**NIMH DSMB Amendment Memo Template**

**Tool Summary** (*Remove Tool Summary before finalizing and distributing the document)*

***Purpose:*** *This template may be used when submitting a protocol or consent document amendment to the NIMH Data and Safety Monitoring Board (DSMB).*

***Audience/User:*** *Principal Investigator and study team members submitting a protocol and/or consent amendment to the NIMH DSMB.*

***How to Use This Template***

*This template contains two types of text: instruction/explanatory and example.****Instruction/explanatory text*** *are indicated by italics and should be deleted. Footnotes to instructional text should also be deleted. This text provides information on the content that should be included.* ***Example text*** *is included to further aid in document development and should either be modified or deleted. Example text is indicated in [brackets in regular font]. Within example text, a need for insertion of specific information is notated by <angle brackets>. Example text can be incorporated as written or tailored to a particular document. If it is not appropriate to the document, however, it too should be deleted.*

*Please ensure letter is on Institutional Letter Head and signed by the study PI*

**Date:**

**To: NIMH Data and Safety Monitoring Board**

**From:** <investigator name, degree>

**Subject**: Amendment to Protocol <protocol title, date and version #>

**1. Requested Changes and Rationale:** *State purpose and provide rationale for each requested change.*

**2. Table of changes:** *add as many rows as needed to cover all amendments made*

|  |  |  |  |
| --- | --- | --- | --- |
| **Amendment:** | **Pages amended: (e.g., protocol, consent, study documents)** | **Pages amended: (e.g., protocol, consent, study documents)** | **Indicate minor or major change** |
|  |  |  |  |
|  |  |  |  |

*A track changed and clean version of the complete protocol and/or consent form(s) incorporating the requested changes is included in the submission.*

**3. Institutional Review Board (IRB) Approval:** *Please indicate if the IRB has approved this amendment. If so, please include IRB approval letter as attachment*

**4. Need to re-consent subjects:** *Please indicate if there is a need to re-consent subjects*

**5. Impact on risk/benefit ratio:** *Brief assessment if the ratio is affected due to the proposed changes*

**Attachments** *(if applicable) (i.e., IRB approval letter)*