Am I Doing What's Right?

Navigating Ethical & Regulatory Issues with VA Patient and Operational Data

November 17, 2015

U.S. Department of Veterans Affairs
Veterans Health Administration
Office of Informatics and Analytics

ORO — Department of Veterans Affairs, Office of Research Oversight

CIPRS — Center for Implementation Practice and Research Support

VIReC — Researchers' Guide to VA Data

Partnered Research Cyberseminar Series

Opening Remarks:

- Joe Francis, MD, MPH, Director of Clinical Analytics and Reporting, Office of Informatics and Analytics

Panelists

- Melissa Bottrell, PhD, Acting Deputy Director, VA National Center for Ethics in Health Care
- Linda Kok, MA, Technical & Privacy Coordinator, VIReC
- Tom Puglisi, PhD, Chief Officer, VA Office of Research Oversight
- Nina Smith, MPH, Communication & Dissemination Coordinator, CIPRS
- Sam White, MPA, CIPP/G, Management & Program Analyst, National Data Systems/Health Information Access

Objectives

- Provide information about the QI Ethics & Compliance Toolkit
- Introduce a framework for ethical and regulatory decision-making re: access, use, and transfer of VA data
- Answer frequently asked questions in this area
- Provide resources for additional concerns in this area

Quality Improvement (QI)/Implementation Research (IR) Ethics & Compliance Toolkit

http://vaww.portal.gla.med.va.gov/sites/Research/HSRD/CIPRS/QIEthics/Pages/default.aspx

- CIPRS product, created with support from QUERI Program and HSR&D COIN in Los Angeles
- Inspired by local (VA Greater Los Angeles) experience with ethical/regulatory issues in quality improvement projects
- Content reflects conversations with the Office of Research Oversight (ORO), the VA National Center for Ethics in Health Care, VIReC, and NDS

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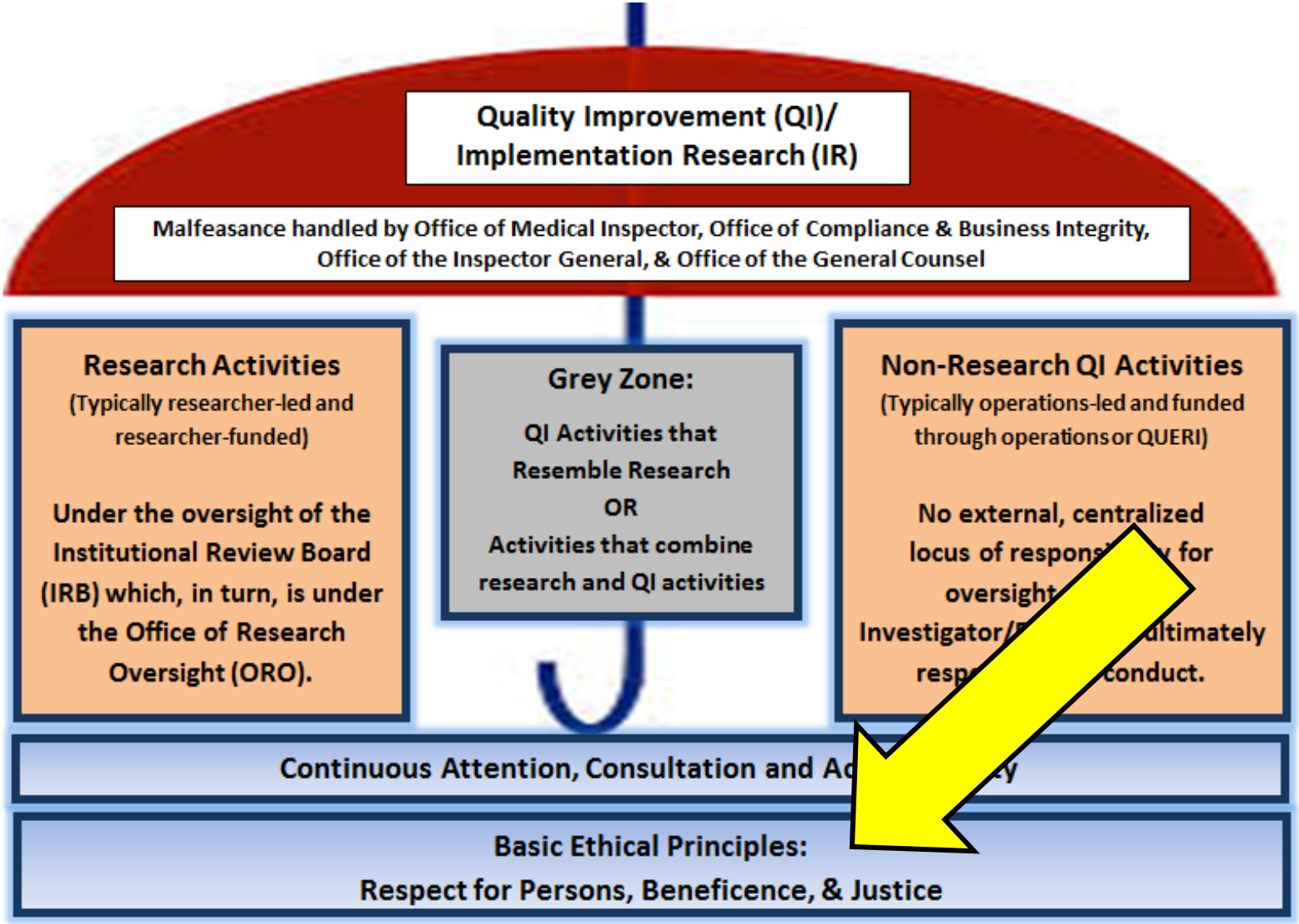
CSHIIP Center for the Study of Healthcare Innovation, Implementation & Policy

VA QUERI Quality Enhancement Research Initiative

Overarching Ethical/Regulatory "Umbrella" Framework



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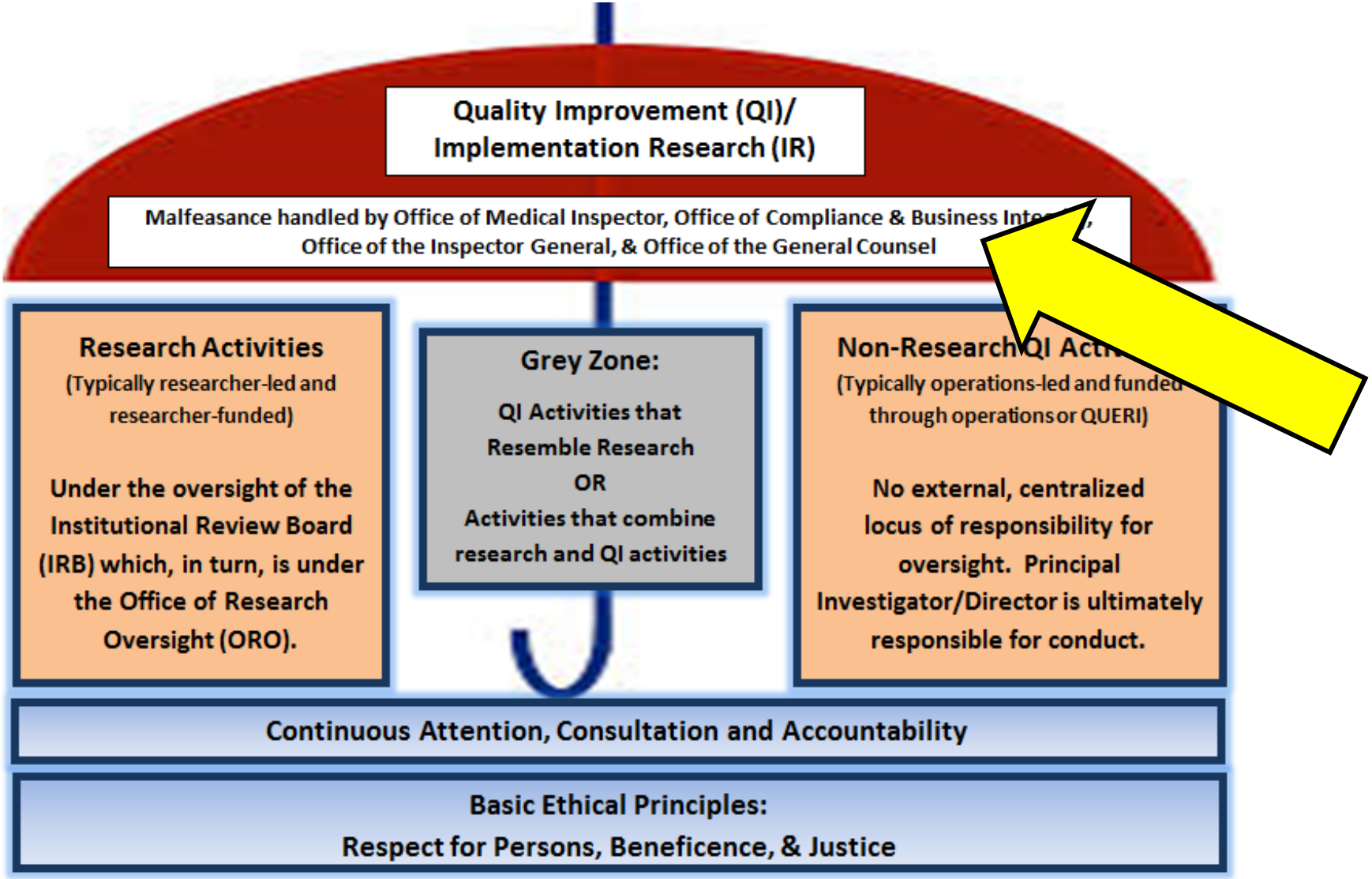

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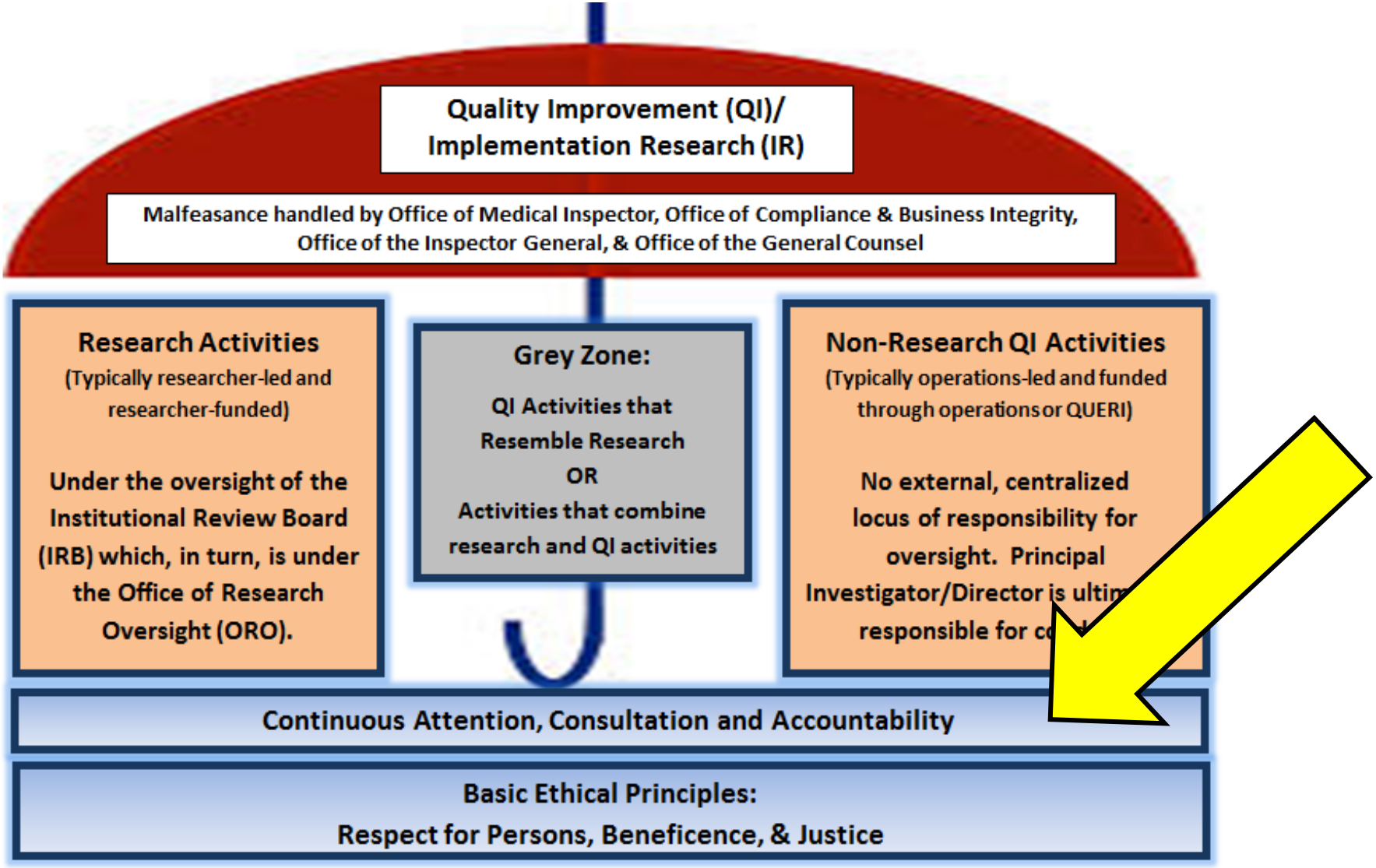

Principles

http://vaww.portal.gla.med.va.gov/sites/Research/HSRD/CIPRS/QIEthics/Pages/Principles.aspx

- Operationalization of the Belmont Ethical Principles into day-to-day issues and considerations

Team & Staff Data Access

Staffing Regulations

Data Security

* Provide clear processes and responsibilities for securely collecting, accessing, and storing electronic and/or hard copy PHI or PII.

* All hardware, software, and other equipment used to collect, store, analyze or access VA sensitive data needs to be approved by the VA.

* VA sensitive data should be transmitted or transported using properly secured and encrypted methods.

* Team members need to obtain all permissions or authorizations needed from the data owner to access and use existing VA data for QI purposes.

VIReC
RESEARCHERS' GUIDE TO VA DATA

Scenarios

http://vaww.portal.gla.med.va.gov/sites/Research/HSRD/CIPRS/QIEthics/Pages/Scenarios.aspx

- Case studies of how ethical/regulatory issues may present in quality improvement/implementation research activities

Scenario 3: Staff Outside the VA

The former lead investigator of an evaluation of new care delivery models obtains a tenured position at a local university. She has to leave the VA to take her new position. She designates a VA colleague to be the new lead investigator, but remains on the project as a collaborator. Since she has knowledge of the evaluation, but no longer has a VA network account, she makes copies of her files – including those with patient identifiable information – and houses them in the university's server. She is also delighted to find out that she has access to university students who can help with the project and starts involving them in data analysis

Ethical issues to consider

Data Security: Does the university server meet requirements for housing VA data? Did she obtain necessary approval for transferring the data to the university, especially the patient data, since she no longer has a VA appointment? Is there a data use agreement with the university that governs the protection and use of information? *NOTE: These questions are also pertinent if the investigator has a dual appointment at VA and the university. She must be careful to distinguish her VA time and activities from her university time and activities because when and where the data were collected affects VA versus university ownership of the data and resultant data security requirements.*

FAQs

http://vaww.portal.gla.med.va.gov/sites/Research/HSRD/CIPRS/QIEthics/Pages/faqs.aspx

4. Can I look at and collect electronic patient data?

Before looking at patient data, consider the following issues:

- Only access and/or collect the minimum necessary protected health information (PKI) and/or personally identifiable information (PII) needed to complete the aims of the project. Consult the Privacy section for more details.
- For ease of reference, here are the 18 HIPAA Identifiers.
- Non-research VHA healthcare operations activities do not generally require HIPAA authorization (see VHA Handbook 1605.1. §12) or informed consent. However, all non–research healthcare operations activities should be verified and documented as such before they are initiated (see VHA Handbook 1058.05 §6 and the Office of Research Oversight (ORO) website at http://www.va.gov/ORO/oropubs.asp).
- Access to sensitive data should be restricted to appropriate team members and only on a "need to know" basis. To stay compliant with VA and privacy regulations (HIPAA) ensure that all members of the project team who have access to or collect identifiable data have: (1) current/not lapsed VA employment status OR (2) Without Compensation (WOC) appointment, AND (3) up to date privacy training. Review the Team and Staff Data Access section for more details.
- Projects that contain research components require signed HIPAA authorization and informed consent (or Institutional Review Board (IRB) waivers) for collection, use or disclosure of protected health information (PHI), identifiable private information (per the human research Common Rule), and/or personally identifiable information. For questions, contact the local Privacy Officer and/or ORO at ORORCEP@va.gov.
- Team members need to obtain all permissions or authorizations needed to access and use existing VA data for QI purposes. VA-approved devices and equipment (encrypted computers, laptops, recorders) must be used to collect and store data, and there must be clear processes and responsibilities for securely collecting, accessing, and storing electronic and/or hard copy Protected Health Information (PHI) or Personally Identifiable Information (PII). For example, consult with your local Information Security Officer (ISO) for more information. The Data Security section provides additional details.

Resources (references, and tools)

http://vaww.portal.gla.med.va.gov/sites/Research/HSRD/CIPRS/QIEthics/Pages/Resources.aspx

Links to Policy

- List of VHA program officials authorized to provide documentation of non-research status (available on ORO site)
- The Belmont Report
- The Common Rule (45CFR46)
- VHA Handbook 1058.05: VHA Operations Activities that may Constitute Research
- VHA Handbook 1080.1: Data Use Agreements
- VHA Handbook 1200.05, Requirements for the Protection of Human Subjects in Research
- VHA Handbook 1200.12: Use of Data and Data Repositories in VHA Research (e.g., For datasets that are created for research purposes (not VA internal operations purposes only)

Samples

Bibliography

National Resources

Local Resources

VIReC
RESEARCHERS' GUIDE TO VA DATA

How does the VA operationalize ethical principles?

- Policies/regulations re: access, use, and transfer of VA data
  - HIPAA Privacy Rule
  - VHA Handbook 6500: Definition of VA sensitive data (see "Definitions")
  - VHA Handbook 1080.1: Data Use Agreements
  - VHA Handbook 1200.12: Use of Data and Data Repositories in VHA Research
  - VHA Handbook 1605.1 Privacy and Release of Information
  - VHA Handbook 1605.02 Minimum Necessary Standard for Protected Health Information

Resources: Tools

- Ethics & Compliance Project Planning Worksheet
  - Answer a series of questions about the project, e.g.,
    - Will you be collecting personally identifiable information or protected health information in this project?
    - Do you plan to access patient medical records or VA organizational data?
    - Will you be sharing personally identifiable information with staff, programs, or collaborators outside the VA?
    - What are your plans to store data and other project records and materials?
  - Lists issues to consider when planning and conducting quality improvement projects, e.g.,

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Frequently Asked Questions

What is VA sensitive data? What type of data requires HIPAA authorization?

I have a dual appointment with a university. Can I house VA data at the university?

As a PhD researcher, can I access the patient medical record?

When do I need a data use agreement? A memorandum of understanding? What is the difference between the two?

What is VA sensitive data? What type of data requires HIPAA authorization?

What is VA sensitive data?

VHA Handbook 6500

Information that requires protection due to the risk of harm that could result from inadvertent or deliberate disclosure, alteration, or destruction of the information. The term includes information whose improper use or disclosure could adversely affect the ability of VA to accomplish its mission. Includes:

- Sensitive personal information,
- Individually identifiable information
- Individually identifiable health information
- Protected health information, and
- Privacy-protected information.

What data requires HIPAA authorization

- Non-research VHA healthcare operations activities do not generally require HIPAA authorization (see VHA Handbook 1605.1. §12) or informed consent. However, all non-research healthcare operations activities should be verified and documented as such before they are initiated (see VHA Handbook 1058.05 §6 and the Office of Research Oversight (ORO) website at http://www.va.gov/ORO/oropubs.asp.

- Projects that contain research components require signed HIPAA authorization and informed consent (or Institutional Review Board (IRB) waivers) for collection, use or disclosure of protected health information (PHI), identifiable private information (per the human research Common Rule), and/or personally identifiable information. For questions, contact the local Privacy Officer and/or ORO at ORORCEP@va.gov.

As a PhD researcher, can I access the patient medical record?

As a PhD researcher, can I access the patient medical record?

- Signed HIPAA authorizations for collection, use or disclosure of patient health information (PHI) and personally identifiable information (PII) needs to be obtained as appropriate when projects or data collections are conducted as quality improvement for health operations. (Waiver of HIPAA Authorization is permitted only for research projects)

- Data containing Protected Health Information (PHI) is restricted to VA researchers. Non-VA researchers desiring access to VA data have limited pathways to obtain it.

I have a dual appointment with a university.
Can I house VA data at the university?

I have a dual appointment with a university. Can I house VA data at the university?

- Do you have necessary approval for transferring the data to the university? Does the university server meet requirements for housing VA data? Is there a data use agreement with the university that governs the protection and use of information? NOTE: These questions are also pertinent if the investigator has a dual appointment at VA and the university. The investigator must be careful to distinguish VA time and activities from university time and activities because when and where the data were collected affects VA versus university ownership of the data and resultant data security requirements.

I have a dual appointment with a university. Can I house VA data at the university? (contd)

- Note that a VA appointment that does not include the project's activities does not provide legitimate access to the project's individually identifiable patient or provider/employee data. Even with a VA appointment that includes the project's activities, dual appointment personnel, including student-hires and WOCs, must be careful to distinguish their VA time and activities from their university time and activities.

- May need to obtain consent if housing patient data at the university.

When do I need a data use agreement? A memorandum of understanding? What is the difference between the two?

When do I need a data use agreement? A memorandum of understanding? What is the difference between the two?

VHA Handbook 1080.1

Data Use Agreements: Govern the sharing of data between a Data Owner and Requestor. It defines data ownership, provides a means to transfer liability for the protection of the data, and establishes criteria for using, disclosing, storing, processing, and disposing of data.

Memorandum of Understanding (MOU): Document which defines the responsibilities of the parties entering into the agreement. MOUs are generally recognized as binding even if no legal claim could be based on the rights and obligations laid down in them.

I'm confused. Can I get a consultation with somebody? Who?

Resources

- QI Ethics & Compliance Toolkit
- Office of Research Oversight Publication & Guidance website
- VIReC Intranet Site
- VHA Data Portal
- hia@va.gov: Inquiries about data access in general, DUAs, CAPRI/VistA Web
- DART@va.gov: Inquires on the Data Access Request Tracker process
- VHA10P2CDataAgreements@va.gov : Inquiries on external data disclosures (also known as NDS Data Request)
- ORORCEP@va.gov: Office of Research Oversight (10R) Research Compliance & Education Program (RCEP)
- virec@va.gov: VIReC Help Desk

Audience Questions?

Other learning opportunities:

- VIReC Database and Methods Seminar Series. Requesting Access to VA Data for Research and Quality Improvement (11/2/2015)
- Upcoming: QUERI Implementation Network. VHA's Moral Obligation to Quality Improvement: Ethics and the Common Rule within a Learning Healthcare Organization (12/3/2015)