**DATA AND SAFETY MONITORING PLAN**

**Instructions:** Please complete this form if:

* Required by a sponsor

OR

* The protocol involves **non-exempt** human subjects research

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| **1. GENERAL INFORMATION**  |
| **Protocol Title:**       | **Date:**       |
|  **Principal Investigator:**       |
|  **Phone:**       | **Email:**       |
|  **Co-Investigator:**       |
| **2. DETERMINATION OF RISK** |
| **[ ]**  | The protocol is determined to be of minimal risk to subjects. (To satisfy the definition of minimal risk, the estimate of anticipated harms and discomforts of the research for the proposed study population may not be greater than an estimate of "the harms and discomforts ordinarily encountered in daily life or during the performance of routine medical and psychological examinations or tests”, i.e. the anticipated harm or discomfort associated with the research is "acceptably-low.”) Describe how you determined that the risk associated with this research is “acceptably low.” |
|       |
| **[ ]**  | The research presents **more than minimal risk of harm** to subjects. Describe the risk of harm to subjects that may potentially be associated with this research (include any potential physical, psychological, financial, legal, or other risks). |
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| **3. INDIVIDUAL OR ENTITY RESPONSIBLE FOR THE OVERSIGHT OF THE DSMP.** Check if the same as above  **[ ]**  |
|  **Responsible Person:**       |
|  **Phone:**       |  **Email:**       |
| **4. ACKNOWLEDGEMENT OF WHAT MUST BE MONITORED AND REPORTED** |
| 1. **Review of collected data to determine change in initial risk-benefit assessment (adverse events, unanticipated problems, subject withdrawals)**
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| 1. **External factors or relevant information that may impact the safety of study participants or ethics of the study such as pertinent scientific literature reports or results of related studies that may have an impact on the safety of study participants or ethical considerations related to the research study**
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| 1. **Study procedures designed to protect the privacy of the research subjects and the confidentiality of their research data**
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| [ ]  I hereby acknowledge the data and safety monitoring requirements associated with this study and agree to promptly report to the IRB any adverse or unanticipated events related to this study. I understand that I am to submit to the IRB, data and safety monitoring reports concurrent with continuing review [ ]  annually [ ]  semi-annually [ ]  monthly |
| **5. DETAILED DESCRIPTON OF PROCEDURES TO PROTECT PARTICIPANT PRIVACY AND CONFIDENTIALITY OF DATA COLLECTED.**  Describe procedures for protecting privacy and maintaining confidentiality including collection, storage and future use of data. If applicable, indicate whether codes will be used as a substitute for names and/or identifiable records and how the code list will be maintained separately from the research data. Describe in detail, specific measures that will be taken to prevent a breach of confidentiality. Describe **who** will have access to the research data, **how long** written records, tapes, or recordings will be maintained, **where** and in what manner they will be maintained and/or destroyed (the retention period for IRB records not containing protected health information is a minimum of three years; the retention period for protected health information is six years). In the event a professional association or other entity requires data be stored for a longer period of time, cite the reference; the investigator is responsible for adhering to the longer retention period. |
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