This is an optional form that can be used to document adverse event determinations.

|  |  |
| --- | --- |
| IRB Study #:       | Title:       |
| PI:       | Unique identifier for this event:       |
| Date of event:       | Subject ID:       |

Summary of the event:

Was this event internal or external? **Click to Select an Event Type.**

Event occurred at an external site and is under the Sponsor-Investigators’ oversight? **Click to Select an Item.**

1. Was this event unanticipated in regard to the known risks of the study drug, device, or procedure, the subject’s disease or condition, or the subject’s predisposing risk-factor profile? [ ]  Yes [ ]  No
*If yes, please explain how the event is unanticipated*:
2. Was this event caused by and/or related to participation in the research?
[ ] Definitely Yes [ ] Possibly Yes [ ] Probably No [ ]  Definitely No

 *If Definitely Yes or Possibly Yes, please explain how the event may be related to the research:*

*If the answer to questions 1 and 2 are “Yes,” the event needs to be submitted within 5 business days* ***to the IRB****.*

1. Is this event an internal **death** considered unanticipated and related to study participation? [ ]  Yes [ ]  No. *If yes, please explain how and report immediately:*

*Internal deaths considered unanticipated and related or possibly related to study participation need to be verbally reported to the IRB of record and AVAHCS Research Office* ***immediately****. Refer to the AVAHCS Reportable Event Policy located on the AVAHCS Research website for more information.*

Does this event need to be submitted promptly to the IRB? [ ]  Yes [ ]  No*.*

Does this event need to be submitted to the IRB at continuing review? [ ]  Yes [ ]  No

*Following IRB of record guidelines.*

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Person completing this form Signature Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Principal Investigator Signature Date

For more information, please consult “Atlanta VAHCS Reportable Events Policy” located on the AVAHCS Research website: <https://www.atlanta.va.gov/services/research/Conducting_Human_Research.asp>