

## - INSTRUCTIONS -

### Local Report for Serious & Non-Serious Adverse Events Report Form

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**How to Report:** This form captures all of the required elements for an effective review of local adverse events. The form data fields automatically expand to allow many lines of text. Use the fields for all comments – even if this expands the form to three or more pages, as the Committee prefers to minimize the number of attachments.

The initial report must be submitted by the deadlines in the policy even if it cannot be determined whether an event is related, it should be reported as “possibly related.” In this case, check “Initial Report” and indicate that a “Complete Report will Follow” in Question #5 of the form. The “Follow-up Report” should be submitted as soon as additional information is available.

The requirements for completing each section of the Local Report for Serious & Non-Serious Adverse Events form are described below.

#### Header Information:

**CHRMS# or CHRBS#:** Indicate the appropriate committee and the unique IRB-assigned number for the study.

**Principal Investigator:** The name of the local Principal Investigator.

**Protocol Title:** The protocol title should be the same as the original application title.

#### Question 1 – Is this a local Adverse Event?

- A local adverse event is a negative side effect that occurred to a subject enrolled at a UVM, FAHC, or other research site under the jurisdiction of the UVM IRB.
- If yes, continue to question 2.

#### Question 2 – Is the adverse event UNEXPECTED?

- An event **does not meet the criteria** of unexpected if it is 1) included in the current protocol, drug/device brochure or the informed consent or 2) due to the subject’s underlying disease or predisposing risk factors.
- If yes, continue to question 3.

### **Question 3 – Is the event RELATED to the therapy or procedures associated with this protocol?**

- An adverse event is considered to be **RELATED** if there is a reasonable possibility that the event may have been caused by the protocol or study interventions.
- If it cannot be determined whether an event is related, it should be reported as “possibly related.”
- If yes, indicate the degree of relation.

### **Question 4 – If Questions 1 – 3 are ALL “YES” proceed to question 5. If not, please do not forward to the Committee, as the event is not reportable as a Local Adverse Event.**

- Only report adverse events that are 1) local, 2) unexpected, and 3) at a minimum possibly related to the protocol on this form.
- Refer to local reporting policies to determine if other safety information needs to be submitted and if so which form(s) to complete.
- Contact IRB staff regarding questions on reporting, if necessary.

### **Question 5 – Adverse Event Details**

**A. Date of Event:** Provide the date the adverse event occurred. This is not the date that you became aware of the adverse event.

#### **Examples:**

- If the event is an abnormal blood level, record the date of the test.
- If the event was not associated with a definable date (i.e., “subject felt chest pain”) but required hospitalization, record the date of admission into the hospital.
- In the event of death, report the date of death.
- For multiple events, record the date of the primary event, or most serious (as determined by the PI). You must further detail the dates of the other concurrent events in question 5.c.

**Initial Report vs. Follow-up Report:** The initial report must be submitted by the deadlines in the policy even if it cannot be determined whether an event is related, it should be reported as “possibly related.” In this case, check “Initial Report” and indicate that a “Complete Report will Follow” in Question #5 of the form. The “Follow-up Report” should be submitted as soon as additional information is available.

- Please contact the IRB office if there is any ambiguity in an event, however as a general rule, if you are even questioning to report an event, err on the side of caution and report to the Committee.
- The “Follow-up Report” section allows for **(1)** the submission of additional information that was missing from the initial report and **(2)** allows changes to be made to the status of a previously reported local adverse event.

**EXAMPLES of (1):**

- An autopsy is pending at the time of initial submission.
- A final diagnosis is pending at the time of the initial submission.
- The subject remains in the hospital and has yet to be discharged.

**EXAMPLES of (2):**

- Additional information or a new diagnosis indicates that the initial report was inaccurate.
- Changes in attribution (“Possibly Related”; “Definitely Related”; or determined to be “Not Related”) or changes in level of seriousness.

**B. Describe Event:**

Mark one of the following options:

- **Fatal:** Check this box if the subject died  
**Only report local deaths that are unexpected AND related to the protocol.**
- **Serious:** An adverse event is serious if it meets one of the following criteria:
  - 1) life threatening (places the subject at immediate risk of death from the event as it occurred);
  - 2) inpatient hospitalization;
  - 3) prolongation of existing hospitalization;
  - 4) persistent or significant disability/incapacity;
  - 5) congenital anomaly/birth defect; or
  - 6) based upon appropriate medical judgment, may jeopardize the subject’s health and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition.
- **Not Serious:** Check this box if the adverse event does not meet the definition of 1) fatal and 2) serious.

**C. Provide a brief summary describing the circumstances of the event.**

A summary of the adverse event is required. The text box for this section will automatically expand to accommodate any length of text. Rather than use an attached page, please keep the summary within the textbox, even if it means expanding the form to three or more pages. The summary should include:

- A description of the timing of study treatment, dosing, or intervention (with start and stop dates of research interventions, if applicable); include reference to the participant’s number and/or initials.
- A description of the adverse event.
- A description of the outcome or current status of the participant.

**Example:**

- "Participant #ADH-0002 was in the clinic on May 16, 2007 for his final interview. He had been actively undergoing treatment since 03/15/05.
- The participant stopped treatment on 5/8/07 due to shortness of breath, chest pains and subsequent admission into FAHC.
- At this time he remains in the hospital, final diagnosis to be determined. Final report to follow pending receipt of final discharge summary."

**D. Provide any relevant history (if applicable attach discharge summary, lab values, etc.)**

Completion of this area will assist reviewers in their determination of relatedness to the study.

**E. Was the protocol discontinued for this subject?**

For the subject on whom you are reporting, was the protocol permanently discontinued? For temporary suspensions, or for subjects who will definitely resume treatment or intervention, check "No".

**Question 6 – Other Similar Events**

**A. Have there been similar events reported here?**

- Check "Yes" if similar events have occurred with locally enrolled subjects.
- Check "No" if this specific adverse event has not occurred in the locally enrolled subject population in the past on the same protocol.

**Are you aware of any similar events reported elsewhere?**

- Check "Yes" or "No" as appropriate.

**If "Yes" to either, provide a list of events.**

- A summary of all of the local or multi-center/non-local adverse events that are similar to the adverse event in question is required if you selected "Yes" to either of the #6 questions.
- The summary for local subjects should include:
  - A description of the timing of study treatment, dosing, or intervention (with start and stop dates of research interventions, if applicable); include reference to the participant's number and/or initials.
  - A description of the adverse event.
  - A description of the outcome or current status of the participant.
- For non-local subjects, provide a list of events.

## Question 7 – How Does This Event Affect Human Subjects, the Protocol, and the Consent Form?

This section requests specific information for internal assessment of the adverse event being reported.

### A. Is the study open to accrual?

We need to establish at the time of the submission, if this new safety information could potentially affect subjects who are being screened/enrolled into the study and if the informed consent and/or the protocol would need to be amended.

- Check “Yes” if the study remains open to accrual (i.e. you are still enrolling subjects into the study)
- Check “No” if the study is closed to accrual

### B. Do you have subjects receiving interventions or treatments now?

- We need to establish at the time of the submission, if this event could potentially affect any local subjects.
- Check “Yes” if there are local subjects currently receiving treatment/interventions or check “No” if none or not applicable.

### C. Should the consent form or any portion of the protocol be revised as a result of this event?

- If **yes**, submit with this report a REQUEST FOR MODIFICATION/AMENDMENT TO APPROVED PROTOCOL form and include a copy of the summary of protocol changes and/or consent with changes highlighted and a consent without the highlighting for IRB approval stamp.
- If **no**, provide rationale in the space provided.

### D. Will currently enrolled participants be notified of this event? Check “Yes” if, in the opinion of the PI, it is necessary for currently enrolled subjects (either those in active treatment, follow-up, off-treatment, etc.) to be notified of this adverse event.

- If yes, describe the proposed method of notification, to include the expected timeframe and which subjects (those in active treatment, follow-up, off-treatment, or all enrolled subjects) will be notified.
- **All written material requires IRB review and approval prior to being utilized.** (We strongly recommend use of a consent form addendum. See *our forms page for consent addendum template.*)
- **If no, why not?**  
Provide justification as to why you do not think it necessary to notify subjects of this event.

## Question 8 - Other Reporting

**A. Has a FAHC SAFE report been filed?**

Check yes or no. See FAHC policy on reporting events occurring at FAHC.

**B. Has the Sponsor been notified?**

Check yes or no. Notification can range from completion of case report forms, email, or phone.

**C. Has a Medwatch Form been filed with FDA?**

Check yes or no. If yes, attach a copy of the submission.

**D. Is this a General Clinical Research Center or Vermont Cancer Center Study?**

Indicate if the protocol has also been reviewed by either the General Clinical Research Center (GCRC) or Vermont Cancer Center (VCC). If "Yes", send copies of the report to the appropriate center(s).

**E. Is this a Gene Therapy Protocol?**

If yes, immediately send a copy of the report to the Institutional Biosafety Committee, Office of Human Research Protection (if applicable), NIH/OBA, and FDA, followed by the submission of a full written report filed with each group.

**F. Is any other institutional reporting required?**

If yes, describe.

## **Question 9 - Signature**

The principal investigator (PI) must review, sign, and date the form. By signing the form, the PI agrees to the following statement, "***By signing below, the Principal Investigator assures the information contained on this form is true and accurate***".