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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | | | **VA Northeast Ohio Healthcare System (VANEOHS)**  **Tracking Log for Non- Reportable Events**  ***Please type this report*** | | | | | | | | | | | |  |
| Per VANEOHS IRB policy, Principal Investigators (PI) are required to report **ONLY** those problems, events, or new information that are unexpected (in terms of nature, severity, or frequency) given the research procedures that are described in the protocol-related documents (IRB-approved research protocol and informed consent documents(s)) and the characteristics of the population being studied **AND** indicates that subjects or others are at a greater risk of harm than was previously known or recognized. Those that do not meet these criteria do not require submission to the IRB Office. However, reports should be reviewed and dated by the Principal Investigator and filed with research documents. If required by the sponsor, you may notify the IRB Office of these events with this form. | | | | | | | | | | | | | | | |
| **Principal Investigator:** | | | |  | | | | | **Study Contact Name & number :** | | | |  | | |
| **IRB # and Title of Protocol:** | | | |  | | | | | | | | | | | |
| **Mfr. Control #**  **Or**  **Reference No.** | | **Report Type**  **Initial or Follow-up** | | | **Name and/or Description of Event** | | | **In the opinion of the PI:** | | | | | | | **PI MUST Initial and Date Review**  **FOR EACH SUBJECT**  *Reports received w/o PI initials/date for each subject will be returned without review.* |
| **Did the event, problem, or new information harm one or more participants or others, or place one or more participants or others at increased risk of harm?** | | **Was the event, problem, or new information unexpected (in terms of nature, severity, or frequency) given the procedures described in the protocol related documents and the characteristics of the population being studied?** | | | | **Was it more likely than not that the event was caused by the research procedures or affects the rights and welfare of current participants?** |
| **If the answers to all three questions are all yes, you must report this event within 10 days using the REPORTABLE EVENT FORM.** | | | | | | |
|  | |  | | |  | | | Yes  No | | | Yes  No | | | Yes  No |  |
|  | |  | | |  | | | Yes  No | | | Yes  No | | | Yes  No |  |
|  | |  | | |  | | | Yes  No | | | Yes  No | | | Yes  No |  |
|  | |  | | |  | | | Yes  No | | | Yes  No | | | Yes  No |  |
|  | |  | | |  | | | Yes  No | | | Yes  No | | | Yes  No |  |
|  | |  | | |  | | | Yes  No | | | Yes  No | | | Yes  No |  |
|  | |  | | |  | | | Yes  No | | | Yes  No | | | Yes  No |  |
|  | |  | | |  | | | Yes  No | | | Yes  No | | | Yes  No |  |
|  | *For IRB Office Staff Use Only* | | | | |  |  | | | |  | Stamp | | | |
|  | Receipt Acknowledged By | | | | |  | Date | | | |  |