**Items to Consider During Convened Modification Review:**

* Does the amendment alter the risk/benefit ratio for subjects?
* Are there any product revisions (i.e. new product, dosing, administration, formulation, preparation, storage, etc.)? Discuss the changes and any impact they might have during the meeting.
* Are the requested changes evident in all appropriate study materials?
* Could the proposed changes affect an active subject’s decision to continue participation in the study?
* Was the informed consent form updated appropriately? Was an appropriate re-consent plan provided?
* Does the current modification request to enroll vulnerable populations? If so, does the study meet the criteria for enrollment of these populations?

**Does the study continue to meet the criteria for approval with the proposed changes?**

* Risks to subjects remain minimized and reasonable
* Risks remain outweighed by, or appropriately balanced by, potential benefits.
* Selection of subjects remains equitable
* Informed consent will be sought and properly documented
* The research plan makes adequate provision for monitoring data to ensure safety
* There are adequate provisions to protect subject privacy and confidentiality of data

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| **Study Background & Progress Summary**  *Please provide a short summary of the progress of the study. Please indicate if the study is open or closed to accrual & note if the modification affects the subject(s) currently enrolled at Penn.* |

**PI Name:**

**Protocol #:**

**Title:**

**Study Progress:**

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| **Summary of Changes**  ***Please provide a summary of the major changes related to the reason for convened review followed by a brief listing of the minor changes if any****.* |

**Protocol Changes:**

**Major:**

**Minor:**

**Procedures Changes:**

**Major:**

**Minor:**

**Consent Form Changes:**

**Major:**

**Minor:**

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| **Issues**  *Create a list of the issues you intend to raise during the meeting. This worksheet is designed to help you differentiate types of issues and how they should be raised.* |
| * **Issues that were identified and resolved pre-meeting**   *If you identified any issues that warranted communication with the team in advance, please include the questions posed to the team and their responses and whether you feel the issue was addressed by the information supplied. These should be mentioned first in the discussion.* |

1. **Question**:

**Response**:

**Reviewer’s Assessment of Response**:

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| * **Issues identified as substantive**   *If you have identified any issues that are* ***directly related to the criteria for approval*** *list your concerns below and raise these before any other issues you identified to allow for discussion time. This is also a good place to list*  *any questions you have for the board based on your review. These questions often lead to stipulations or*  *recommendations to improve clarity. Please also include suggestions for how these issues should be phrased to the*  *study team to ensure the IRB staff has the right idea.* |

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| * ***Issues identified as non-substantive:***   *If you have identified issues* ***not related to criteria for approval,*** *these should be outlined after the substantive issues are raised. This may include reminder notes, editorial recommendations, discrepancies between documents and the HS ERA application. Please do not reiterate administrative stipulations outlined in the agenda. If you feel any administrative stipulations are incorrect, please address that here.* |

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| **Recommendation Options**  ***This is a 3 part decision to be made when the board has completed the review of an action item.*** |

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| --- | --- | --- |
| **Part 1: Choose one overall decision for the agenda item:** | | |
| * Approval | | |
| * Withheld Approval   (pending responses to the non-substantive issues raised) | | |
| * Tabled   (to address the substantive issues raised for which responses require convened review) | | |
| **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 might not be determined with a Tabled decision since the convened board must review the responses.

**Additional Resources for Modification Reviewers**

**[Click here to review the IRB Modification Submission Requirements](https://irb.upenn.edu/how-submit-penn-irb/how-submit-modifications)**

[**Click here to access the IRB Member Toolbox**](http://www.upenn.edu/IRB/mission-institutional-review-board-irb/irb-member-toolbox)