

	WORKSHEET: Review Materials		
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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 as applicable to each study. 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 or the electronic equivalent. For individuals who have electronic system computer access 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. See SOP: IRB Member Review Expectations (HRP-045) for additional information on review expectations. ¹

1 GENERAL INFORMATION FOR ALL IRB MEMBERS FOR CONVENED MEETINGS

- List of protocols approved using the expedited procedure via link through the agenda.
- Information for Other Business items Educational Materials

2 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 without reviewer access to the submission
<ul style="list-style-type: none"> <input type="checkbox"/> Investigator's application/protocol and related documents <input type="checkbox"/> HRP-401 - CHECKLIST - Pre-Review or Pre-Review stipulations <input type="checkbox"/> HRP-314 - WORKSHEET - Criteria for Approval <p>Include when the protocol involves these items:</p> <ul style="list-style-type: none"> <input type="checkbox"/> HRP-315 - WORKSHEET - Advertisements <input type="checkbox"/> HRP-316 - WORKSHEET - Payments <input type="checkbox"/> HRP-318 - WORKSHEET - Additional Federal Agency Criteria <input type="checkbox"/> HRP-333 - WORKSHEET - Certificate of Confidentiality <input type="checkbox"/> HRP-410 - CHECKLIST - Waiver or Alteration of Consent Process <input type="checkbox"/> HRP-411 - CHECKLIST - Waiver of Written Documentation of Consent <input type="checkbox"/> HRP-412 - CHECKLIST - Pregnant Women <input type="checkbox"/> HRP-415 - CHECKLIST - Prisoners <input type="checkbox"/> HRP-416 - CHECKLIST - Children <input type="checkbox"/> HRP-417 - CHECKLIST - Cognitively Impaired Adults <input type="checkbox"/> HRP-418 - CHECKLIST - Non-Significant Risk Device 	<p>Include:</p> <ul style="list-style-type: none"> <input type="checkbox"/> HRP-320 - WORKSHEET - Scientific or Scholarly Review <p>Include when they exist:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Scientific evaluation 	<p>Include:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Correspondence to consultants <input type="checkbox"/> Include as appropriate materials provided to any other reviewer.

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
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3 FOR EACH PROTOCOL UNDERGOING CONTINUING REVIEW	
Documents for All IRB Members and Alternate IRB Members	Documents for Consultants and individuals without reviewer access to the submission
<ul style="list-style-type: none"><input type="checkbox"/> Investigator's application/protocol and related documents<input type="checkbox"/> HRP-401 - CHECKLIST - Pre-Review or Pre-Review stipulations<input type="checkbox"/> HRP-314 - WORKSHEET - Criteria for Approval <p>Include when the protocol involves these items:</p> <ul style="list-style-type: none"><input type="checkbox"/> HRP-315 - WORKSHEET - Advertisements<input type="checkbox"/> HRP-316 - WORKSHEET - Payments<input type="checkbox"/> HRP-318 - WORKSHEET - Additional Federal Agency Criteria<input type="checkbox"/> HRP-333 - WORKSHEET - Certificate of Confidentiality<input type="checkbox"/> HRP-410 - CHECKLIST - Waiver or Alteration of Consent Process<input type="checkbox"/> HRP-411 - CHECKLIST - Waiver of Written Documentation of Consent<input type="checkbox"/> HRP-412 - CHECKLIST - Pregnant Women<input type="checkbox"/> HRP-415 - CHECKLIST - Prisoners<input type="checkbox"/> HRP-416 - CHECKLIST - Children<input type="checkbox"/> HRP-417 - CHECKLIST - Cognitively Impaired Adults<input type="checkbox"/> HRP-418 - CHECKLIST - Non-Significant Risk Device	<p>Include:</p> <ul style="list-style-type: none"><input type="checkbox"/> Correspondence to consultants<input type="checkbox"/> Include as appropriate materials provided to any other reviewer.



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4 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 and individuals without reviewer access to the submission
<p>Include:</p> <ul style="list-style-type: none"><input type="checkbox"/> Investigator's application/protocol and related documents<input type="checkbox"/> HRP-401 - CHECKLIST - Pre-Review or Pre-Review stipulations<input type="checkbox"/> HRP-314 - WORKSHEET - Criteria for Approval <p>Add when modification involves these items:</p> <ul style="list-style-type: none"><input type="checkbox"/> HRP-315 - WORKSHEET - Advertisements<input type="checkbox"/> HRP-316 - WORKSHEET - Payments<input type="checkbox"/> HRP-318 - WORKSHEET - Additional Federal Agency Criteria<input type="checkbox"/> HRP-333 - WORKSHEET - Certificate of Confidentiality<input type="checkbox"/> HRP-410 - CHECKLIST - Waiver or Alteration of Consent Process<input type="checkbox"/> HRP-411 - CHECKLIST - Waiver of Written Documentation of Consent<input type="checkbox"/> HRP-412 - CHECKLIST - Pregnant Women<input type="checkbox"/> HRP-415 - CHECKLIST - Prisoners<input type="checkbox"/> HRP-416 - CHECKLIST - Children<input type="checkbox"/> HRP-417 - CHECKLIST - Cognitively Impaired Adults<input type="checkbox"/> HRP-418 - CHECKLIST - Non-Significant Risk Device	<p>Include:</p> <ul style="list-style-type: none"><input type="checkbox"/> HRP-320 - WORKSHEET - Scientific or Scholarly Review (if the amendments are substantive)	<p>Include:</p> <ul style="list-style-type: none"><input type="checkbox"/> Correspondence to consultants<input type="checkbox"/> Include as appropriate materials provided to any other reviewer.



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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	Documents for Consultants
<p>Include:</p> <ul style="list-style-type: none"><input type="checkbox"/> HRP-321 - WORKSHEET - Review of Information Items<input type="checkbox"/> HRP-314 - WORKSHEET - Criteria for Approval <p>Add when the problem involves a protocol and the new information affects these items:</p> <ul style="list-style-type: none"><input type="checkbox"/> HRP-315 - WORKSHEET - Advertisements<input type="checkbox"/> HRP-316 - WORKSHEET - Payments<input type="checkbox"/> HRP-318 - WORKSHEET - Additional Federal Agency Criteria<input type="checkbox"/> HRP-333 - WORKSHEET - Certificate of Confidentiality<input type="checkbox"/> HRP-410 - CHECKLIST - Waiver or Alteration of Consent Process<input type="checkbox"/> HRP-411 - CHECKLIST - Waiver of Written Documentation of Consent<input type="checkbox"/> HRP-412 - CHECKLIST - Pregnant Women<input type="checkbox"/> HRP-415 - CHECKLIST - Prisoners<input type="checkbox"/> HRP-416 - CHECKLIST - Children<input type="checkbox"/> HRP-417 - CHECKLIST - Cognitively Impaired Adults<input type="checkbox"/> HRP-418 - CHECKLIST - Non-Significant Risk Device	<p>Include:</p> <ul style="list-style-type: none"><input type="checkbox"/> Correspondence to consultants<input type="checkbox"/> Include as appropriate materials provided to any other reviewer.