

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 is to be completed by the Designated Reviewer, signed, dated, and retained.

IRB Number:			
Study Title:			
Short Title:			
Investigator:			
<input type="checkbox"/>	Initial review	<input type="checkbox"/>	Modification
<input type="checkbox"/>	Continuing review	<input type="checkbox"/>	Request for <u>Human Research</u> or engagement determination
<input type="checkbox"/>		<input type="checkbox"/>	Review of Modifications Required to Secure Approval

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

I do **not** have a Conflicting Interest.

2 REVIEW LEVEL (Select one of the following)

Level	Documents to use	Categories
<input type="checkbox"/> Not <u>Human Research</u>	3.207 (HRP-310) - WORKSHEET - Human Research Determination	
<input type="checkbox"/> <u>Human Research</u> Not Engaged	3.208 (HRP-311) - WORKSHEET - Engagement Determination	
<input type="checkbox"/> Exempt	3.209 (HRP-312) - WORKSHEET - Exemption Determination 3.213 (HRP-319) - WORKSHEET - Limited IRB Review and Broad Consent	<input type="checkbox"/> (1) Educational settings <input type="checkbox"/> (2)(i) Tests, surveys, interviews, or observation (non-identifiable) <input type="checkbox"/> (2)(ii) Tests, surveys, interviews, or observation (low risk) <input type="checkbox"/> (2)(iii) Tests, surveys, interviews, or observation (identifiable); and for which limited IRB review was conducted via expedited review <input type="checkbox"/> (3)(i)(A) Benign behavioral interventions (non-identifiable) <input type="checkbox"/> (3)(i)(B) Benign behavioral interventions (low risk) <input type="checkbox"/> (3)(i)(C) Benign behavioral interventions (identifiable); and for which limited IRB review was conducted via expedited review <input type="checkbox"/> (4) Secondary research on data or specimens (no consent required) <input type="checkbox"/> (5) Demonstration projects <input type="checkbox"/> (6) Taste and food quality <input type="checkbox"/> (7) Storage or maintenance of data or specimens (broad consent required); and for which limited IRB review was conducted via expedited review <input type="checkbox"/> (8) Secondary research use of data or specimens (broad consent required); and for which limited IRB review was conducted via expedited review
<input type="checkbox"/> Expedited	4.201 (HRP-313) - WORKSHEET - Expedited Review 4.202 (HRP-314) - WORKSHEET - Criteria for Approval	<input type="checkbox"/> Minor modifications to previously approved research <input type="checkbox"/> (1)(a) Drug studies <input type="checkbox"/> (1)(b) Device studies <input type="checkbox"/> (2)(a) Blood samples from healthy, non-pregnant adults <input type="checkbox"/> (2)(b) Blood samples from others <input type="checkbox"/> (3) Noninvasive biological specimens <input type="checkbox"/> (4) Noninvasive procedures <input type="checkbox"/> (5) Data, documents, records, or specimens

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			<input type="checkbox"/> (6) Voice, video, digital, or image recordings <input type="checkbox"/> (7)(a) Behavioral research <input type="checkbox"/> (7)(b) Social science methods <input type="checkbox"/> (8)(a) Long-term follow-up <input type="checkbox"/> (8)(b) No subjects enrolled <input type="checkbox"/> (8)(c) Data analysis <input type="checkbox"/> (9) Convened IRB determined <u>Minimal Risk</u>
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3 DETERMINATION (Select one of the following)

<input type="checkbox"/>	Meets criteria
<input type="checkbox"/>	Modifications required to meet criteria
<input type="checkbox"/>	Send to convened IRB

Additional information: Describe modifications required to secure approval, if required in section 3 above. Or, if review must be sent to the convened IRB, provide rationale for this determination (e.g. describe why research cannot be approved via expedited review, explain why research appearing on the expedited review list is actually more than Minimal Risk, etc.):

4 Continuing Review (for Expedited Review only)

<input type="checkbox"/>	Continuing review not required. Status report
<input type="checkbox"/>	Continuing review required. Rationale:

Attach required completed checklists and documentation of protocol-specific findings justifying regulatory determinations.

Reviewer Signature:		Date:	
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