ARROWHEAD
REGIONAL MEDICAL CENTER

The Heart of a Healthy Community

Reporting Problems and Adverse Events

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Reporting Problems

- Any changes or issues while conducting your study must be reported to the IRB as soon as possible
- Most problems are considered either Adverse Events (AE) or Serious Adverse Events (SAE)
- If unsure on determining whether an event is an AE or SAE please refer to the following link: https://www.hhs.gov/ohrp/regulations-and-policy/guidance/reviewing-unanticipated-problems/index.html#Q2

Adverse Event Defined:

- According to HHS an Adverse Event is any unfavorable medical occurrence in a human subject including abnormal signs, symptoms, or disease that is temporarily associated with the subjects participation in the research
- This can be both psychological or physical harms
- The IRB has the right to suspend or terminate research that is being conducted if it is deemed necessary

Adverse Events

- The AE form is to inform the IRB of any occurrences that happened while conducting the study
- The Principal Investigator must acknowledge and assess the AE and sign the form
- The form must be submitted to the IRB for review within 30 days of the event

ARMC IRB ADVERSE EVENT REPORTING FORM

Protocol #:

Protocol Title:

Principal Investigator:

☐ Initial Report ☐ Follow-Up Report

Date and Location of Adverse Event: Date of Report to IRB:

Subject Identifier:

Description of Adverse Event (include any treatment provided and when):

Describe subject's prognosis:

Has this type of adverse event been reported before for any subject enrolled in the study? ☐Yes ☐No

Is this type of event likely to occur again? ☐ Yes ☐ No

In your judgement is the overall risk-benefit relationship of the research still acceptable in light of the information concerning this adverse event report? ☐ Yes ☐No

In your judgement, is a change in protocol necessary to reduce or eliminate risk? ☐ Yes ☐No

Are any changes required in the informed consent document to better inform and protect the rights and welfare of subjects? ☐Yes ☐No (if yes, you must submit an amendment)

Number of subjects to be enrolled in the study:

Number of subjects enrolled to date in this study:

Total adverse events occurring to date:

Principal Investigator Certification

Your signature here certifies that you have assess the information concerning the adverse event and that in your judgement the risks of this research are minimized to the greatest extent possible and continue to be outweighed and continue to be outweighed or balanced by the potential benefits.

Principal Investigator Signature Date

Printed Name

Serious Adverse Events Defined

- The HHS & OHRP defines a SAE that may result in any of the following:
  - Death
  - Is life threatening
  - Results in hospitalization
  - Results in persistent or significate disability
  - Results in a congenital anomaly or birth defect
  - May jeopardize the subjects health and may require surgical intervention

Serious Adverse Events

- SAE must be reported to the IRB within 24 hours of the incident occurring
- You must fill out the form (pictured here) and submit to the IRB

ARMC IRB SERIOUS ADVERSE EVENT REPORTING FORM

***Clinical Trial SAE Reporting Form may be used in lieu of this form**

Protocol #:

Protocol Title:

Principal Investigator:

☐ Initial Report ☐ Follow-Up Report

Date and Location of Serious Adverse Event:

Date of Report to IRB:

Study Sponsor (if applicable):

Subject Identifier:

Description of Serious Adverse Event:

List all drugs (investigational and otherwise) listed in the protocol (if any):

What treatment for the serious adverse event was provided to the subject (if any)?

Date of treatment for serious adverse event:

Describe subject's prognosis:

Is the study closed to enrollment? ☐ Yes ☐ No

Are subjects on study-related medication? ☐Yes ☐ No

Are subjects still on drug? ☐Yes ☐No ☐ N/A

Has this type of adverse event been reported before for any subject enrolled in the study? ☐Yes ☐No

Is this type of event likely to occur again? ☐ Yes ☐ No

In your judgement is the overall risk-benefit relationship of the research still acceptable in light of the information concerning this adverse event report? ☐ Yes ☐No

Serious Adverse Events Cont'd

- **The Principal Investigator must sign the form acknowledging the SAE**
- **SAE will immediately be reviewed by the IRB and in some circumstances may require an impromptu meeting of the members**

In your judgement, is a change in protocol necessary to reduce or eliminate risk? ☐ Yes ☐No

Are any changes required in the informed consent document to better inform and protect the rights and welfare of subjects? ☐Yes ☐No (if yes, you must submit an amendment)

Number of subjects to be enrolled in the study:

Number of subjects enrolled to date in this study:

Total serious adverse events occurring to date:

Total serious adverse events reported by study subjects enrolled at ARMC site:

Is there any additional information you would like to provide to the IRB?

Principal Investigator Certification

Your signature here certifies that you have assess the information concerning the adverse event and that in your judgement the risks of this research are minimized to the greatest extent possible and continue to be outweighed and continue to be outweighed or balanced by the potential benefits.

_____

Principal Investigator Signature Date

_____

Printed Name