**IRB Member Amendment Reviewer Checklist**

IRB Meeting Date:Click or tap here to enter text. eBridge #: Click or tap here to enter text.

Principal Investigator:Click or tap here to enter text. Reviewer: Click or tap here to enter text.

A review of the proposed Amendment must be conducted by the IRB. **Please address EACH of these points during your oral presentation of this amendment at the IRB meeting.**

1. Begin your review by stating the Project Number, the PI’s name, and the short title. Provide a brief summary of the project, including if any other sites are relying on the MCW IRB for review Click or tap here to enter text.
2. Briefly discuss the following points:
   1. Summarize the amendment and the proposed changes.

Click or tap here to enter text.

* 1. Are the changes consistent with the aims and design of the original project? (If no, should this be submitted as a sub-project?) Yes  No 
     1. If no, should this amendment be submitted as a new project?

Yes  No

* 1. Is the project adding non-English speaking subjects?
     1. Yes  No  N/A  *(project is already approved to enroll non-English speaking subjects)*
     2. If Yes, is there a plan or procedures to ensure ongoing consent, data collection & subject communication including translated documents and/or interpreter services? *(Refer to AME section 2.1 and section 12.2, section 52.1 for uploaded documents)* Yes  No  N/A
  2. Is the project adding new funding as a part of the amendment?

Yes  No

* + 1. Is the funding or support coming from one of the identified federal agencies? (DoD, EPA, DoJ, or BoP) Yes  No 
       1. If yes, please complete the [*IRB Member Form: Additional Federal Agencies Requirement Checklist*](http://www.mcw.edu/hrpp/IRBCommittees/CommitteeMemberResources.htm)and attach with your review.
    2. Is the new funding coming from a For-Profit Contract? Yes  No 
       1. If Yes, has the HRPP office completed the funding review? Yes  No   *If no, the amendment can not be approved until the funding review is completed.*
  1. Is the project funded by the DoD? Yes  No 
     1. Have the substantive changes in this amendment undergone scientific review? Yes  No  N/A  *If NO, the amendment cannot be approved at this time*
  2. Is the project funded by NIH? Yes  No 
     1. Does the information remain consistent between the grant (i.e. purpose, population, procedures) and the amended eBridge SmartForm *(see Section 11 & linked funding)*?

Yes  No  If no, *the IRB should ask the PI to clarify differences between the grant and the IRB application.*

* + 1. Does the consent form contain NIH’s certificate of confidentiality language Yes  No  *if no, request this language be added or a justification provided*
    2. For new NIH funding,did the team upload the NIH Data Sharing and Management Plan (DMP) Yes  No  N/A
    3. For new NIH funding, does the consent form contain NIH Data Sharing Language? Yes  No  N/A  *if no, request this language be added or a justification provided*
  1. Is there a change in the risk(s) and/or benefits associated with the protocol? (Increase, decrease, or no change.) Yes  No
  2. Are the risks still reasonable in relationship to anticipated benefits?

Yes  No

* 1. If applicable, have the following documents been updated: eBridge PRO SmartForm, consent form(s), questionnaires, and/or other supporting documents? *Compare the previously approved document(s) with the highlighted changes in the new document(s) (smartform changes tab in eBridge).* Yes  No  N/A 
     1. Are the changes consistent with description in the eBridge AME SmartForm? Yes  No  N/A

*If No, describe the changes which need to be made by the project team*

* 1. Indicate all requirements that must be satisfied for IRB approval:

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|  | Department of Health and Human Services (DHHS)  45 CFR 46.111 | All greater than minimal risk research submitted for review by the MCW IRB and/or receiving federal funding |
|  | Food and drug Administration (FDA) 21 CFR 56.111 | Research that involves a drug, device, biologic, in-vitro diagnostic, botanical medical food or dietary supplement that is part of the research intervention |

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| **Comments/Concerns for Discussion**  Discussion should be focused on the Risk/Benefit analysis. |
| Click or tap here to enter text. |

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| **Recommended Modifications**  Modifications must be made by the investigator before final approval can be granted. In eBridge, modifications to the new eBridge SmartForm must be entered as Reviewer Notes. |
| Click or tap here to enter text. |

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| --- | --- |
| **Recommendation** | |
| Approve as submitted | Conditionally approve pending minor modifications  \*\**These modifications must qualify for expedited review. If not, the project should be tabled.* |
| Table  Click or tap here to enter text. | Approval Denied |

Reviewer Name:Click or tap here to enter text. Date: Click or tap here to enter text.