|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 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: |  |