

	OIA-402 CHECKLIST: Non-Committee Review		
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The purpose of this checklist is to provide support for designated reviewers conducting non-committee review. This checklist, or equivalent, is to be used. It does not need to be completed or retained.

IRB Number:	
Protocol Name:	
Investigator:	

<input type="checkbox"/>	Initial review	<input type="checkbox"/>	Modification	<input type="checkbox"/>	Request for <u>human research</u> or engagement determination
<input type="checkbox"/>	Continuing review	<input type="checkbox"/>	Closure		

1 REVIEWER CRITERIA (Check if “Yes.” Must be checked) **Otherwise, sign the form, and return all materials.**)

<input type="checkbox"/>	I do not have a <u>conflicting interest</u> .
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2 REVIEW LEVEL (Select one of the following)

Level	Documents to use	Categories ¹	Continuing Review Interval
<input type="checkbox"/> Not <u>human research</u>	<i>OIA-310 WORKSHEET: Human Research Determination, or equivalent</i>		
<input type="checkbox"/> <u>Human research</u> not engaged	<i>OIA-311 WORKSHEET: Engagement Determination, or equivalent</i>		
<input type="checkbox"/> Exempt	<i>OIA-312 WORKSHEET: Exemption Determination, or equivalent</i>		
<input type="checkbox"/> Expedited	<i>OIA-313 WORKSHEET: Expedited Review, or equivalent</i> <i>OIA-314 WORKSHEET: Criteria for Approval and Additional Considerations,² or equivalent</i>		

3 DETERMINATION (Select one or more of the following)

<input type="checkbox"/>	Meets criteria for not <u>human research</u> or <u>human research</u> not engaged.
<input type="checkbox"/>	Meets criteria for exempt review. When determined to be exempt under categories 45 CFR 46.104 2(iii) , 3(i)(C) , or 4(i)(iii) when not federally funded, it is also determined that the privacy and confidentiality provisions dictated under 45 CFR 46.111(a)(7) have been met.
<input type="checkbox"/>	Meets criteria for approval and other considerations as outlined in <i>OIA-314 WORKSHEET: Criteria for Approval and Additional Considerations</i> , or equivalent, for expedited review.
<input type="checkbox"/>	Modifications required to meet criteria for approval and other considerations as outlined in <i>OIA-314 WORKSHEET: Criteria for Approval and Additional Considerations</i> , or equivalent, for expedited review.
<input type="checkbox"/>	<u>Conflict of interest</u> committee <u>management plan</u> reviewed and accepted if the principal investigator disclosed a <u>related financial interest</u> .
<input type="checkbox"/>	Send to convened IRB.
<input type="checkbox"/>	Close

Delineate modifications required to secure approval or notes:

¹ Use the categories for the associated worksheet. Under the expedited review category use “MM” for minor modifications to previously approved research. Use “HUD-CR” for continuing review of a humanitarian use device (HUD).

² Use *OIA-323 WORKSHEET: Criteria for Approval and Additional Considerations HUD*, or equivalent, for HUD review.