non-Committee Reviewers	**Documents for Consultants**

Include:
• Electronic submission system initial application
• *OIA-401 CHECKLIST: Pre-Review*, or equivalent
• All submitted materials to include:
  ○ Expanded access consent document
  ○ Documentation of FDA authorization including the IND or IDE number (may be an email)
  ○ Investigator's Brochure, or equivalent
  ○ Single patient:
  ○ For drugs:
  ○ FDA Form 3926, if use will be under new IND (most common) rather than existing IND (less common)
  ○ All correspondence with FDA
  ○ Individual Treatment Plan (for drugs, only needed if detail in FDA Form 3926 is insufficient)
  ○ For devices:
  ○ Authorization from the device manufacturer
  ○ A description of the device/equivalent
  ○ Independent assessment from an uninvolved physician
  ○ Group:
  ○ Treatment Protocol
  ○ Consent Template for multi-site protocols
• *OIA- 314 WORKSHEET: Criteria for Approval and Additional Considerations*, or equivalent
 	
Include when they exist:
• *OIA-509 TEMPLATE QUESTIONNAIRE: UCSD Local Context Questionnaire*, or equivalent
	Include:
	• Cover letter to consultants
	• Include as appropriate materials provided to any other reviewer.

FOR EXPANDED ACCESS UNDERGOING CONTINUING REVIEW	
Include: • Electronic submission system renewal application • *OIA-401 CHECKLIST: Pre-Review*, or equivalent • Single Patient Treatment Plan or Group Treatment protocol • Relevant documents referenced by the investigator's research plan or master protocol • *OIA-314 WORKSHEET: Criteria for Approval and Additional Considerations*, or equivalent Include when they exist: • Current and proposed consent document(s) • Consultant review comments • Any modifications to the protocol previously approved by the IRB • *OIA-509 TEMPLATE QUESTIONNAIRE: UCSD Local Context Questionnaire*, or equivalent	Include: • Cover letter to consultants • Include as appropriate materials provided to any other reviewer.

FOR EXPANDED ACCESS UNDERGOING REVIEW OF AMENDMENTS

Include: • Electronic submission system amendment application • *OIA-314 WORKSHEET: Criteria for Approval and Additional Considerations*, or equivalent Include tracked and clean copies of all modified documents. Include when they exist: • Summary of changes documents • Consultant review comments • All other materials provided by the investigator • *OIA-509 TEMPLATE QUESTIONNAIRE: UCSD Local Context Questionnaire*, or equivalent	Include: • Cover letter to consultants • Include as appropriate materials provided to any other reviewer.