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, and uploaded into the eProst system.

<table>
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<th>IRB Number:</th>
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<th>Study Title:</th>
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<table>
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<tr>
<th>Initial review</th>
<th>Modification</th>
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<tbody>
<tr>
<td>Continuing review</td>
<td>Review of Modifications Required to Secure Approval</td>
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</tbody>
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1 **Answer the following**

- [ ] I do not have a **Conflicting Interest**. *(Must be checked)*
- [ ] This protocol involves only treatment use of an HUD (not a clinical investigation of the HUD) *If checked, the form is complete.*

2 **Expedited Review Categories** *(One must be checked)*

- [ ] (1)(a) Drug studies  
- [ ] (1)(b) Device studies  
- [ ] (2)(a) Blood samples from healthy, non-pregnant adults  
- [ ] (2)(b) Blood samples from others  
- [ ] (3) Noninvasive biological specimens  
- [ ] (4) Noninvasive procedures  
- [ ] (5) Data, documents, records, or specimens  
- [ ] (6) Voice, video, digital, or image recordings  
- [ ] (7)(a) Behavioral research  
- [ ] (7)(b) Social science methods  
- [ ] (8)(a) Long-term follow-up  
- [ ] (8)(b) No subjects enrolled  
- [ ] (8)(c) Data analysis  
- [ ] (9) Convened IRB determined minimal risk  
- [ ] (10) Minor Modification to previously approved research

3 **Review Continuation**

- [ ] The criteria for approval are met.  
- [ ] The consent process is adequate  
- [ ] N/A consent is waived  
- [ ] Modifications are required to meet criteria  
- [ ] The submission should be sent to the convened IRB for further review.

**Additional Determinations** *(Check all that apply)*

- [ ] Children may be included - complete and include Checklist Children (HRP 416)  
- [ ] Prisoners may be included - complete and include Checklist Prisoners (HRP 415)  
- [ ] Pregnant Women may be included - If funded by an agency/department requiring specific determinations, complete and include Checklist Pregnant Women (HRP 412)  
- [ ] Cognitively impaired adults may be included – complete and include Checklist Cognitively Impaired Adults (HRP 417)  
- [ ] The requirement for informed consent is waived – complete and include Checklist Waiver of Consent (HRP 410)  
- [ ] The requirement for documenting consent is waived – complete and include Checklist Waiver of Documentation of Consent (HRP 411)

Delineate modifications required to secure approval or notes:
### CHECKLIST: Non-Committee Review

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<td>06/04/2019</td>
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Continuing Review (for Expedited Review only)

- [ ] Continuing review not required.
- [ ] Continuing review required. Rationale:

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

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