

## Where? cont

If the sponsor requires prompt reporting of IND Safety Reports that do not, in the opinion of the local investigator, meet the IRB reporting requirements, documentation of IRB submission may be obtained by using the Tracking Log for Non-Reportable Events.

The tracking log for Non-Reportable Events can be found on the IRB web site, [www.etsu.edu/irb](http://www.etsu.edu/irb).

Events reported on the tracking log that do not meet the IRB requirements for prompt reporting and reviewing will be acknowledged by the IRB Chair, but not reviewed by the convened IRB.

## Why?

Federal regulations require the organization to ensure the prompt reporting of any unanticipated problems involving risks to subjects or others to the IRB, regulatory agencies and Institutional Officials.

**For more information about unanticipated problems involving risks to participants or others, see IRB Policies and Procedures on our web site ([www.etsu.edu/irb](http://www.etsu.edu/irb)). Contact the IRB at 439-6053 with any questions.**

## Institutional Review Board

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# East Tennessee State University

Human Research Protection Program

ETSU and ETSU/VA

Institutional Review Board



**ETSU**



**Reporting Unanticipated  
Problems Involving Risks  
to Subjects or Others:  
(UPIRTSO)**

**What Investigators Need to  
Know**

**Office for the Protection  
of Human Research  
Subjects**

Phone: (423) 439-6053  
Fax: (423)439-6060  
Website: [www.etsu.edu/irb](http://www.etsu.edu/irb)

PO Box 70565  
Johnson City, TN 37614

## Unanticipated Problems Involving Risks to Participants or Others

### The Five W's

#### Who?

The ETSU IRB and ETSU/VA IRB require investigators to report any unanticipated problem or event that involves risk to subjects or others to the IRB within 10 working days.\* **See VA section for exception**

#### What?

Unanticipated problems or events are those that are NOT already described as potential risks in the consent form, NOT listed in the Investigator Brochure, or NOT part of an underlying disease.

Unanticipated problems or events involving risks to subjects or others includes those events that:

1. are not expected given the nature of the research procedures and the subject population being studied; and
2. suggest that the research places subjects or others at a greater risk of harm or discomfort related to the research than was previously known or recognized.

#### What

Investigators must promptly report:

- a. any event, including on-site and off-site adverse events, injuries, side effects, deaths, or other problems, which in the opinion of the local PI, was unanticipated, involved risk to participants or others, and was possibly, probably or definitely related to the research.

#### What Cont'd...

- b. Any serious accidental or unintentional change to the IRB approved protocol that involves risks or has the potential to recur.
  - c. Any deviation from the protocol taken without IRB approval to eliminate apparent immediate hazard to a research participant.
  - d. Any publication in the literature, safety monitoring report, (including Data and Safety Monitoring Reports), interim result, or other finding that indicates an unexpected change to the risk/benefit ratio of the research.
  - e. Any breach in confidentiality that may involve risk to the participant or others.
  - f. Any complaint of a participant that indicates an unanticipated risk or that cannot be resolved by the research staff.
  - g. Any local death, whether anticipated or not.
  - h. Incarceration of a participant.
  - i. Any other possibly related event which in the opinion of the investigator constitutes an unanticipated risk.
- Follow-up reports of an off-site event may be submitted on a tracking log without an accompanying Form 109 if the following are true:
1. the initial report of the event was submitted as a UPIRTSO on a Form 109
  2. the local PI has determined that the follow-up information does not contribute meaningful new information

#### \* VA Reporting of Loss or Theft of VA research data/information

The loss or theft of VA research data/information or portable media such as laptops or personal computers must be immediately reported (as soon as it is discovered that there has been a loss) as follows:

- Report the loss to security/ police officers

**IMMEDIATELY.** If within a VA health care facility, notify the VA police. If the loss or theft occurs while on travel or at another institution, notify the security police officers at the institution (such as hotel security, university security, etc.) as well as the police in the jurisdiction where the event occurred.

- Obtain the case number and the name and badge number of the investigating officer. If possible, a copy of the case report should be obtained.
- Report the incident IMMEDIATELY to:
  1. your immediate supervisor
  2. VA Privacy Officer at your facility
  3. VA Information Security Officer at your facility
  4. ACOS at your facility

#### When Cont'd...

Any problem or event that meets criteria a-i must be reported to the IRB (and VA R&D if applicable) within 10 working days.

**Note:** VA reporting requirements require immediate reporting of the loss or theft of VA research data/information or portable media such as laptops or personal computers— See VA Reporting of Loss or Theft of VA research data/information section.

All problems or events that do not meet criteria a-i must be reported to the IRB in summary form at the time of the next continuing review.

#### Where?

All problems or events that meet these criteria must be reported to the IRB on a Form 109 Unanticipated Problem Form can be found on the IRB web site, [www.etsu.edu/irb](http://www.etsu.edu/irb).

At continuing review, report events or problems that do not meet these criteria on a spreadsheet or tracking log.