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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. |
| Protocol |  |
| Investigator |  |
| [ ]  | Initial review | [ ]  | Review of modifications required to secure exemption determination |
| [ ]  | Continuing review | [ ]  | Review of modifications required to secure approval using the exempt or expedited procedure. |
| [ ]  | Minor change to previously approved research | [ ]  | Review of modifications required by the convened IRB to secure approval. |
|  |
| 1. REVIEWER CRITERIA ((All must be “Yes” or “N/A.” Otherwise, sign the form, and return all materials.)
 |
| [ ]  Yes [ ]  No | I do **not** have a Conflicting Interest. |
| [ ]  Yes [ ]  No | All contingencies noted on “CHECKLIST: Pre-Review” have been met. |
| [ ]  Yes [ ]  No[ ]  N/A | The regulatory criteria for approval have been met. (Select “N/A” for exempt determinations and review of modifications required by the convened IRB, expedited, or exempt procedure.) |
|  |
| 1. FINAL DETERMINATION (Select one of the following)
 |
| [ ]  | The activity qualifies for an exempt determination. (Complete CHECKLIST: Exemption Determination.) |
| [ ]  | The activity is approved using the expedited procedure. (Complete CHECKLIST: Eligibility for Review Using the Expedited Procedure.) |
| [ ]  | The activity requires review by a convened IRB. (Return submission to Analyst; Non-Committee checklist does not require completion). |
| [ ]  | The modification(s) is a minor change to previously approved research and is approved using the expedited procedure. (Complete CHECKLIST: Review Using the Expedited Procedure.) |
| [ ]  | The modification(s) is a minor change to previously approved exempt research. |
| [ ]  | The modification is to transfer IRB oversight to: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| [ ]   | The modifications required by the convened IRB, expedited, or exempt procedure were made. |
| [ ]  | Modifications required to secure approval: |
|  | [ ]  | The Human Research would be exempt from IRB review and meet ethical criteria if the following modifications were made:  |
| [ ]  | The Human Research would be approved using the expedited procedure if the following modifications were made: |
| [ ]  | The following modifications required by the convened IRB have yet to be made: |
| Delineate modifications required to secure approval:       |
| 1. Re-consenting Requirement (for Expedited Review only)
 |
| [ ]  | N/A | [ ]  | Required for all subjects on active treatment |
| [ ]  | Not required | [ ]  | Required for all subjects |
| [ ]  | Not required, no local subjects enrolled | [ ]  Other:  |
| 1. Continuing Review (for Expedited Review only)
 |
| [ ]  | Continuing review not required. |
| [ ]  | Continuing review required. Rationale:       |
| Attach completed checklists that need to be filed and documentation of protocol-specific findings justifying regulatory determinations. |
| Reviewer Completing Checklist: |       | Date: |       |