|  |  |
| --- | --- |
| **IRB Meeting Date :** Click or tap to enter a date. | **eBridge #:** Click or tap here to enter text. |
| **Principal Investigator:** Click or tap here to enter text. | **Reviewer Name:** Click or tap here to enter text. |

The review of possible unanticipated problems or events of serious or continuing noncompliance must be conducted by the convened IRB. **Please address EACH of these points during your oral presentation of this event 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. Type of Event:

Internal event

External event

Site relying on MCW IRB

* 1. Briefly describe the event which occurred:

Click or tap here to enter text.

* 1. Was the event related to research project participation?

Yes No Describe:Click or tap here to enter text.

* 1. Was the IRB approved protocol followed?
     1. Yes No N/A    
        If No, does to the noncompliance rise to the level of

Serious noncompliance

Continuing noncompliance

Neither

* 1. Was the event described or noted in the study documents (ex. smartform, protocol, ICF, IB) as a possible risk

Yes No N/A  Describe:Click or tap here to enter text.

* 1. Was the event unexpected in terms of nature, frequency, severity, or the study population? Yes No N/A 
     1. If yes, indicate which aspects were unexpected:

Nature

Frequency

Severity

Population

Please describe further:Click or tap here to enter text.

* 1. Did the event place subjects/others at a GREATER RISK OF HARM than previously known or recognized?

Yes No Describe:Click or tap here to enter text.

* 1. Is there a change in the risk(s) and/or benefits associated with the protocol? (Increase, decrease, or no change.)

Increase to Risk  Decrease to Risk  No Change to Risk

* + 1. Are the risks still reasonable in relationship to anticipated benefits?Click or tap here to enter text.
  1. Does the PI, Sponsor or Data/Safety Monitoring Committee propose a corrective action plan?

Yes No N/A  Describe:Click or tap here to enter text.

* + 1. Is it adequate?

Yes No (If no, please request modification/additional information form the study team).

* 1. Does the PI, Sponsor or Data/Safety Monitoring Committee recommend amending the protocol?

Yes No N/A  Describe:Click or tap here to enter text.

If applicable, has an amendment been opened or submitted for IRB review?   
Yes No

* 1. Does the PI, Sponsor or Data/Safety Monitoring Committee recommend revising the consent form?

Yes No N/A  Describe:Click or tap here to enter text.

If applicable, has an amendment been opened or submitted for IRB review?   
Yes No

* 1. Is the study is federally-funded (i.e. NIH, NCI, DOD) Yes No
  2. Is this an FDA regulated study? Yes No

# **MCW IRB Definitions (to assist in making a determination):**

**Non-compliance**. Non-compliance is defined as failure to comply with any of the regulations and policies described in this document and failure to follow the determinations of the IRB. Non-compliance may be minor or sporadic or it may be serious or continuing.

**Serious non-compliance.** Serious non-compliance is defined as failure to follow any of the regulations and policies described in this document or failure to follow the determinations of the IRB and which, in the judgment of either the IRB Chair or the convened IRB, increases risks to participants, decreases potential benefits, or compromises the integrity of the human research protection program. Research being conducted without prior IRB approval is considered serious noncompliance.

**Continuing non-compliance.** Continuing non-compliance is defined as a pattern of non-compliance that, in the judgment of the IRB Chair or convened IRB, suggests a likelihood that instances of non-compliance will continue without intervention. Continuing non-compliance also includes failure to respond to a request to resolve an episode of non-compliance.

**Unanticipated problems involving risk to participants or others (UPIRSO)**:

Any incident, experience, or outcome that meets **all** of the following criteria:

1. Unanticipated (in terms of nature, severity, or frequency) given (a) the research procedures described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document, Instructions for Use/Device Manual and/or Investigator’s Brochure; and (b) the characteristics of the subject population being studied;
2. related or possibly related to participation in the research (in this guidance document, *possibly related* means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research) or test article; and
3. suggests that the research places subjects or others at a greater risk of harm (includin*g physical, psych*ological, *economic, or social harm*) than was previously known or recognized.

After reviewing the event, if needed, identify if additional actions are required from the list below:

**Potential IRB Actions**

1. Require a correction action plan from the investigator
2. Require modification of the protocol.
3. Require changes to the consent document.
4. Require current participants to re-consent to participation.
5. Notify subjects (past or current), if the information might affect their willingness to continue participation
6. Verification that participant selection is appropriate and observation of the actual informed consent by QI/QA team
7. An increase in data and safety monitoring of the research activity
8. Modify the continuing review cycle
9. Request additional Investigator and staff education
10. Request a directed audit of targeted areas of concern by QI/QA team
11. Request a status report after each participant receives intervention
12. After consulation with the HRPP Office, referral to other organizational entities (e.g. legal counsel, risk management, Institutional Official)
13. Suspend the study
14. Terminate the study approval

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

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

|  |  |
| --- | --- |
| **Recommendations** | |
| Acknowledge as submitted | Tabled to address major questions and concerns*.* |
| Acknowledge, require additional action. Recommended Action (see IRB actions above):Click or tap here to enter text. |  |
| Reviewer determination re: UPIRSO or Noncompliance  Internal Event:  Serious Noncompliance  Continuing Noncompliance  UPIRSO requiring reporting to Institutional Official and/or Federal Agencies  Not a UPIRSO  External Event:  Serious Noncompliance  Continuing Noncompliance  UPIRSO  Not a UPIRSO  Site relying on MCW IRB:  Serious Noncompliance  Continuing Noncompliance  UPIRSO  Not a UPIRSO  Risk benefit ratio:  Still acceptable  No longer acceptable  Original study approval:  Remains the same  Modifed as indicated: Click or tap here to enter text. | |

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