A Dialogue with VA

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I have no relevant personal/professional/financial relationship(s) with respect to this educational activity

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Objectives: Office of Research and Development

Update the VA and other interested parties on

- Educational Activities
- Regulatory and Enterprise initiatives
  - VA Innovation Research Review System (VAIRRS)
  - VA’s Use of Commercial IRBs
- Upcoming Initiatives
  - VA Electronic Determination Aid (VAEDA)
  - Document Policy and FAQ Tool
Last Year, the Office of Research and Development (ORD) Presented this Slide at the 2020 AER Conference:

- COVID-19 Pandemic
- Other Issues
- Conduct of Studies Remotely
- Rest of 2018 Common Rule Requirements
This Year

The Sky Is Still NOT Falling

COVID-19 Pandemic
Supply Chain Shortages
Conduct of Studies Remotely
Other Issues
Virtual Work Environment
A primary focus of the Office of Research Protections, Policy and Education (ORPP&E) focus on the past year has been on providing tools and training to assist VA Facilities in the conduct of VA research.
Educational Initiatives: Guidance Documents

- Substantial Focus on Webinar Activities
- Examples:
  - ORD Policy Updates - Technical Amendments to VHA Directives 1200.01, 1200.05, and 1200.08
  - Enterprise Research Data Security Plan (ERDSP) Role-Based Training for Principal Investigators/Institutional Review Board (IRB)/Research & Development (R&D) Committee Stakeholders
  - VA Central IRB Researcher and Study Team Training
  - Electronic Documentation of Written Informed Consent
  - A New Process for filing Single IRB Exception applications: Effective May 1, 2021
  - Launch of the Veterans Health Administration (VHA) Central Research Privacy Board (CRPB)

Located on ORD’s Policy and Guidance Webpage at: https://www.research.va.gov/resources/policies/
Summary for Fiscal Year 2021:
- Number of Webinars: 52
- Number of Registrants: 29,624
- Number of Unique Logins: 18,425
- Average # of Unique Logins per webinar: 394.21*
Number of Webinars

FY 2020

FY 2021

52

35

FY 2021
FY 2020

0 10 20 30 40 50 60

PRIMER
PUBLIC RESPONSIBILITY IN MEDICINE AND RESEARCH
Educational Initiatives: Toolkits Introduced in 2021

- Focus on implementation of ORD Policies with example forms, tools, and templates

Research Information Security & Cybersecurity

Located at ORPP&E’s toolkit webpage at:
https://www.research.va.gov/programs/orppe/education/tools.cfm
Educational Initiatives: Frequently Asked Questions Searchable Database

Office of Research & Development

Search Policy and Guidance FAQs

Enter keyword: [ ] Search

Data last updated: 09/29/20

ORD has created a new database of research-related Frequently Asked Questions. The keyword search box is used to search published FAQs that are found on the ORD policy and Guidance webpage. NOTE: The search currently does not allow for a Boolean search (i.e. use of AND, OR).

Topics included in database: Animal Research; Biosafety; Certificates of Confidentiality; Conflicts of Interests; COVID-19; Exempt research; Information Security; Informed Consent; IRB Membership; COVID Convalescent Plasma; Non-Veterans; Privacy; R&D Committee; VA Central IRB; VAIRRS

- All VHA Medical Centers with Research Programs now on board!
VA Innovation and Research Review System

VAIRRS – Enabling Enterprise-level Reporting

- The centralized VAIRRS dataset fuels ORD’s enterprise dashboards to provide ORD leadership with a high-level view of the VHA research ecosystem.

- Data capture tools are scalable to respond to changing organizational needs and prioritized research topic areas.

Example: In response to ORD’s need to report COVID research data, the VAIRRS data capture tools were updated to collect relevant data at the Principal Investigator level. VAIRRS now captures all new COVID-related research performed at 106 VA Medical Centers. Data is compiled at the enterprise level and reported in the organization’s COVID Research Dashboard.
Allows for real-time reporting

Source for active cases: VA COVID-19 National Summary
Amendment to VHA Directive 1200.05: VHA Directive 1200.05 was amended on March 3, 2020 permitting VA Facilities to use commercial IRBs for cooperative (multi-site) research activities as approved by ORD:

“VA will permit use of a commercial IRB as an IRB of Record for VA facilities if it has been specifically designated by ORD as a commercial IRB that may serve as an IRB for cooperative research.”

VHA Directive 1200.05, Paragraph 5.b.
VA’s Implementation of the Cooperative Research Provision/Use of Commercial IRBs

Number of VA Facilities with IRB Reliance Agreements with ORD-approved Commercial IRBs:

- **Advarra**: 71
- **WCG**: 71
- **Sterling**: 9

https://www.research.va.gov/programs/orppe/single_irb.cfm
Number of VA Studies Approved by ORD-Approved Commercial IRBs

- **Sterling**: 2 studies
- **WCG**: 51 studies
- **Advarra**: 111 studies
# Types of IRBs Used by VA Facilities

<table>
<thead>
<tr>
<th>Type of IRB</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>VA Central IRB</td>
<td>1</td>
</tr>
<tr>
<td>Commercial IRBs</td>
<td>3</td>
</tr>
<tr>
<td>Other Federal IRB (National Cancer Institute IRB, All of Us IRB,</td>
<td>3</td>
</tr>
<tr>
<td>Department of Energy Oakridge IRB)</td>
<td></td>
</tr>
<tr>
<td>University IRB</td>
<td>30</td>
</tr>
<tr>
<td>VA Facility IRB</td>
<td>58</td>
</tr>
<tr>
<td>Total Number of IRBs Currently Approved by ORD</td>
<td>95</td>
</tr>
</tbody>
</table>
Number of IRBs Used by VA Facilities

Number of IRBs Used by the Individual VA Facilities

- Total Number of VA Facilities = 106

- Number of VA Facilities by Number of IRBs Used:
  - 0: 5
  - 1: 3
  - 2: 7
  - 3: 10
  - 4: 14
  - 5: 22
  - 6: 28
Will VA Become Part of the SMART IRB

The SMART IRB platform cannot be used by VA at the present time.

VA is actively negotiating with other federal agencies as we work with the SMART leadership on being able to join the SMART IRB platform.
Planned ORD Initiatives:

- VA Electronic Determination Aid (VAEDA)
  - Currently in soft launch
- Document Policy and FAQ Portal Tool
- ORD Community IRB Panel
- Proactive Calling Application Portal
- Expansion of central privacy reviews for multi-site studies
Summary

- ORD has provided a number of resources to help VA Facilities.
- ORD continues to work on numerous educational activities, policy evaluations, standardized forms, and other initiatives to support VA research.
Thank You
Review of the Reporting Requirements for VA Human Subjects Research

Lindsay Masterson & Kristina Borror
Learning Objectives

1. Familiarize yourself with ORO’s reporting tools and guidance

2. Understand the elements to include in a report to ORO

3. Understand the process for ORO HRP’s remote compliance oversight from case submission through case closure
We’re All Responsible...

... for ensuring the responsible conduct of VA research.

VA personnel are responsible for reporting the following events related to human subjects research:

- Deaths of human subjects that are believed to be both unexpected and related or possibly related
- Apparent Unanticipated Problems Involving Risk to Subjects or Others (UPIRTSO)
- Apparent Serious and/or Continuing Noncompliance
- Systemic Deficiencies
- Apparent Information Security or Privacy Incidents

See VHA Directive 1058.01 §5.1.
Steps in Reporting Human Subjects Research Events

- **VA Personnel Responsible for** reporting research related events to IRB/R&DC.
- **IRB/R&DC responsible for** reviewing events, making associated determinations, and reporting to ACOS/R&D, RCO, and VA medical facility Director, as necessary.
- **VA medical facility Director responsible for** reporting events and associated determinations, as necessary, to ORO.
ORO Guidance and Tools

https://www.va.gov/ORO/oropubs.asp

- Decision Chart: Reporting Human Deaths, Unanticipated Problems and Accident, Injury, Illness and Exposure in VA Research (March 2021)
- Decision Chart: Reporting of Systematic Deficiencies and Noncompliance in VA Research (March 2021)
- Examples of Events in VA Human Subjects Research that Constitute Serious or Continuing Noncompliance (March 2021)
- Guidance on Reporting Deficient HIPAA Authorizations (March 2021)
This decision chart assists facilities and VA personnel through the process of reporting human deaths and UPIRTSOs, and ensuring appropriate determinations are made and reported in accordance with VHA requirements.
This decision chart guides the user through the process of reporting systemic deficiencies and noncompliance and the associated required determinations.
This guidance document provides examples of noncompliance in VA human subjects research that ORO typically considers to meet the definition of serious or continuing noncompliance under VHA Directive 1058.01.
Guidance on Reporting HIPAA Deficiencies


This document provides guidance on various reporting requirements and considerations related to deficient HIPAA authorizations.
1. What to include in the report
2. How to send reports to ORO
3. What to expect after reporting to ORO
What to include in reports to ORO

OFFICE OF RESEARCH OVERSIGHT (ORO)
GUIDANCE ON INFORMATION TO BE INCLUDED IN REPORTS TO ORO
September 23, 2021

The Office of Research Oversight (ORO) receives hundreds of incident reports annually from VA medical facilities that conduct research. To assist facilities with fulfilling their reporting responsibilities as described in VHA Directive 1558.01, "Research Compliance Reporting Requirements" (dated October 22, 2020), this document provides guidance on information that should be included in reports of research-related incidents sent to ORO. This guidance describes the information most commonly requested by ORO to effectively exercise its oversight responsibilities when reviewing such events. In many instances, it is anticipated that adherence to the guidance will reduce the need for ORO follow-up requests for information, thereby reducing burden on VA medical facility personnel.

VHA Directive 1558.01 describes requirements for reporting select events involving VA research to the research review committee(s), VA medical facility leadership, and ORO. Events are categorized in the Directive according to the type of research involved and the nature of the event. Specific processes for the review and reporting of events are delineated in the following sections of the Directive:

- Systemic Deficiencies (§8)
- Non-Exempt Human Subjects Research (§7)
- Exempt Human Subjects Research (§4)
- Animal Research (§5)
- Research Laboratory Safety and Security (§10)
- Research Information Security and Privacy (§11)

Using a parallel structure to the Directive, this guidance provides a description of information that should be included in notifications to ORO of reportable events in each section of the Directive (see Appendices A through F of this guidance document). During the course of its oversight, ORO may request additional information not addressed in this guidance such as meeting minutes from when the event was reviewed by a research review committee, documentation of completion of remedial actions, etc.

Notifications of events reportable to ORO should be directed to the ORO workplace with the appropriate subject matter expertise and assigned oversight responsibilities that encompass the research oversight area that the event falls within. In some instances, an event may fall under the oversight of more than one ORO workplace. In such instances, facility personnel need only send the initial notification to one of the ORO workplaces with applicable oversight responsibilities.

- Reportable events pertaining to noncompliance with VHA Directive 1208.01, including Research & Development Committee (R&D) operations, research under the oversight of the R&D, and Research Compliance Officer (RCO) responsibilities, should be reported to ORO’s Comprehensive Research Oversight Workgroup (CROWS).
- Reportable events pertaining to human subjects research and Institutional Review Board (IRB) operations should be reported to ORO’s Human Research Protection (HRP) Workgroup.

NOTE: The Department of Health and Human Services (HHS) Office for Human Research Protections (OHRP) requires submission of the OHRP incident Report Form for any incident report made to OHRP in accordance with 45 CFR part 46. The form and the associated instructions may be found on the HHS OHRP website here. VA facilities who utilize the OHRP incident Report Form for reporting to HHS-OHRP may also submit that form to ORO for incidents.

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https://www.va.gov/ORO/Docs/Checklists/Guidance_on_Info_to_Include_in_Reports_to_ORO.pdf
1. Name of the VA facility reporting the event.
2. Title, protocol number, and name of PI/LSI for project(s) involved.
3. Sponsor(s) and grant number(s) associated with support for the research involved.
4. Indication of whether the research involved is being conducted as part of a multi-site study and, if so, the name of the institution serving as the coordinating center.
5. Risk level associated with the research (e.g., minimal risk or greater than minimal risk).
6. Indication of whether investigational drugs and/or devices are used in the research and, if so, the associated IND/IDE number.
7. Clinicaltrials.gov number.
8. Detailed description of the event, including:
   a. The date of the event;
   b. The type of reportable event (SAE, UPIRTSO, serious or continuing noncompliance, suspension or termination, etc.);
   c. Number of research subjects affected; and
   d. Underlying cause and outcome of the event.

9. Description of how the event was identified, including whether identified internally (by VA medical facility personnel or entities acting as agents of the facility such as a research review committee operated by another entity but relied upon by the facility through a formal agreement) or externally (by individuals not associated with or acting as agents of the facility such as by a VHA Program Office, external monitoring/auditing/accreditation organization, etc.).
10. Name of IRB that reviewed the event, date reported to the IRB, resulting determination(s) made by the IRB, and date of the IRB determination(s).

11. Actions facility is taking or plans to address the event (protocol/ICD revisions, subject enrollment suspensions, protocol terminations, enrolled subjects notifications, increased monitoring, education/training, return/transition to clinical care and/or standard of care management of disease or condition, etc.) and anticipated deadlines for completing any pending or proposed actions.

12. Indication of whether the event represents a repeat programmatic noncompliance identified previously within the past three (3) years.

13. Indication of whether the deficiency involves noncompliance by a study team member who has been responsible for other research noncompliance in the past three (3) years.
14. Names of other Federal agencies or entities notified, or to be notified, of the event and when notification occurred (e.g., OHRP, FDA, etc.).

15. Documents relevant to the determination (e.g., PO reports, review committee minutes where issue was discussed, related protocol documents, and applicable SOPs, policies, MOUs, or agreements).

16. Name and contact information (telephone number and email address) of the VA medical facility point of contact with whom ORO can follow-up for additional information.
How to send reports to ORO

• Reportable events pertaining to noncompliance with VHA Directive 1200.01, including R&DC operations, research solely under the oversight of the R&DC, and RCO responsibilities, should be reported to ORO’s Comprehensive Research Oversight Workgroup (CROW) at OROCROW@va.gov.

• Reportable events pertaining to human subjects research and IRB operations should be reported to ORO’s Human Research Protection (HRP) Workgroup at OROHRP@va.gov.

• Reportable events pertaining to animal research, IACUC operations, and research laboratory safety and security should be reported to ORO’s Research Safety and Animal Welfare (RSAW) Workgroup at ORORSAW@va.gov.

• Reportable events pertaining to research information security and privacy should be reported to ORO’s Research Information Security (RIS) Workgroup at ORORISP@va.gov.
What to expect after reporting to ORO HRP

1. Acknowledgment of receipt
2. Preliminary review of report
3. Creation of ORO case
4. Formal ORO communication
5. Updates as necessary
6. Case closure
How to improve reports to ORO HRP

Common items missed when reporting to ORO:

IRB Review:

- Appropriate/complete determinations not made per VHA Directive 1058.01
  - Protocol/consent modifications
  - Reconsent of previously enrolled participants
  - Consideration of appropriate remedial actions
  - Consideration that event could be both serious/continuing noncompliance and UPIRTSO
How to improve reports to ORO HRP

Report Omissions:

• Study sponsor/funding source
• Copies of associated IRB meeting minutes
• Confirmation that remedial actions have been completed, as applicable
• Health status of the subject for reports of UPIRTSOs, as applicable
• Confirmation that privacy incidents have been reported to the ISSO/PO as necessary and the associated outcomes
OHRP Reporting Template

• New OHRP Incident Report Form
• Required for any incident report made to OHRP
• Form link:
  irpt-pra-incident-report-form.pdf (hhs.gov)
• OHRP Incident Report Form Instructions:
  irpt-pra-instructions.pdf (hhs.gov)

**Office for Human Research Protections’ Incident Report Form**

**Applicability:** The U.S. Department of Health and Human Services (HHS) regulations of 45 CFR part 46 require that institutions engaged in or reviewing nonexempt HHS-conducted or supported human subjects research establish and follow written procedures for ensuring prompt reporting to OHRP of the following:

1. Any unanticipated problems involving risks to subjects or others;
2. Any serious or continuing noncompliance with 45 CFR part 46 or the requirements or determinations of the institutional review boards (IRBs); and
3. Any suspension or termination of IRB approval (pre-2019 Requirements at 45 CFR 46.102(b)(5) and 45 CFR 46.113, and the 2019 Requirements at 45 CFR 46.102(b)(4) and 45 CFR 46.113).

Submission of this form is required for any incident report made to OHRP in accordance with 45 CFR part 46. If an organization is unable to utilize this form, please email OHRP at IRPT@HHS.GOV to discuss alternatives.

### 1. Report Status:
- Full Report
- Follow-up Report
- Initial Report

### 2. Report Type (check all that apply):
- Unanticipated Problem
- Serious Non-compliance
- Continuing Non-compliance
- Suspension of IRB Approval
- Termination of IRB Approval

### 3. If Unanticipated Problem (check all that apply):
- Risk of Breach or Breach of Confidentiality
- Any Other Incident

### 4. Category of the Incident Related to Non-compliance, Suspension, or Termination (check all that apply):
- Research conducted without IRB approval
- Issues related to informed consent or assent
- Failure to follow IRB-approved protocol
- Issues related to the IRB
- Other

### 5. FWA or IRROG number of reporting organization:

### 6. FWA/App of the Institution(s) Conducting the Research (separated by comma):

### 7. Study Title(s):
1.
2.
3.

### 8. Principal Number(s):
- Principal Investigator(s): 1. 2. 3.
- Research Sponsor(s): 1. 2. 3.
- Award Number(s): 1. 2. 3.

### 9. Brief Description of the Research (if applicable):
1.
2.
3.

### 10. Detailed Description of the Incident:

### 11. Corrective Action Plan Description:

### 12. Corrective Action Plan Category (check all that apply):
- Re-seeking consent or notifying subjects
- Revising IRB policies and procedures
- Revising protocol or consent form
- Educating or training for IRB members/staff, investigators, research staff, or institutional officials
- Suspending or revoking principal investigator’s privileges to conduct human subject research
- Audit plan for research
- Other

**The submitting organization certifies that the information provided above is correct.**

### 13. Name of FWA Signatory Official or IRROG Site/Head Office:

### 14. Name of FWA Human Protections Administrator (HPA) Name or IRROG Information Provider:

### 15. Name of Person Submitting this Form:

### 16. Name and address of the organization submitting this form:

### 17. Name and address of the organization submitting this form:

### 18. Date:
VA facilities who utilize the OHRP Incident Report Form for reporting to HHS-OHRP may also submit that form to ORO.

When using the form, additional information indicated in Appendix B (which is marked with an asterisk) must be included in the submission to ORO.
Additional Info to Include (not on form)

- Indication of whether the research protocol(s)/project(s) involved are part of a multi-site study and, if so, the name of the coordinating center.
- Risk level associated with the research protocol(s)/project(s) involved.
- Indication of whether investigational drugs and/or devices are used in the research and, if so, the IND or IDE #.
- Clinicaltrials.gov number.
- Number of research subjects affected.
- A description of how the event was identified, including whether identified internally or externally.
- Name of reviewing IRB, date they reviewed the event, the determinations made and date made.
- Whether event is repeat programmatic noncompliance.
- Whether noncompliance by study team member responsible for other noncompliance in the last 3 years.
- Names of other Federal agencies or entities notified, or to be notified, of the event and when notification occurred.
- Documents *relevant* to the determination (e.g., PO reports, review committee minutes, related protocol docs, SOPS).
Resources

- ORO Publications and Guidance (including VHA Directive 1058.01 and guidance on reporting):
  
  https://www.va.gov/ORO/oropubs.asp

- OHRP Guidance on Reporting (including OHRP Incident Report Form):
  

Email us – ORO HRP: OROHRP@va.gov  ORO P&E: OROPE@va.gov
Thank You