**General Instructions**

1. Please **refer to the agenda notes and other screening documents** (e.g. the convened checklist, the drugs and devices form) uploaded in the HS-ERA comments. These materials will flag any special determinations that need to be made (e.g. non-significant risk device, sub-parts, waivers, deception, etc.) along with any other major issues that need to be considered.
2. Please **carefully review the administrative stipulations, recommendations and notes** to avoid duplicating work already completed during the administrative screening process.
3. Please email your **notes**, **consent form revisions**, and any **substantive concerns or questions for the study team** to your IRB Staff members **at least 3 *business* days before the meeting**. This significantly reduces the time to complete minutes after the meeting.
	1. If you are providing a marked version of the consent form, please label each edit in such a way as to identify it as either a stipulated or recommended revision.
4. Please only raise substantive consent form issues during the meeting.
5. Please come to the meeting prepared with notes for each of your assigned reviews. If all sections are completed, then you are ready to present a thorough review.

**Identify the Study Information**

**IRB #:**

**Principal Investigator:**

**Protocol Title:**

|  |
| --- |
| **Draft a Study Summary***Mention any notable features about the research that you feel are important to frame the conversation at the convened meeting. This may include the study purpose, eligibility criteria, design, study products, other study required procedures, etc.*  |

**Summary**:

|  |
| --- |
| **Assess the Study against the IRB Criteria for Approval***If you cannot confirm a criterion for approval has been met, this is a substantive issue that should be discussed at the IRB meeting. If there is time, please email substantive issues to the study team or IRB staff to try to resolve before the meeting.*  |

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| --- |
| 1. **Risks to subjects are minimized:**
	1. By using **procedures which are consistent with sound research design** and which **do not unnecessarily expose subjects to risk**
	2. Whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes
 |

**Notes:**

**This criterion is met:**

**Yes** [ ]

**No** [ ]  **🡪 Identify Concerns, Questions, or Required Changes:**

|  |
| --- |
| 1. **Risks to subjects are reasonable** **in relation to anticipated benefits**, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.
 |

**Notes:**

**This criterion is met:**

**Yes** [ ]

**No** [ ]  **🡪 Identify Concerns, Questions, or Required Changes:**

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| --- |
| 1. **Selection of subjects is equitable**
* *Take into account the purposes of the research and the setting in which the research will be conducted*
* *Ensure no one is being excluded or included without appropriate rationale*
* *Consider whether any additional safeguards are required to protect the rights and welfare of vulnerable populations, if included (e.g., pregnant women and fetuses, prisoners, children, mentally disabled persons, economically or educationally disadvantaged persons, homeless, etc.)*
 |

**Notes:**

**This criterion is met:**

**Yes** [ ]

**No** [ ]  **🡪 Identify Concerns, Questions, or Required Changes:**

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| --- |
| 1. **Informed consent will be sought and properly documented** from each prospective subject or the subject's legally authorized representative.
 |

**Notes:**

**This criterion is met:**

**Yes** [ ]

**No** [ ]  **🡪 If no, is a waiver of the process of consent or documentation of consent requested?**

**Yes** [ ]

**No** [ ]

**Identify Concerns, Questions, or Required Changes:**

|  |
| --- |
| 1. **If the research is greater than minimal risk:** the research plan makes **adequate provision for monitoring** the data collected **to ensure the safety of subjects.**
 |

**Notes:**

**This criterion is met:**

**Yes** [ ]

**No** [ ]  **🡪 Identify Concerns, Questions, or Required Changes:**

|  |
| --- |
| 1. **There are adequate provisions to protect the privacy of subjects AND to maintain the confidentiality of data**
 |

**Notes:**

**This criterion is met:**

**Yes** [ ]

**No** [ ]  **🡪 Identify Concerns, Questions, or Required Changes:**

|  |
| --- |
| **Summarize Correspondence with the Study Team Before the Meeting***If you identified any substantive issues that warranted communication with the team, please include the questions posed to the team and their responses and whether you feel the issue was addressed by the information supplied.*  |

1. **Question**:

**Study team Response**:

**Reviewer’s Assessment of Response**:

1. **Question**:

**Study team Response**:

**Reviewer’s Assessment of Response**:

1. **Question**:

**Study team Response**:

**Reviewer’s Assessment of Response**:

1. **Question**:

**Study team Response**:

**Reviewer’s Assessment of Response**:

|  |
| --- |
| **Outline Non-Substantive Issues that should be Stipulated in the IRB Letter** *If you have identified issues* ***not related to criteria for approval,*** *these should be outlined.* * *Don’t re-iterate the administrative stipulations included in the agenda; if you feel any of those are wrong, point that out here*
* *Summarize common issues (e.g. instead of pointing out every discrepancy between the online application and the full protocol, mention sections where there are inconsistencies and request reconciliation)*
* *When identifying non-substantive issues, please be prepared with a potential solution to streamline the discussion.*
 |

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| **Make Recommendations***This is a 3-part decision to be made when the board has completed the review of an action item.* |
| **Part 1: Choose one overall decision for the agenda item:** |
| Approval  | All criteria for approval are met No changes are required | [ ]  |
| Withheld Approval(pending responses to the issues raised) | All criteria for approval are met Non-substantive changes are required | [ ]  |
| Tabled\*(to address the issues raised for which responses require convened review) | Criteria for approval are **not** metSubstantive changes are required | [ ]  |

|  |  |
| --- | --- |
| **Part 2: Choose the appropriate risk level** | **Part 3: Choose the appropriate frequency for renewal** |
| Greater than Minimal Risk | * [ ]  Convened Annual Renewal Required
* [ ]  Convened Renewal Required at increased frequency (e.g., every 6 months or after a certain number of participants have been enrolled)

Rationale for increased frequency of review: Click or tap here to enter text. |
| Minimal Risk | * [ ]  No continuing review required
* [ ]  Convened annual renewal required. Rationale for elevated level of continuing review: Click or tap here to enter text.
* [ ]  Expedited annual review (category 9) required. Rationale for continuing review: Click or tap here to enter text.
 |

\*Review frequency and risk level may not be determined with a Tabled decision since the convened board must review the responses.