



*The University of Vermont*

Committees on Human Research

Serving the University of Vermont and  
Fletcher Allen Health Care

Date: July 1, 2009

To: Whom It May Concern

From: University of Vermont Committees on Human Research

RE: UVM IRB Policy on Reporting Adverse Events and Unanticipated Problems  
Involving Risks to Subjects or Others

Federal regulations require Institutional Review Boards' (IRB) to establish written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, and applicable regulatory agencies, of any unanticipated problems or adverse events involving risks to subjects or others. The full policy can be found in the UVM IRB Research Manual located on our website.

The following attachment is an excerpt from the policy which provides the categories of safety information that are reportable to the IRB.

Please note that it is the Committee's policy not to provide verification of receipt of safety submissions. In addition, any safety submissions, noted in the following attachment, that do not meet the IRB's reporting requirement will be returned to the researcher without review.

**RESEARCH PROTECTIONS OFFICE**

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## Unanticipated problems or safety information that requires local reporting to the IRB

1. **LOCAL ADVERSE EVENTS** whether serious or not serious, that are unexpected **AND** possibly, probably, or definitely related to study participation.
  - A. A **LOCAL ADVERSE EVENT** is a negative side effect resulting from the study intervention that occurred to a subject enrolled at UVM, FAHC, or other research site under the jurisdiction of the UVM IRB.
  - B. **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.
  - C. **RELATED:** 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. A related event has a strong temporal relationship to the drug, device or intervention, and an alternative etiology is unlikely. If it cannot be determined whether an event is related, it should be reported as "possibly related."

Local adverse events should be reported to the IRB utilizing the "LOCAL REPORT FOR SERIOUS AND NON-SERIOUS ADVERSE EVENTS" form.

2. **OTHER NEW SAFETY INFORMATION** that may impact human subject safety. For example:
  - A. Revised Investigator Drug/Device Brochures (IDB);
  - B. Toxicity Reports/NCI Action Letters;
  - C. Data and Safety Monitoring Reports/Progress Reports;
  - D. Literature Reviews; or
  - E. other safety information that may impact human subject welfare.

New Safety information should be reported to the IRB utilizing the "NEW SAFETY INFORMATION" form.

### 3. PROTOCOL DEVIATIONS

Those protocol deviations that involve harm or **have the potential** to impact the health or welfare of the subject(s) or others must be reported in writing to the IRB by utilizing the "REPORT OF PROTOCOL-RELATED PROBLEMS & DEVIATIONS" form. ***Deviations not affecting risk to subjects or others should be summarized and reported at time of continuing review.***

4. **OTHER UNANTICIPATED PROBLEMS** that are 1) unexpected, 2) related, **AND** 3) involve harm or pose a **potential** for harm to participants or others.

Unanticipated problems meeting the above criteria are to be reported to the IRB utilizing the "REPORT OF PROTOCOL-RELATED PROBLEMS & DEVIATIONS" form.

### NOTE REGARDING IND SAFETY REPORTS

Individual IND Safety Reports do not necessarily meet the reportable criteria and are recognized by OHRP and the FDA to not yield information that is useful to IRBs. The reports often lack context and detail, are often incomplete and unanalyzed, and as such, inhibit an IRB's ability to assure the protection of human subjects. **Therefore, IND safety reports do not require submission to the IRB.**

If an IND report triggers a revision to the protocol or consent, a copy of the IND safety report must accompany the amendment form as supporting documentation.