A Dialogue with VA

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Disclosures:

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
  - Webinars
  - Guidance
  - Frequently Asked Questions
- Regulatory initiatives
  - VA Innovation Research Review System (VAIRRS)
  - VA Central IRB
  - VA’s Use of Commercial IRBs
- Planned regulatory initiatives
  - VA Central Privacy Reviews
  - ORD Privacy Board
Last Year, Office of Research and Development (ORD) Presented this Slide at the 2019 AER Conference:

Don't Believe Chicken Little

The Sky is NOT Falling
This Year: The Sky is Still Not Falling!

COVID-19 Pandemic

Other Issues


Conduct of Studies Remotely

Rest of 2018 Common Rule Requirements
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: Webinars

- Summary for Fiscal Year 2020:
  - Number of Webinars: 35
  - Number of Registrants: 17,267
  - Number of Unique Logins: 12,343
  - Average # of Unique Logins per webinar: 363.03*
Number of Webinars

FY 2019
FY 2020

FY 2020  FY 2019

15  35
Webinars: Total Number of Registered Users and Logins

- FY 2019:
  - Registrant #: 5,404
  - Total Logins: 3,710

- FY 2020:
  - Registrant #: 17,267
  - Total Logins: 12,343
Total Number of Logins Per Webinar

- FY 2019: 247
- FY 2020: 363
Educational Initiatives: Guidance Documents

- Substantial Focus on Covid-19 Pandemic

- Examples:
  - ORD Guidance on Remote Monitoring of VA Clinical Trials by External Monitors Using the WebEx Collaboration Technology Sharing Platform (June 18, 2020)
  - ORD Guidance on VA Employee Participation in VA-Conducted COVID-19 Research Studies (September 24, 2020)

Located on ORD’s Policy and Guidance Webpage at: https://www.research.va.gov/resources/policies/
Educational Initiatives: Toolkits

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

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

- **Examples of Published FAQs:**
  - COVID-19 (SARS-CoV-2) Research Specimens - Frequently Asked Questions (Original Publication Date: April 4, 2020)
  - Human Subject Protection Issues Related to COVID-19 - Frequently Asked Questions (Original Publication Date: April 6, 2020)
  - Frequently Asked Questions (FAQs) - COVID-19 and VA Animal Care and Use Programs (Original Publication Date: April 13, 2020)
  - VHA Directive 1200.01 FAQs, “Research and Development Committee” (Original Publication Date: June 3, 2020) Frequently Asked Questions (FAQs) Regarding COVID-19 Impacts on Research (Original Publication Date: June 22, 2020)
  - Frequently Asked Questions (FAQs) - COVID-19 and VA Animal Care and Use Programs (Original Publication Date: April 13, 2020)
Educational Initiatives: Frequently Asked Questions

WHERE DO I FIND...?
Educational Initiatives: Frequently Asked Questions Searchable Database

Office of Research & Development

Search Policy and Guidance FAQs

Enter keyword:  

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

VA Innovation and Research Review System (VAIRRS)

- 48 VHA Medical Centers now on board
- Central IRB is in training along with the 30+ Tier 2 facilities
  - Onboarding beginning in Sep 2020
- Information Security, Office of Research Oversight, VHA Privacy, VA Office of General Counsel: Specialty Team Advising Research, Technology Transfer
  - Demonstrations in progress for adoption
Regulatory Initiatives:
Policy Revision for Use of Commercial IRBs

- 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
- **WIRB-WCG**: 70
- **Sterling**: 3

https://www.research.va.gov/programs/orppe/single_irb.cfm
Panels:

• Expanded to 2 panels
• All members of Panel 2 are alternates to Panel
• 4 Chairs/Co-Chairs

During Pandemic:

• Weekly ad hoc IRB meetings to meet the COVID review needs
• Average review time 10 days from submission
• Average approval time 12 days (not counting investigator response or privacy and R&DC review)

Future Expansion of VA Central IRB Panels
Planned Regulatory Initiative:
Central Privacy Reviews of Select Commercial IRB Studies

ORD is currently piloting an ORD central privacy review of a subset of studies submitted by VA Facilities to a commercial IRB

- COVID-19 Vaccine Studies
- Include preliminary and final privacy reviews for study initiation and any study modifications throughout the life of the study
- VA Facilities would have ability to choose to conduct their own privacy reviews if they did not wish to use the central privacy review service offered by ORD for the study.
- The pilot is currently being conducted with a multi-site COVID-19 vaccine study.
Planned Regulatory Initiative: ORD Central Privacy Board

- ORD is establishing a VA Central Office-ORD privacy board
  - Overseen by ORD’s Privacy Officer
  - Will be authorized to approve waivers of HIPAA authorization
  - Scope of review activities currently being defined
  - Requires establishment of memorandum of understanding between ORD and VA Facility
  - Planned launch: January/February 2021
Regulatory Initiatives: Planned Policy Revisions

- Planned technical amendments within the next 90 days to:
  - VHA Handbook 1200.01: Research and Development Committee
  - VHA Directive 1200.05: Requirements for the Protection of Human Subjects in Research
  - VHA Directive 1200.08: Safety of Personnel and Security of Laboratories Involved in VA Research

- Planned substantial policy revisions within the next 12 months to:
  - VHA Handbook 1080.01: Data Use Agreements
  - VHA Handbook 1108.04: Investigational Drugs and Supplies
  - VHA Directive 1200.12: Use of Data and Data Repositories in VHA Research
 summary

▪ ORD has provided a number of resources to help VA Facilities.
▪ ORD continues to work on numerous educational activities, policy evaluations, agreement templates, and other initiatives to support VA research.
Thank You
Office of Research Oversight
Policy Update:
Revisions to VHA Directives 1058.01 and 1058.03

Presented by: Kristina Borror, Ph.D.
Director, Policy and Education, ORO
VHA Directive 1058.01

§1
VHA Directive 1058.01

Research Compliance Reporting Requirements

Dated October 22, 2020

Requirements for reporting select events in VA research to research review committees, VHA officials, and ORO
Considerations for Revisions

1. Reduce burden to facilities
2. Harmonize with other Federal agencies (particularly OHRP)
3. Facilitate mandated use of single IRBs
### Major Changes to 1058.01

<table>
<thead>
<tr>
<th>Harmonizes reporting requirements for human, animal, safety and info security</th>
<th>Added flexibility for reviewing and reporting requirements for external review committees</th>
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<tbody>
<tr>
<td>Added flexibility with regard to whom the RCO reports</td>
<td>Decrease timeframe for reporting of deaths</td>
</tr>
<tr>
<td>Change timeframe for committee review and determination</td>
<td>Change timeframe for completion of remedial actions</td>
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Flexibility to Whom the RCO Reports - Background

Allows, but does not mandate, RCO reporting to another individual who reports directly to the MFD.

Facility can still require the RCO to directly report to the MFD.

MFDs want to have flexibility with regard to who must report directly to them and to have a single point person on risk management/compliance issues.

Coordinated effort by VHA Program Offices with oversight responsibilities to provide this flexibility.
Harmonizes Reporting Requirements

• Creates parallel structures for the reporting in different types of research
  – Human
  – Animal
  – Safety and
  – Information security
Timeframe for Remedial Actions

• Remedial actions to correct noncompliance identified by ORO or that is otherwise required to be reported to ORO must be completed within 180 calendar days after any determination of noncompliance, except where extenuating circumstances exist.

• Where remedial actions cannot be completed in 180 calendar days, the MFD must provide ORO with written justification and timeline.

§5.g.(6)(a)&(b)
VHA Directive 1058.03
VHA Directive 1058.03

“Assurance of Protection for Human Subjects in Research”

- Sets forth policy related to the Human Subject Protection Assurances that VA medical facilities are required to provide under 38 CFR Part 16.
- The first version of the VHA Handbook 1058.03 was issued May 10, 2007.
- The second version of the HB was issued in 2014 without any substantive changes from the first version.
- Third (current) version dated September 17, 2020; was revised into a Directive with major changes.
Only VA medical facilities engaged in non-exempt human subjects research must hold a recognized assurance of compliance.

Elimination of requirement for facilities to report IRB roster changes to ORO.

Only IRBs operated by the facility must be designated on the FWA or, only the primary external IRB relied upon must be designated.

Responsibility for approving the restriction or suspension of an FWA based on recommendation by the ORO ED, has been assigned to the USH.
<table>
<thead>
<tr>
<th>Previous Version</th>
<th>Current Version</th>
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<tbody>
<tr>
<td>[E]ach VA medical facility engaged in research involving human subjects or human biological specimens must hold an effective FWA approved by OHRP with an effective VA FWA Addendum approved by ORO.</td>
<td>[E]ach VA medical facility engaged in <strong>non-exempt</strong> human subjects research covered by the requirements of 38 CFR 16 must hold a valid FWA approved by HHS-OHRP with an effective VA FWA Addendum approved by ORO.</td>
</tr>
</tbody>
</table>

§6.a.
### Previous Version

[All] IRBs used by VA medical facilities, whether operated by VA or by another entity, must be registered with OHRP and designated as an IRB of Record on the facility’s FWA.

### Current Version

(a) All IRBs operated by a VA medical facility (internal IRBs) must be designated on the VA medical facility’s FWA.

(b) If a VA medical facility does not operate its own internal IRB, the external IRB that oversees the greatest percentage of the VA medical facility’s non-exempt human subjects research studies must be designated on the VA medical facility’s FWA.

§6.a.(3.)
### Suspending/Restricting FWAs

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<th>Current Version</th>
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<td>Where the ORO Chief Officer determines that restriction or suspension of a VA medical facility’s Assurance is necessary to safeguard the safety, rights, or welfare of human subjects, the ORO Chief Officer so notifies the Under Secretary for Health and the facility’s IO, and provides the IO with a written statement of the reasons for the restriction or suspension.</td>
<td>Where the ORO Executive Director (ED) determines that restriction or suspension of a VA medical facility’s Assurance or associated VA FWA Addendum is necessary because the ORO ED reasonably believes the action is necessary to safeguard the safety, rights, or welfare of human subjects, the ORO ED must recommend such restriction or suspension to the Under Secretary for Health. (§6.f.)</td>
</tr>
<tr>
<td>Previous Version</td>
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<tr>
<td>Regardless of whether the IRB of Record is operated by the VA medical facility or by another entity, the VA medical facility holding the FWA must provide ORO with an updated roster within 30 days of any change in membership.</td>
<td>[Language removed]</td>
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</tbody>
</table>
• ORO Guidance and FAQs on **VHA Directive 1058.01** can be found at:
  Directive, Summary of Major changes, and Table of Changes:  [https://www.va.gov/ORO/oropubs.asp](https://www.va.gov/ORO/oropubs.asp)

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FWA Registration & Information:  
[https://www.va.gov/ORO/FWA.asp](https://www.va.gov/ORO/FWA.asp)

FWA Registration & Information:  
[https://www.va.gov/ORO/IRB.asp](https://www.va.gov/ORO/IRB.asp)

Questions about VHA Directive 1058.03 or FWA/IRB registration or MOUs:  [orofwa@va.gov](mailto:orofwa@va.gov)
Questions
Common Findings Identified During ORO’s Combined Program Reviews

Yen B. Nguyen, PharmD
Director, Informatics and Data Analytics (IDA)
Office of Research Oversight (ORO)
Veterans Health Administration (VHA)
Office of Research Oversight (ORO)

- Oversees and monitors VA programs for compliance with VA and other Federal research requirements
- On-site reviews of VA facility research programs:
  - Combine Program Reviews (CPRs)
    - Broad, prospective, integrated, all research areas
  - Focused Reviews
  - For-Cause Reviews
  - Technical Assistance Reviews
ORO Combined Program Reviews

• Include evaluations of a facility’s
  – General research administration (GRA)
  – Human research protection program (HRPP)
  – Research information security (RIS) practices
  – Animal care and use program (ACUP)
  – Research safety and security programs (RSSP)
• Conducted at each VA facility on a cyclical basis
• Utilizes a standard assessment instrument
• Findings collected via electronic tracking system
Today’s Discussion

• Programmatic noncompliance captured in ORO Combined Program Review reports issued during calendar year 2019

• “Common” defined as a finding identified at greater than 25% of the programs reviewed
Overview of Facilities/Program Evaluated

- 18 unique VA facilities

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<thead>
<tr>
<th>Program Areas</th>
<th>Number of VA Facilities Where the Program Area Was Reviewed</th>
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</thead>
<tbody>
<tr>
<td>General Research Administration</td>
<td>17</td>
</tr>
<tr>
<td>Human Research Protection Program</td>
<td>17</td>
</tr>
<tr>
<td>Research Information Security Practices</td>
<td>17</td>
</tr>
<tr>
<td>Animal Care and Use Program</td>
<td>9</td>
</tr>
<tr>
<td>Research Safety and Security Program</td>
<td>9</td>
</tr>
</tbody>
</table>
General Research Administration

• Resources and infrastructure for the research program
• Composition and operations of the Research and Development Committee (R&DC)
• R&DC oversight of the research program
• Practices of the Research Compliance Officer (RCO)
1. Deficient documentation pertaining to R&DC reviews and operations
   - Deficient documentation in R&DC meeting minutes for member recusal due to conflicts of interest
   - Deficient documentation in R&DC meeting minutes and committee roster for primary/alternate members
   - Deficient documentation in R&DC meeting minutes for member votes on committee actions

2. Research records not managed in accordance with policy
   - Storage of research records not properly documented to ensure retrieval and retention
   - Research records not managed in accordance with VA records disposition policies
Human Research Protection Program

• Federalwide Assurance (FWA) for human research
• Composition and operations of the Institutional Review Board (IRB)
• IRB oversight of human research
• Investigational drug program and research pharmacy
• Investigational device program
HRPP Common Findings

1. Lack of or deficient HRPP/IRB SOPs
   - IRB SOPs not updated to effectively implement the 2018 Common Rule
   - Lack of documented procedure for determining if and when a research activity approved by the IRB prior to January 21, 2019, can transition to fall under the requirements of the 2018 Common Rule
   - IRB SOP did not contain VA requirements for reporting and reviewing unanticipated human deaths
   - IRB SOP did not contain requirement for determining which projects need verification from sources other than the investigators that no material changes have occurred since prior IRB review

2. Deficient documentation pertaining to IRB determinations and operations
   - IRB meeting minutes did not document all criteria for approval of research were satisfied
   - Deficient documentation in IRB minutes for member attendance and votes on actions taken by members

3. Deficient initial review/approval procedures
   - Noncompliant application of IRB exemption criteria
   - No Facility Director approval for international research
   - IRB did not consider whether additional safeguards were required for subjects likely to be vulnerable to coercion or undue influence
   - Requirements for informed consent and HIPAA authorizations or waivers were not reviewed
   - IRB approved noncompliant script for informed consent
Research Information Security Practices

• Information technology (IT) networks and connections used for research
• Management of VA information, VA sensitive information (VASI)
• Use of mobile, portable and wireless devices used for research
• Use of VA and non-VA information systems
RIS Common Findings

1. Mobile or portable device(s) not properly encrypted
   • VA laptops used for research not properly encrypted
   • VA portable devices used for research not properly encrypted
   • VA and Non-VA portable storage media containing VASI not properly encrypted

2. No or incomplete inventory of IT equipment used for VA research
   • Non-VA IT equipment (e.g., affiliate-owned) not listed in facility property accountability system
   • VA IT equipment not listed in appropriate/required inventory system
   • VA IT equipment (laptop, desktop computers) not physically present in documented location
   • Non-VA IT equipment not inventoried on an annual basis
RIS Common Findings continued

3. No or inappropriate terms/conditions for VA research information on non-VA information systems
   - Terms/conditions not established for processing, storage and transmission of VA research data on external information systems
   - MOU for use of external information system did not accurately reflect actual VA research use

4. Inadequate restrictions on access to VA information
   - Inadequate restrictions on access to electronic VASI stored in VA network folders
   - Inadequate restrictions on access to hard copy VASI

5. Use of mobile/portable/wireless devices for research without required approval
   - Mobile devices used for VA research without appropriate approvals
   - Portable storage devices used for VA research without appropriate approvals
   - Personally-owned devices used without appropriate approvals
Discussion

• Common findings from 2019 CPR reports reviewed
• Data provides insight into potential areas of focus for:
  – Education
  – Research policy development/clarification
  – Research-related quality improvement initiatives
  – Site visit preparation in conjunction with
    • ORO checklists
    • Annual FDC checklist of research-related requirements
• Data from future CPRs will continue to be collected and shared
Questions

Yen.Nguyen8@va.gov or OROIDA@va.gov