Reporting Adverse Events in Research to ORO

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What is a Handbook?

Handbooks are part of the VA directives management system that contain mandated procedures for implementing policy

PURPOSE OF HANDBOOK

Sets out the requirements for reporting certain adverse events in research to ORO

NOTE: Handbook does NOT replace or change any of the applicable adverse event reporting requirements for VA, other agencies (federal or state) and/or commercial sponsors

Goals of the new reporting requirements

- Facilitate ORO's oversight of adverse events in VA research
- Specify
  - Which adverse events to report to ORO
  - Details to be reported
  - Timeline for reporting
- Collect information to provide better oversight
- Assist IRBs in taking appropriate action

What do the VA regulations on research require with respect to reporting adverse events?

38 CFR 16.103(b) …Assurances applicable to federally supported or conducted research shall at a minimum include:

(5) Written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, and the department or agency head of (i) any unanticipated problems involving risks to subjects or others….

Application of the regulation to the operation of an institution's HRPP and IRB

There should be detailed instructions on how to report and manage adverse events in SOPs that are also consistent with all relevant regulations and VHA policies, including National Patient Safety Improvement Handbook (1050.1)

What are the contents of this new Handbook?

New, more narrowly defined requirements for reporting research adverse events to ORO.

IMPORTANT: these requirements are ONLY for reporting adverse events to ORO and do not relate to any other reporting requirements

NEW – each VHA facility must report to the appropriate ORO Regional Office (RO) all AEs (or imminent threats of) in research that meet specific criteria

- new definitions specific to Handbook

Definitions specific to new Handbook

Adverse Event in Research (AE) –

- any untoward occurrence (physical, psychological, social or economic) in a human subject participating in research.
- any unfavorable or unintended event including abnormal laboratory finding, symptom, disease, or death associated with the research or the use of a medical test article.
- may occur even in the absence of any error or protocol deviation, and does not necessarily have to be caused by any identifiable aspect of the research.

Definitions specific to new Handbook

Imminent Threat of an AE in Research –

Any situation in which an AE in research has not yet occurred but is very likely to occur without preventative measures

- determination of imminent threat can be made by an IRB, research or clinical team member

Definitions specific to new Handbook

Substantive Action – Action taken by an IRB

1] That materially alters

- substance and meaning of a protocol
- informed consent form or process
- investigator status, including (but not limited to) restriction, suspension or termination of a study or investigator participation

2] To prevent future occurrence(s) of the adverse event

Definitions specific to new Handbook

Unexpected Death –

Death of a research subject in a trial in which a high risk of death is not projected, as indicated by the written protocol, informed consent form, and/or sponsor brochure

NOTE: Does not include death

- from terminal condition unless clearly hastened by research intervention
- clearly not associated with the research

New Handbook reporting requirements

Each VHA facility must report to appropriate ORO Regional Office all AEs (or imminent threats of) in research *conducted on site* that result in

1] IRB taking substantive action(s), as defined in this Handbook

- written report of (imminent threat of) AE in research and IRB actions within 10 working days

2] unexpected death of a research subject, regardless of IRB action

- report no later than 2 working days after IRB informed of death

Requirements for written report

(1) Separate report for each AE (or imminent threat of) in research prepared by institutional official (VHA facility Director) or designee
(2) Institutional Official/designee initials report and facilitates submission to ORO RO Director (using express mail and e-mail or fax)
(3) Copy of IRB minutes from meeting(s) in which AE and subsequent action(s) were discussed, ratified, or summarized accompanies report, or follows within 4 weeks if not immediately available

POINTS TO REMEMBER

- Definitions of what to report specific to this Handbook (limited to most severe AEs)
- Reporting limited to events that meet specific criteria also specific to this Handbook
- Report made to appropriate ORO Regional Office
- Applies ONLY to reports made to ORO (does NOT affect other reporting responsibilities)
- Talk will be posted on ORO website

http://www1.va.gov/oro/