**Unanticipated Problem Reporting Form**

**IRB# \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ CPA# \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Instructions:** S*ubmit this form to the IRB Office. Please contact the VANEOHS IRB office if you have any questions at (216) 791-3800 ext. 64658.*

**Reportable Event: Any event, problem, or new information that may represent an unanticipated problem involving risks to participants or others.**

* Investigators must report any reportable event to the IRB within five (5) days of receiving notice of the event, if the event requires **immediate intervention** to prevent serious harm to participants or others.
* Investigators must report any reportable event to the IRB as soon as possible but no later than ten (10) business days from the date of the event or from the date the investigator is notified of the event.
* Investigators must report any reportable events that occur within thirty (30) days of a participant’s active participation or treatment in a research study.   
    
  See the Human Research Protection Program Standard Operating Procedures Section 8 for more information concerning unanticipated problems and/or serious adverse events.

**Section 1 – General Information**

**1. Date:**

**2. Title of Study:**

**3. Principal Investigator (****PI)****and degrees****:**

**VA E-mail:**       **Alternate E-mail:**

**Phone Number:**       **Cell Phone Number:**       **Pager Number:**

**4. Research Contact/Research Coordinator and degrees:**

**VA E-mail:**       **Alternate E-mail:**

**Phone Number:**       **Cell Phone Number:**

**Section 2 – Type of Problem, Event, or New Information**

* **Unanticipated Problem:** An Unanticipated Problem results in risk to subjects or others that is not discussed in the protocol and informed consent document.
* **Protocol Violation/Deviation**: An accidental or unintentional change to the IRB approved protocol
* **Unexpected AE.** An unexpected adverse event is any adverse event and/or reaction, the specificity or severity of which is not consistent with the informed consent, current investigator brochure or product labeling. Further, it is not consistent with the risk information described in the general investigational plan or proposal.
* **Event Related to the Research**: In the opinion of the principal investigator, it was more likely than not to be caused by the research procedures or if it is more likely than not that the event affects the rights and welfare of current participants.
* **Serious Adverse Event (SAE):** A SAE is one that results in death, a life-threatening experience, inpatient hospitalization or prolongation of hospitalization, a persistent or significant disability/incapacity, or a congenital anomaly/birth defect.  
    
  **Adverse Event (AE):** An AE is defined as any untoward occurrence (physical, psychological, social or economic) in a human subject participating in research. An AE can be any unfavorable or unintended event including abnormal laboratory finding, symptom or disease associated with the research or the use of a medical investigational test article. Some adverse events are expected and can be anticipated. **DO NOT REPORT ADVERSE EVENTS THAT ARE EXPECTED AND NOT RELATED**
* **Unanticipated Adverse Device Effect**: Any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects (21 CFR 812.150(a).

5. Report:

Initial

Follow-up

6. Report Type (check all that applies).

**Adverse event which is both UNEXPECTED and RELATED**

**Information indicating a change to the risks or potential benefits of the research which is now different from what was initially presented to the IRB**

**Protocol violation/deviation**

**Breach of confidentiality or privacy involving potential risk to participants or others.**

**Change in FDA labeling or withdrawal from marketing of a drug, device, or biologic used in a research protocol**

**Change to the protocol made without prior IRB review to eliminate an apparent immediate hazard to a research participant**

**Incarceration of a participant**

**Sponsor imposed suspension for risk**

**Complaint of a participant**

**Unanticipated adverse device effect**

**Event that requires prompt reporting to the sponsor**

**Other**

**Section 3 – Description of Event, Problem, or New Information**

7. Date of event, problem, or new information:

8. Date this was identified and/or discovered:

9. Please provide a brief summary and attach as necessary supplementary information (DO NOT SUBMIT DOCUMENTS WITH IDENTIFIABLE PATIENT/SUBJECT INFORMATION):

10. If subjects or others were placed at risk or suffered any physical, social, psychological, or economic harm as a result of the event describe the plan to address these consequences.

**11. Provide a summary of the corrective action taken or will be taken to ensure that the problem is corrected and will not occur again.**

12. Is the event resolved?

Yes  No

**13. Provide the following subject information: ID No, age, gender:**

**Subject’s recovery was:  N/A  Complete  Partial  Minimal or none**

**Subject’s study involvement will be:  Continued  Discontinued  Delayed**

**Please describe any treatment provided to the subject for this event:**

**Section 4 – Principal Investigator’s (PI) Judgment**

14. As the PI determine if event was unforeseen

Yes  No

15. As the PI does this information indicate that the research procedures caused harm to participants or others or indicate that the research procedures now place participants or others at increased risk of harm?

Yes  No

16. As PI should the consent document and/or Research Plan be revised?

Yes  No

**If yes, describe the proposed changes and attach revised documents *(attach one (1) copy with additions identified with bolded text and deletions identified as strikethrough text and one (1) clean copy)*:**

17. As the PI should currently enrolled participants and/or subjects that completed study participation be notified?

No  Yes - submit a notification with this form for IRB review

**Section 5 – Reporting**

18. The event, problem, or new information has been reported to the following (check all that apply):

No reporting

Study Sponsor

Food and Drug Administration (FDA)

Federal Agency supporting the research

LSCVAMC Privacy Officer and/or Information Security Officer (for unauthorized use, loss, or disclosure of individually identifiable patient information and violations of information security requirements)

Office of Biotechnology Activities (OBA) (for projects that involve recombinant DNA or gene transfer)

Other (describe):

**Section 6 – Principal Investigator Statement of Assurance**

I have personally reviewed this report and agree with the above assessment. I understand that I cannot initiate any changes in my approved protocol before I have received approval and complied with all contingencies.

**Signature of Principal Investigator Date**

**Section 7 – Attachments**

Please attach the following:

**Latest version of the approved informed consent document and Research Plan**

**Relevant documents**

|  |  |  |
| --- | --- | --- |
| FOR IRB USE ONLY **Review Criteria for the IRB Chairperson (or designee):**  **Determine whether the event is unforeseen  Yes    No**  **Determine whether the event indicates that subjects or others are at increased risk of harm  Yes  No**  **\*If both “yes” the event is considered an unanticipated problem involving risks to subjects or others.**  After review of this event, I find:  **This event does not represent an unanticipated problem involving risks to participants or others, no further actions needed**  **Referral to IRB for review as a possible unanticipated problem involving risks to participants or others**  **Referral to IRB for potential research compliance**  **The proposed changes are reviewed and approved under** **expedited review as minor changes in previously approved research 45 CFR 46.110(b)(2)**  **Referral to convened IRB for review of proposed modifications**      **As a reviewer, are you an investigator, consultant, collaborator, or study personnel on the proposed study; do you have a financial interest in the study; or do you have any other conflict of interest with this study?  If yes, please do not perform the review and contact the IRB Office at (216) 791-3800 ext. 64658.**  **Yes** **No** | | |
| **Signature of IRB Chair or Designee**  **Name:** |  | **Date** |