|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| The purpose of this checklist is to provide support for IRB staff and members conducting review. This checklist or equivalent is to be completed by the IRB staff or IRB reviewer and retained in the system of record. When a box is checked, it indicates the requirements of the corresponding worksheet and/or checklist are satisfied. | | | | | | | | | | | | |
| **IRB Number:** | | |  | | | | | | | | | |
|  | | | | | | | | | | | | |
| 1. **Study Regulatory Oversight** *(Check all that apply)* | | | | | | | | | | | | |
|  | DHHS: Pre-2018 |  | DOD |  | DOJ | |  | | EPA |  | Other Federal | |
|  | DHHS: 2018 |  | DOE |  | ED | |  | | VA |  | ICH-GCP | |
|  | FDA |  | Unregulated - Standards applied: | | | | | | | | | |
|  | | | | | | | | | | | | |
| 1. **Special Determ**in**ations** (With each review, check all special determinations that are appliable for this study overall. Complete and upload required checklists or equivalent only at initial approval and with changes to special determinations.) | | | | | | | | | | | | |
|  | Waiver/Alteration of the consent process (HRP-410) |  | Prisoners (HRP-415) | | |  | | Not significant risk device (FDA) (HRP-418) | | | | |
|  | Waiver of documentation of consent (HRP-411) |  | Children (HRP-416) | | |  | | Waiver of HIPAA authorization for recruitment (HRP-441) | | | | |
|  | Pregnant people (HRP-412) |  | Wards (HRP-416) | | |  | | Waiver of HIPAA authorization for the study (HRP-441) | | | | |
|  | Non-viable neonates (HRP-413) |  | Cognitively impaired adults in a clinical trial (HRP-417) | | |  | | COIC Management Plan accepted | | | | |
|  | Neonates of uncertain viability (HRP-414) |  | Waiver of consent for emergency research (HRP-419) | | |  | |  | | | | |
|  | | | | | | | | | | | | |
| 1. **Reviewer Conflict of Interest** | | | | | | | | | | | | |
|  | The IRB reviewer(s) do **not** have a Conflicting Interest. | | | | | | | | | | | |
|  | | | | | | | | | | | | |
| 1. **Review type** (Select one of the following) | | | | | | | | | | | | |
| Level | | | Documents to use | | | | Categories[[1]](#footnote-2) | | | | | Continuing Review Interval |
|  | Not Research /Not Human Research | | WORKSHEET: Human Research (HRP-310) | | | |  | | | | |  |
|  | Human Research Not Engaged | | WORKSHEET: Engagement (HRP-311) | | | |  | | | | |  |
|  | Exempt | | WORKSHEET: Exemption (HRP‑312) | | | |  | | | | |  |
|  | Expedited | | WORKSHEET: Expedited Review (HRP‑313)  WORKSHEET: Criteria for Approval (HRP-314)[[2]](#footnote-3) | | | |  | | | | |  |
|  | Convened Board | | WORKSHEET: Criteria for Approval (HRP-314)[[3]](#footnote-4) | | | |  | | | | |  |
|  | | | | | | | | | | | | |
| 1. Determination (Select one or more of the following) | | | | | | | | | | | | |
|  | Meets criteria for Not Research or Not Human Research determination (HRP-310). | | | | | | | | | | | |
|  | Meets criteria for Not Engaged determination (HRP-311). | | | | | | | | | | | |
|  | Meets criteria for Exemption determination (HRP‑312). When Limited Review is required, an IRB has determined the requirements of 45 CFR 46.111(a)(7) have been met. | | | | | | | | | | | |
|  | Meets criteria for approval (HRP-314) and meets criteria for all applicable special determinations. | | | | | | | | | | | |
|  | Criteria for approval (HRP-314) and applicable special determinations will be met when directed modifications have been completed. | | | | | | | | | | | |
|  | Research is not approved. | | | | | | | | | | | |
|  | Research is suspended. | | | | | | | | | | | |
|  | Research is closed. | | | | | | | | | | | |
| **Review Summary** | | | | | | | | | | | | |

1. Use the categories for the associated worksheet. Under the expedited review category use “MM” for minor modifications to previously approved research. Use “HUD-CR” for continuing review of a humanitarian use device [↑](#footnote-ref-2)
2. Use WORKSHEET: Criteria for HUD Approval (HRP-323) for HUD uses. [↑](#footnote-ref-3)
3. Use WORKSHEET: Criteria for HUD Approval (HRP-323) for HUD uses. [↑](#footnote-ref-4)