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| The purpose of this checklist is to provide support for the IRB Analyst, designated reviewers and convened IRB reviewing Reportable New Information (RNI) items. Including, but not limited to: reports of Serious Non-Compliance, Continuing Non-Compliance, Unanticipated Problem Involving Risks to Subjects or Others, Suspension of IRB Approval, and Termination of IRB Approval.  This checklist should be completed by an IRB Analyst and retained in the submission file. See the flow chart (pg. 3) and definitions provided below:   |  |  | | --- | --- | | **Definitions - SH Research Policy: Reportable New Information to the IRB for Previously Approved Research** | | | Non-Compliance | Failure to follow the research regulations, SH Policy or the requirements or determinations of the IRB. | | Continuing Non-Compliance | A pattern of non-compliance (serious or non-serious) that suggests a potential for future non-compliance without intervention; a repeated unwillingness to comply with applicable research standards, regulations or determinations of the IRB; or a persistent lack of knowledge of how to comply on the part of the investigator or a willful lack of commitment by the investigator and study team to protect human participants. | | Serious Non-Compliance | Non-Compliance that has, or could, reasonably be anticipated to have the potential to increase a physical, psychological, safety, or privacy risk to, or impair the rights of, local subjects. | | Unanticipated Problem (UAP) Involving Risks to Subjects or Others | Any information or event that is (1) unanticipated or unexpected in nature, severity or frequency; (2) indicates that subjects or others are at increased risk of harm than was previously known or recognized; and (3) related to the research. Harm can be physical, emotional/psychological, social, or economic, and can include privacy harms. | |
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| Protocol Title | $$ProtocolTitle$$ |
| Principal Investigator | $$piformattedname$$ |

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| 1. Preliminary Determination: (at least one must be checked)   If the information presented is not sufficient, additional information may be requested from the investigator prior to making a determination. Information should be in sufficient detail to tell the full story of the event and to describe in detail the steps that will be/have been taken to correct the error and the process to prevent future recurrence. Corrections should eliminate any risks or hazards related to the error and preventive steps should address the underlying cause/reason of the error/non-compliance | |
| Yes | Information presented in the RNI is sufficient to make a determination not requiring board review: *(If* ***Yes,*** *Analyst to proceed with expedited review)*  Non-compliance that is neither Serious nor Continuing (board review not required)  Acknowledge the reportable new information item (board review not required) |
| Yes | Information presented in the RNI is sufficient to make a possible determination of the following: *(If* ***Yes****, Analyst to place on FB meeting agenda)*  Unanticipated Problem Involving Risks to Subjects or Others  Serious Non-Compliance  Continuing Non-Compliance  Suspension of IRB Approval  Termination of IRB Approval  Other – please describe: |
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| 2 Corrective Action Plan: | |
| Yes No Undetermined | The Corrective and Preventive Action Plan (CAPA) presented adequately protects the rights, safety, and welfare of participants and/or others, and the integrity of the research data. *(If undetermined move to section 3, “Considerations for Corrective Action Plan”)* |

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| 3 Considerations for Corrective Action Plan: | | | |
|  | Modify the protocol. |  | Terminate IRB approval. |
|  | Modify the information disclosed during the consent process. |  | Suspend IRB approval. |
|  | Provide additional information to current subjects (Whenever the information may relate to the subject’s willingness to continue.) |  | Transfer subjects to another investigator. |
|  | Provide additional information to past subjects. |  | Make arrangements for clinical care outside the research. |
|  | Have current subject’s re-consent. |  | Allow continuation of some research activities under the supervision of an independent monitor. |
|  | Increase the frequency of continuing review. |  | Require adverse events or outcomes to be reported to the IRB and the sponsor  Obtain additional information. |
|  | Observe the research. |  | Require follow-up of subjects for safety reasons. |
|  | Observe the consent process. |  | If loss of confidentiality/HIPAA violation – notify Alicia Beck and Director. |
|  | Request SAFE review. |  | Obtain additional information. |
|  | Require additional training of the investigator or study staff. |  | Notify investigators at other sites. |
|  | Consider whether changes without prior IRB review and approval were consistent with ensuring the subject’s continued welfare. |  | **Other:** |
| **Summarize the Reportable New Information and Corrective Action Plan Below:** | | | |

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| **Final Determination – to be used for Expedited or Administrative Reviews**  For Administrative Reviews, only one signature is required below (Analyst signature) | |
| Non-compliance that is neither serious nor continuing  Acknowledge the reportable new information item | |
| Analyst Signature | Date |
|  |  |
| Designated Reviewer Signature | Date |
|  |  |



Undetermined