Reportable New Information

START

1. Event/Information Type: [MULTIPLE, CHECKBOXES, REQUIRED]

{/reportable-new-info/info-category}

* 1. Non-local adverse event <non-local-adverse-events>
  2. Local adverse event <local-adverse-events>
  3. Accidental or unintentional protocol deviation <protocol-violation>
  4. Unanticipated adverse device effect <unanticipated-adverse-device-effects>
  5. Protocol deviation to eliminate immediate apparent harm <change-or-deviation>
  6. Breach of confidentiality <breach-of-confidentiality>
  7. Participant complaint <complaint>
  8. Incarceration of a subject in a study not approved for the enrollment of prisoners <incarceration>
  9. Change in FDA labeling or withdrawal of drug, device, or biologic used in the research protocol <change-in-fda>
  10. Restriction, suspension or termination of the study<restriction-suspension-termination>
  11. Premature completion of the study <premature-completion>
  12. Notification of pending audit, inquiry or investigation by federal agency <notification-of-audits>
  13. Written reports from study monitor <written-report-from-monitor>
  14. Other new information <new-information>
  15. Other problem <other>

Examples of “Other New Information” that are reportable include MedWatch reports indicating that a side effect is more frequent or severe than expected, or a publication showing that an arm of a study is of no therapeutic value.

1. [IF NON-LOCAL ADVERSE EVENT (START A) ONLY] Has the sponsor determined that the event is an Unanticipated Problem Involving Risks to Subjects or Others (UPIRTSO)? [YES/NO]

If No, [CLOSE OUT FORM; GET MESSAGE]

This event/information does not meet the criteria for an Unanticipated Problem Involving Risk to Subjects or Others (UPIRTSO) and does not require immediate reporting to the IRB.

Please submit the information in summary format at Continuing Review.

If you need to update documents now, please do so using a Modification action.

BASIC DETAILS

1. Please describe the event/information that you are reporting. [TEXTBOX, REQUIRED]
2. Event/Information Date [Date, Required],
3. Event/Information Location [Drop-down, REQUIRED]
4. UAMS
5. ACH
6. Other [TEXTBOX]
7. In the opinion of the Principal Investigator, should the study consent or protocol be changed because of the event/information, or should subjects be notified of the event/information? [YES/NO]

If Yes,

1. Describe the changes/notifications that should take place. [TEXTBOX]
2. [IF UNANTICIPATED ADVERSE DEVICE EFFECT (START D) ONLY] Please provide the following information about the Adverse Device Effect that you are reporting:
   1. Was the adverse effect (or problem related to rights, safety, or welfare) serious or life-threating, or did it result in death, for the research subjects? [YES/NO, REQUIRED]

If Yes, Describe [TEXTBOX]

* 1. Was the effect, problem, or death, caused by, or associated with, the device? [YES/NO, REQUIRED]

If yes, Describe [TEXTBOX]

* 1. Was the effect, problem, or death previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application)? [YES/NO, REQUIRED]

If No, Describe [TEXTBOX]

[SKIP TO SUBMIT SECTION]

REPORT

1. In the opinion of the Principal Investigator, was the event/information **unexpected or unanticipated**? [YES/NO, REQUIRED]

Unanticipated: Unforeseeable at the time it occurred

Unexpected: The specificity, nature, severity or incidences are not accurately captured in the approved consent form

If Yes, Describe the manner in which the event was unexpected or unanticipated. [TEXTBOX]

IF NO, [LOCAL ADVERSE EVENT, OTHER NEW INFORMATION, OR OTHER PROBLEM (START B, N, or o) ONLY],

[CLOSE OUT FORM; GET MESSAGE]

This event/information does not meet the criteria for an Unanticipated Problem Involving Risk to Subjects or Others (UPIRTSO) and does not require immediate reporting to the IRB.

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1. In the opinion of the Principle Investigator, was the event/information **related to the research**? [YES/NO, REQUIRED]

Related to the research: Caused by participation in the research activity, or there is a reasonable possibility that the event may have been caused by the procedures involved in the research.

If Yes, Describe how the event relates to the research. [TEXTBOX]

IF NO, [LOCAL ADVERSE EVENT, OTHER NEW INFORMATION, OR OTHER PROBLEM (START B, n, or o) ONLY],

[CLOSE OUT FORM; GET MESSAGE]

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1. In the opinion of the Principal Investigator, did the event/information **involve new or increased risks to, or affect the rights, safety, or welfare of, subjects or others**? [YES/NO, REQUIRED]

Risks: The probability of harm or injury occurring as a result of participation in the research study.

If Yes, Describe the nature of the risks/effects. [TEXTBOX]

IF NO, [LOCAL ADVERSE EVENT, OTHER NEW INFORMATION, OR OTHER PROBLEM (START B, N, or o) ONLY)],

[CLOSE OUT FORM; GET MESSAGE]

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SUBMIT

By signing this document, I hereby attest that the information provided is complete and accurate to the best of my knowledge.

Get message that says,

Your Reportable New Information form has been submitted. The IRB Chair or Designee will review this report and determine if the event /information is an Unanticipated Problem Involving Risk to Subjects or Others (UPIRTSO), or if the event/information is an issue of potential non-compliance.

Please upload any supporting documents at this time: Revised protocols or consents; sponsor determination forms; corrective action plans; ; revised investigator brochures, package inserts, or device manuals; publications in the literature; data and safety monitoring reports; interim results or findings; audit/inquiry/investigation notifications; written monitor reports; and so on.