|  |
| --- |
| 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 | HRP-310 - WORKSHEET - Human Research Determination |  |
|[ ]  Human Research Not Engaged | HRP-311 - WORKSHEET - Engagement Determination |  |
|[ ]  Exempt | HRP-312 - WORKSHEET - Exemption DeterminationHRP-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 | 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 |
|  |
| 1. DETERMINATION (Select one of the following)
 |
|[ ]  Meets criteria |
|[ ]  Modifications required to meet criteria |
|[ ]  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.):      |
|  |
| 1. Continuing Review (for Expedited Review only)
 |
|[ ]  Continuing review not required. Status report  |
|[ ]  Continuing review required. Rationale:       |
|  |
| Attach required completed checklists and documentation of protocol-specific findings justifying regulatory determinations. |
| Reviewer Signature: |       | Date: |       |