Reportable Events

Reporting requirements for:

- Noncompliance
- Unanticipated Problems Involving Risk to Subjects or Others (UPIRTSO)
- Deaths
- Information Security and Privacy Incidents Involving VA Research

03/23/2023

Objectives

- **What** has to be reported
- **To whom** it is reported
- Reporting **timeframe**
- **How** to report
- Resources

Presentation Summary of VA's Reporting Requirements

This presentation summarizes VA's reporting requirements – sponsored or funded studies may have different reporting requirements. Ensure that you meet reporting requirements for all applicable entities.

Some important terms

Non-Exempt research: research involving human participants and/or their identifiable private information which is under the oversight of an IRB.

Exempt research: research involving human participants and/or their identifiable private information which is NOT under the oversight of an IRB. In VA, most Exempt research is instead under the oversight of the R&D Committee.

Related to participation in the research: a logical sequence of cause and effect shows that the study procedures were the reason for the incident, experience, or outcome.

Unexpected (or Unanticipated): an incident, experience, or outcome that is new or greater than previously known in terms of nature, severity, or frequency, given the procedures described in protocol-related documents and the characteristics of the study population.

Serious Adverse Event in Human Subjects Research: an untoward occurrence, whether or not considered related to a subject's participation in research, that results in death, a life-threatening experience, inpatient hospitalization, prolongation of hospitalization, persistent or significant disability or incapacity, congenital anomaly or birth defect, or that requires medical, surgical, behavioral, social or other intervention to prevent such an outcome

What has to be reported: Noncompliance

"Noncompliance is any failure to adhere to applicable requirements for overseeing, reviewing, approving, or conducting VA research set forth in law, regulation, policy, or study agreements (such as reliance agreements, memoranda of understanding, data use agreements), including any failure to conduct research in accordance with a VA study protocol approved by a research review committee"

VHA Directive 1058.01

When: report apparent noncompliance *within 5 business days* of identifying apparent noncompliance

To Whom:

Non-exempt research (i.e., research under the oversight of an IRB): to the IRB of record

- Minneapolis VA IRB
- Advarra
- WCG IRB
- National Cancer Institute Central IRB
- NIH All of Us IRB
- VA Central IRB

Exempt research (i.e., research which has received an Exempt determination): to the research review committee overseeing the study. Most commonly this is the MVAHCS R&D Committee (RDC).

What has to be reported: UPIRTSO

"An unanticipated problem involving risks to subjects or others (UPIRTSO) in human subjects research is an incident, experience or outcome that is: unexpected; related or possibly related to participation in the research; and indicative of the research placing subjects or others at substantively greater risk of harm (including physical, psychological, economic or social harm) than was previously known or recognized."

When: report an apparent UPIRTSO within *5 business days* of identification

To Whom:

Non-exempt research (i.e., research under the oversight of an IRB): to the IRB of record

- Minneapolis VA IRB
- Advarra
- WCG IRB
- National Cancer Institute Central IRB
- VA Central IRB

Exempt research (i.e., research which has received an Exempt determination): to the research review committee overseeing the study. Most commonly this is the MVAHCS R&D Committee (RDC). *This will be rare. Contact IRBMN@VA.GOV to discuss.*

* Serious Adverse Events (SAEs) which are determined by the MVAHCS PI to be **Related or Possibly Related** to participation in the research *AND* are **Unexpected** are to be reported as possible UPIRTSOs.

What has to be reported: Deaths

Deaths of local research participants are to be reported to the IRB of record ONLY if the death is Unexpected ***and*** Related/Possibly Related to research participation.

When: report an Unexpected *and* Related/Possibly Related death **IMMEDIATELY** (within 1 hour of becoming aware of the event) to the IRB of record **AND** the Associate Chief of Staff/Research. Follow up with a written report within 1 business day.

To Whom:

Non-exempt research (i.e., research under the oversight of an IRB): to the IRB of record

- Minneapolis VA IRB
- Advarra
- WCG IRB
- National Cancer Institute Central IRB
- VA Central IRB
- NIH All of Us IRB

Exempt research (i.e., research which has received an Exempt determination): to the research review committee overseeing the study. Most commonly this is the MVAHCS R&D Committee (RDC). *This will be rare. Contact IRBMN@VA.GOV to discuss.*

What has to be reported:
Information Security & Privacy Incidents Involving VA Research

Apparent information security or privacy incidents related to VA research include any inappropriate access, loss, theft, noncompliant storage, transmission, removal or destruction of PHI or other VA research information deemed to be sensitive; theft, loss or noncompliant destruction of equipment containing PHI or other VA research information deemed to be sensitive; or uses and disclosures of PHI for research without legal authority (e.g., without a valid authorization or waiver of authorization).

When: report an apparent Information Security & Privacy Incident *within 5 business days* of identification

To Whom:

Non-exempt research (i.e., research under the oversight of an IRB): to the IRB of record

- Minneapolis VA IRB
- Advarra
- WCG IRB
- National Cancer Institute Central IRB
- VA Central IRB
- NIH All of Us IRB

Exempt research (i.e., research which has received an Exempt determination): to the research review committee overseeing the study. Most commonly this is the MVAHCS R&D Committee (RDC).

How to report

- Studies under the oversight of the Minneapolis VA IRB:
  - Unanticipated Problem Report form found in IRBNet, or
  - SAE/Death Immediate Reporting form (IRBNet)
- Studies under VA Central IRB
  - Report of SAE and UAP form (IRBNet), or
  - Report of Protocol Deviation (IRBNet)
- Studies under WCG IRB, Advarra, NCI CIRB or NIH All of Us CIRB
  - Use applicable reporting forms from their platform/website

Unsure? Contact IRBMN@VA.GOV for guidance

Resources

- Local SOP 10-004: *Reporting of Research Noncompliance and Other Select Research-related Events in VA Human Research* *https://www.va.gov/MINNEAPOLISRESEARCH/policies.asp*
- VHA Directive 1058.01: *RESEARCH COMPLIANCE REPORTING REQUIREMENTS* *https://vaww.va.gov/vhapublications/ViewPublication.asp?pub_ID=9082*

Ask us: IRBMN@VA.GOV