Idaho State Univeristy
Human Subjects Committee
Mail Stop 8130

Submit by Email | Print Form

Adverse Event Report

All incidents of injury or other adverse effects by subjects in research must be reported to the HSC. This report should be submitted as soon as possible, but **NO LATER THAN 5 WORKING DAYS** after the first awareness of the problem. The investigator should provide his/her opinion and support for any proposed changes in the protocol and/or consent form or procedure.

Date of Report | Date of Event | Date PI learned of event

Protocol Information

Principal Investigator

Title of Project

HSC # | Date Originally Approved

Is this a multi-center research project ? | If Yes, give home IRB and phone /address

Did the adverse event or incident involve the ISU arm of the multi-center research?

Does the proposal involve an FDA approved IND or IDE? | Provide the IND or IDE Number

Provide the name of the drug or device

Adverse Event Information

Did the adverse event and/or involve the drug or device?

Did the adverse event and/or incident involve a research procedure?

Was the drug/device/procedure intended to directly benefit the subject?

Was the effect described in the IND or IDE information? | Has the home IRB been informed of the adverse event?

Has the off-campus site director been informed of the adverse event?

Comments:

Was the effect listed in the risks section of the protocol?

Was the effect listed in the informed consent document?

How many subjects are to be enrolled in this research project?

How many subjects have been enrolled to date?

How many adverse events reports have been filed with the HSC on this project?

Date of Event | The adverse event was:

The adverse event was:

Description of Adverse Event

Provide a brief description of the adverse event, including the subject's demographic information.

Treatment Provided to the Research Subject

Date of Treatment

The subject's recovery was:

Describe the treatment that was provided to the subject.

Change Necessitated by Adverse Event

Is a change in the protocol necessary to reduce or eliminate the possibility of a reoccurrence of this event in other subjects:

Please provide a rationale for not changing the protocol.

Please provide a rationale for not changing the consent document or process.

Changes to Protocol Necessitated by Adverse Event

Are changes required in the informed consent process or document?

Is it necessary to re-consent subjects who have not completed all the research procedures?

If YES, explain how the re-consent process will be accomplished.

If NO, provide a rationale for not re-consenting subjects.

Please provide any additional information you feel would be helpful to the HSC in assessing this adverse event.

HSC Initials _____

Date _____

Full Board _____