FRIENDS RESEARCH INSTITUTE, INC.
INSTITUTIONAL REVIEW BOARD
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Serious Adverse Event (SAE)/Unanticipated Problem Report Form

Name of Investigator: IRB Study #:

Title of Protocol:

Please complete and submit this form if:

1) **The IRB has determined that the study is greater than minimal risk; or**
2) **The IRB has determined that the study is minimal risk and the PI believes the SAE/unanticipated problem is possibly or definitely related to the protocol.**

A. Phase of Report

☐ Initial ☐ Follow-up ☐ Final

Date of Initial Report (w/in 48 hrs; 24 hrs for death): _____
Date of Follow-up Report: _____
Date of Final Report: _____

B. Protocol Data

1. Research involves:

   ☐ Drug
   If checked, list name of the drug _____

   ☐ Device
   If checked list the name of the device _____

   ☐ Procedure
   If checked list the name of the procedure _____

2. Number of participants to be enrolled: _____

3. Number of participants enrolled to date: _____

4. Number of SAEs/unanticipated problems to date: _____

C. Description of SAE/Unanticipated Problem

1. Date of event: _____

2. Nature of the event:

   ☐ Death or a life-threatening event
   ☐ Hospitalization or prolongation of hospitalization
   ☐ Persistent or significant disability or incapacity

☐ Birth defect or congenital malformation
☐ Represents, in the PI's judgement, other significant hazards, or potentially serious harm to research participants or others
☐ Any other event as defined in the research protocol

3. Severity of the event:

☐ Mild ☐ Moderate ☐ Severe ☐ Fatal

4. Relationship to protocol:

☐ Definitely ☐ Possibly ☐ Not Related

Note: Possibly related means that there is a reasonably possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research.

5. Location of event:

☐ Internal (Occurrence involves subjects/participants enrolled in a project approved by the FRI IRB and directed by a PI employed by FRI or one whose project is under the purview of the FRI IRB.)

☐ External (Occurrence involves subjects/participants enrolled in multi-center research projects that do not fall under the purview of the FRI IRB.)

6. Description of the event. Please provide any additional documents when necessary (e.g., death certificate, hospital reports, etc).

7. If this is a follow-up or final report, describe any new information obtained since the initial report of this event. Please provide any additional documents when necessary (e.g., death certificate, hospital reports, etc).

D. Treatment Provided to the Subject

1. Date of treatment: _____

2. Description of treatment.

E. Changes in Risk Level

1. Is the event/risk listed in the protocol and/or investigational brochure?

☐ Yes ☐ No

2. Do you think that a change in protocol is necessary to reduce risk? If yes, please submit an Application for an Amendment/Addendum and revised protocol.

☐ Yes ☐ No

3. Is the event/risk listed in the consent form?

☐ Yes ☐ No

4. Do you think that any changes in the informed consent documents are necessary to better inform and protect the rights and safety of the subjects/participants? If yes, please submit an Application for an Amendment/Addendum and revised consent form. (No new subjects/participants may be enrolled until the revised consent form is approved by the IRB.)

   ☐ Yes ☐ No

5. Do you think that the event was unexpected in terms of nature, severity, or frequency given the research procedures that are described in the research protocol and consent form? If yes, explain how.

   ☐ Yes ☐ No

6. Do you think that the event was unexpected given the characteristics of the study population? If yes, explain how.

   ☐ Yes ☐ No

7. Are subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized as a result of the event? If yes, explain how.

   ☐ Yes ☐ No

F. <u>Additional Comments</u>

_____ _____

Principal Investigator's Signature Date