



CHECKLIST: Non-Committee Review

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.ⁱ

Submission Information

Basic Information	Submission Details
IRB Number:	Click or tap here to enter text.
Study Title:	Click or tap here to enter text.
Short Title:	Click or tap here to enter text.
Investigator:	Click or tap here to enter text.

Type of submission:

- Initial Review
- Modification
- Continuing Review
- Request for Human Research or engagement determination
- Review of Modifications Required to Secure Approval

1. Reviewer Criteria (Check if "Yes." Otherwise, sign the form, and return all materials.)

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

2. Review Level (Select one of the following)

- Not Human Research (use HRP-310 - WORKSHEET - Human Research Determination)
- Human Research Not Engaged (use HRP-311 - WORKSHEET - Engagement Determination)
- Exempt (use HRP-312 - WORKSHEET - Exemption Determination, HRP-319 - WORKSHEET - Limited IRB Review and Broad Consent)
 - (1) Educational settings
 - (2)(i) Tests, surveys, interviews, or observation (non-identifiable)
 - (2)(ii) Tests, surveys, interviews, or observation (low risk)
 - (2)(iii) Tests, surveys, interviews, or observation (identifiable); and for which limited IRB review was conducted via expedited review
 - (3)(i)(A) Benign behavioral interventions (non-identifiable)

- (3)(i)(B) Benign behavioral interventions (low risk)
 - (3)(i)(C) Benign behavioral interventions (identifiable); and for which limited IRB review was conducted via expedited review
 - (4) Secondary research on data or specimens (no consent required)
 - (5) Demonstration projects
 - (6) Taste and food quality
 - (7) Storage or maintenance of data or specimens (broad consent required); and for which limited IRB review was conducted via expedited review
 - (8) Secondary research use of data or specimens (broad consent required); and for which limited IRB review was conducted via expedited review
- Expedited (use HRP-313 - WORKSHEET - Expedited Review, HRP-314 - WORKSHEET - Criteria for Approval)
- Minor modifications to previously approved research
 - (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
 - HUD continuing review

3. Determination (Select one of the following)

- Meets criteria
- Modifications required to meet criteria
- Send to convened IRB

4. 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.):

Click or tap here to enter text.

5. Continuing Review (for Expedited Review only; select one of the following)

- Continuing review not required.
- Continuing review required. Rationale: Click or tap here to enter text.

Reviewer Signature

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

X

Date of Signature: Click or tap here to enter text.

ⁱ 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