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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:** |       |
|[ ]  Initial review |[ ]  Modification |[ ]  Request for Human Research or engagement determination |
|[ ]  Continuing review |  |  |[ ]  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. |
|  |
| 1. REVIEW LEVEL (Select one of the following)
 |
| Level | Documents to use | Categories |
|[ ]  Not Human Research | WORKSHEET: Human Research (HRP-310) |  |
|[ ]  Human Research Not Engaged | WORKSHEET: Engagement (HRP-311) |  |
|[ ]  Exempt.  | WORKSHEET: Exemption (HRP‑312)WORKSHEET: Limited IRB and Broad Consent (HRP-319) | [ ]  (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. | WORKSHEET: Expedited Review (HRP‑313) WORKSHEET: Criteria for Approval (HRP-314) | [ ]  Minor modification[ ]  (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 |
|  |
| 1. DETERMINATION (Select one of the following)
 |
|[ ]  Meets criteria |
|[ ]  Modifications required to meet criteria |
|[ ]  Send to convened IRB |
|  |
| Delineate modifications required to secure approval or notes:      |
|  |
| 1. 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. |
| Reviewer Signature: |       | Date: |       |