



IRB Newsletter:

Review of Policy and Procedure Changes June 2009

NEW UPIRTSO Policy

Be sure to use the revised form 109 when submitting!

Policy revisions were based on recent new rules issued by the VA (for VA investigators) and on recent guidance from OHRP.

Here's the Highlights (see [policy 18](#) for all the details)

New definitions

Addition of events requiring prompt reporting

New VA considerations and reporting requirements

New requirement for modification request to be submitted with form 109– see Revised form 109

New Definitions include:

Unanticipated Problem Involving Risks to Subjects or Others (UPIRTSO): Includes those events that (1) are not expected given the nature of the research procedures and the subject population

being studied (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 and (3) are related or possibly related to the research.

Possibly related: there is a **reasonable possibility** that the incident, experience, or outcome may have been caused by the procedures involved in the research

Unexpected: unexpected in terms of nature, severity or frequency given the research procedures that are described in the protocol-related documents, such as

the IRB-approved research protocol and informed consent document and given the characteristics of the subject population being studied

See Policy 18 for definitions and explanations of serious adverse event and unexpected adverse event.

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Addition of Events Requiring Prompt Reporting

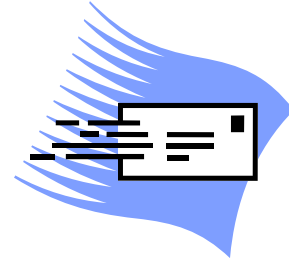


The following events have been added to the list that requires prompt reporting:

- interruptions of subject enrollment or other research activities due to concerns about the safety, rights, or welfare of human research subjects, research staff, or others.
- Any work-related injury

to personnel involved in human research, or any research-related injury to any other person, requiring more than minor medical intervention or that leads to serious complication or death.

- Any Data Monitoring Committee (DMC) report or any sponsor analysis describing a safety problem



VA Investigators Only

New VA rules change timeline and reporting requirements

New VA reporting requirements require Investigators, VA Research Compliance Officers, and other members of the VA research community to report all problems involving, or suggest-

ing, risks to subjects or others in VA Research to the Associate Chief of Staff for Research (ACOS for R) and the ETSU/VA IRB as soon as possible but no later than **five** business days after becoming aware of the problem. Additionally, for VA studies, members of the re-

search community must report possible non-compliance with VA or other Federal requirements related to human research or IRB requirements or determinations to both the Associate Chief of Staff for Research (ACOS for R) and the IRB (within 5 working-days).

VA Investigators Only

New VA rules add events requiring prompt reporting

Addition of these events requiring prompt reporting:

- VA National Pharmacy Benefits Management (PBM) Bulletins or Com-

munications (sometimes referred to as PBM Safety Alerts) relevant to a VA research study

- Any local Serious Adverse Event (see definition in Policy 18)

- Any problem that involves or suggests risks to VA research subjects or anyone else in VA research.

VA Investigators Only (Internal Adverse Events)

Per VA Rules, IRB Policy 18 was amended to include the following responsibilities for VA investigators:

Upon becoming aware of an internal adverse event, VA PIs are required to promptly assess the event and make 2 determinations.

1. Is the event a local SAE?
(see definition in Policy 18)

If the event is a local SAE, the PI must report the event to the ACOS for R and the ETSU/VA IRB using form 109 as soon as possible, but no later than 5 business days after the event has become known to the investigator.

2. If the event is not an SAE, the PI must evaluate each event by the following three criteria in order to determine whether the event is a UPIRTSO.

1. Is the adverse event unexpected?
2. Is the adverse event related or possibly related to participation in the re-search?
3. Does the adverse event suggest that the research places subjects or others at a greater risk of harm than was previously known or recognized?

VA Investigators Only (Internal Adverse Events) Continued

If the answer to the three questions is “yes”, then the event is a UPIRTSO and must be submitted to the IRB within 5 business days using the Form 109 and a modification request. The modification request must outline the

necessary revisions to the IRB approved protocol, consent document or other associated documents to incorporate the event’s impact on the risk-potential benefit profile of the study. If all three questions are not answered “yes”, then the event does not meet the definition of a UPIRTSO. The event is

not required to be reported to the IRB within 5 days but is reportable to the IRB in summary format at the time of continuing review. Regardless of the determination, PIs also are responsible for ensuring that the adverse event is reported to the monitoring entity if required under the monitoring provisions described in the IRB-approved protocol or by institutional policy.

VA Investigators Only (External Adverse Events)

When PIs receive a report of an external adverse event, PIs are required to promptly assess the event and determine whether the event is a UPIRTSO. Only external adverse events that are

identified as meeting the three criteria above must be reported promptly to the IRB as UPIRTSOs. If all three questions are not answered “yes”, then the event does not meet the defini-

tion of a UPIRTSO. The event is not required to be reported to the IRB within 5 days but is reportable to the IRB in summary format at the time of continuing review.

VA Investigators Only (External Adverse Events) continued

If all three questions are answered “yes”, then the PI must within 5 business days submit BOTH a form 109 and a modification request. The modification request must outline the necessary revisions to the IRB approved protocol, consent document or other associated documents to incorporate the event's impact on the risk-potential benefit profile of the study.

Reports of off-site events occur-

ring in studies that are completed and closed at the local site should be reported if the event meets the IRB definition as detailed above AND the local PI judges that this event may affect risk to participants who have completed the study.

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:

- the initial report of the event was submitted as a UPIRTSO on a Form 109
- And the local PI has determined that the follow-up information does not contribute meaningful new information

All problems/events that do not meet these criteria should be reported to the IRB in summary form (table or spreadsheet) at the time of continuing review.

VA Investigators Only—New Additional Definition of Serious Non-Compliance

New VA rules add definitions regarding non-compliance

For VA studies an additional definition applies when the IRB is determining whether non-compliance is serious: Failure to adhere to the laws, regulations

or policies governing VA research that 1) results in substantive harm or damage (or risk of substantive harm or damage) to the safety, rights, or welfare of human subjects, research staff, or others; or

2) substantively compromises the integrity or effectiveness of research protections, either systematically or relative to a particular protocol or project is serious non-compliance.

VA Investigators Only—New Definition of Continuing Non-Compliance

For VA studies, an additional definition applies when determining whether non-compliance is continuing” Continuing non-compliance is persistent or repeated failure, either in the past or extending into the present, to

satisfy VA or other Federal research requirements .



Questions about these new policies?

Contact the IRB Office at 439-6054.