	<b>CHECKLIST: Non-Committee Review</b>		
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The purpose of this checklist is to provide support for Designated Reviewers conducting Non-Committee Review. This checklist or equivalent form is to be completed by the Designated Reviewer.<sup>1</sup>

<b>IRB Number:</b>	
<b>Protocol Name:</b>	
<b>Investigator:</b>	
<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"/> 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.**

<input type="checkbox"/> I do <b>not</b> have a <u>Conflicting Interest</u> .
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**2 REVIEW LEVEL** (Select one of the following if **Approve** checked above)

Level	Documents to use	Categories
<input type="checkbox"/> Not <u>Human Research</u>	HRP-310 - WORKSHEET - Human Research Determination	
<input type="checkbox"/> <u>Human Research</u> Not Engaged	HRP-311 - WORKSHEET - Engagement Determination	
<input type="checkbox"/> Exempt.	HRP-312 - WORKSHEET - Exemption Determination HRP-319 - WORKSHEET - Limited IRB Review t	<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.	HRP-313 - WORKSHEET - Expedited Review 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 <input type="checkbox"/> (6) Voice, video, digital, or image recordings <input type="checkbox"/> (7)(a) Behavioral research

<sup>1</sup> This document satisfies AAHRPP elements I.1.A, I.6.B, I.7.A, I-9, II.1.D, II.2.A-II.2.C, II.2.F-II.2.F.3, II.5.A, II.5.B

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<input type="checkbox"/>			<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>
<input type="checkbox"/>	Delayed Onset	WORKSHEET: Delayed Onset: 46.118	
<input type="checkbox"/>	Personnel Change, ONLY		

**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

	Delineate modifications required to secure approval or notes:
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**4 Continuing Review (for Expedited Review only)**

<input type="checkbox"/>	Continuing review not required.
<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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