1. **Please utilize this worksheet to guide your reviews.**
2. **Please send any comments, concerns, or questions to the IRB coordinator and IRB administrator at least 3 business days before the meeting.**
3. **If all sections are completed then you are ready to present a thorough review**

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| **Review Summary**  *To organize your thoughts, you may find it helpful to outline a summary below regarding the progress of the study during the last approval period. This might include the enrollment status, any adverse events that met IRB reporting criteria, if a vulnerable population has been enrolled, or if a DSMB recommendation was made etc. This summary does not need to be presented at the meeting. In your presentation to the board, give a brief overview of the study and then focus your presentation on any issues that may affect criteria for approval below under Items for Board Consideration.* |

**Member Reviewer Name:**

**PI:**

**IRB Protocol #:**

**Purpose:**

**Notes for the meeting:**

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| **Items for Board Consideration**  *The purpose of continuing review is to confirm the study continues to meet criteria for approval listed below. Below are questions to guide your review to confirm that criteria for approval continue to be met.*   * ***Risks to subjects remain minimized*** *(by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk; and whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.)* * ***Risks remain outweighed by, or appropriately balanced by, potential benefits.*** * ***Subject selection remains equitable.*** * ***Informed consent is being sought and appropriately documented****.* * ***When appropriate, there are adequate provisions to protect subject privacy and confidentiality of data.*** * ***When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.*** * ***When appropriate, additional safeguards are included for vulnerable populations.*** |

* 1. Review enrollment. Are there any problems with recruitment or enrollment? Consider the protocol design and relevant characteristics of the patient population.
  2. Review the summary of subject experiences.
     + 1. Does the summary suggest protocol modifications are warranted?
       2. Have there been any significant new findings that arose from the continuing review process *that may relate to participants’ willingness to continue participation*? If so, should additional information be provided to subjects (e.g., via a consent addendum, re-consent, or participant letter)?
  3. Review the summary of AEs.
     + 1. Does the summary suggest protocol or consent modifications are warranted?
       2. Is increased monitoring of the research warranted?
  4. Review the summary of deviations and study monitoring section of the CR form.

1. Does the site need more resources to continue the conduct of this study?
2. Do any of the deviations (and if applicable exception requests) suggest the potential need for an amendment?
3. Do any of the deviations not already reported to the IRB in an expedited fashion appear to require separate reporting to the IRB for a serious or continuing noncompliance\* assessment?

**Serious noncompliance** is a failure of the research staff, research support entities, University / Hospital employees or agents, and any member of the human research protection program to adhere to applicable regulations, the protocol, and/or IRB policies/determinations that: adversely affects

* + the rights and welfare of participants, including *actual* or *potential* **substantive** harm, OR
  + the scientific integrity of the study

**Continuing noncompliance** is a pattern of **repeated** ***serious*** noncompliance, including inadequate efforts to take corrective actions within a reasonable timeframe.

* 1. Review the safety monitoring information in the CR form.
  2. If a Data Safety Monitoring Board (DSMB), Data Safety Monitoring Committee (DSMC)\*\*, or other safety monitoring committee (SMC) has been established for this study, and issues reports to sites:
     1. Does the report contain any information requiring modification to the research project?
  3. Does the monitoring summary contain any other information that suggests that safety monitoring is inadequate on the part of the PI, medical monitor / medical director (whether established by the site or the Sponsor), DSMB/ DSMC/ SMC, etc.?

*\*\*NOTE: The Abramson Cancer Center DSMC activities should not be considered in these assessments as the ACC DSMC reports any significant issues directly to the IRB.*

**If yes to any of the above, type up your questions, comments, and concerns below. Email concerns to the chair (cc IRB staff) in advance of the meeting. Discuss any unresolved issues at the meeting.**

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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 between different kinds 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.* |

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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:** | | |
| * Re-Approval | | |
| * Conditional Re-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. |