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) and the VA National Center for Ethics in Health Care
- Provides guidance to:
  - Pre-emptively identify and address potential harms or unintended consequences
  - Minimize the potential for misunderstanding of project activities
  - Provide documentation to clarify a project’s research and/or QI status
Basic ethical principles of respect for persons, beneficence, and justice apply to all activities.

Maintain a constant ethical mindset, always pay attention to potential ethical & compliance issues, and seek ongoing consultation & accountability.
HOME PAGE

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About this site:
This web-based repository of guidance, resources, and tools was created to help VA researchers successfully adhere to the above three principles. The resources available within this website are intended to present researchers with many of the ethical issues that can be considered during a QI/IR project, share guidance and tools, and broaden awareness of potential ethical concerns. Quick Links are provided below for immediate access to some of the most used tools and resources, otherwise you may access our Principles, Scenarios, or Resources pages. For answers to frequently asked questions, please visit our FAQs page.

What you will find on this site:

- Principles: A comprehensive matrix of ethics topics, discussion points, and links to scenarios related to VA QI/IR ethics. The matrix is based on the Belmont Report’s basic ethical principles of respect for persons, beneficence, and justice.
- Scenarios: Case studies and scenarios that illustrate ethical and compliance issues that may present themselves during VA QI/IR projects.
- Resources: A collection of resources, references, and tools related to VA QI/IR ethics and compliance issues. This includes guidance on obtaining research approval, documentation requirements, and accountability of ethical issues.
- FAQs: Answers to frequently asked questions about ethical and compliance issues in VA QI/IR projects.

Quick Links:
Immediate access to some of the most used tools and resources:

- Office of Research Oversight (ORO) Decision Chart for QI vs Research: This document contains the criteria to determine if QI activity constitutes research or can be determined a non-research activity.
- Level of Review Recommendations Based on Project Activities: This document helps a project team to promptly and effectively identify and address potential ethical issues. Note: This worksheet is to be used only if the project is not a QI activity.
- Ethics & Compliance Project Planning Worksheet: This document provides a list of different project planning activities, including the identification of potential ethical issues, analysis of participants and proximity to research activities, and suggests the level of oversight for the project.

Information about what you will find on this site.

Quick Links (hyperlinks) for those familiar with the site (e.g., link to list of officials who can give a determination of non-research)

Discussion Board
Do you have questions or discussion topics about QI Ethics & Compliance issues? Please post them here.

*Note: This board is moderated

Post to the Discussion Board for questions and/or feedback
Operationalization of the Belmont Ethical Principles into day-to-day issues and consideration

Hyperlinks to Scenarios (case studies) and FAQs that illustrate the topic

**Principles**

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

<table>
<thead>
<tr>
<th>Topic</th>
<th>Discussion points and things to consider</th>
<th>Scenarios/FAQs</th>
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| Privacy      | * For projects that involve direct patient interaction, are the patient’s wishes to maintain a private personal space considered?  
* The QI team should access or collect only the minimum necessary personally identifiable information needed to complete the aims of the project  
* Consider and respect gender or culturally-specific privacy needs. | Scenario 6: Evaluation vs Privacy  
FAQ #4: Can I look at and collect electronic patient data?  
FAQ #5: Can I contact patients for my non-research project? |
| Consent      | * Create a transparent process of obtaining consent which includes participant’s acknowledgement that they have received information about the project.  
* Is the consent process documented? This may or may not involve written consent from the participant, depending on the nature of the project. For example, in some cases, tracking and documenting patient contact and the existence of a protocol for providing consistent information is sufficient.  
* If participants are contacted about involvement in the QI intervention or evaluation, are they provided with information that ensures:  
* Management in the project ensures that the data are not lost or destroyed  
* Management in the project maintains the confidentiality of the data  
* Management in the project makes sure that the data are not used or disclosed to other people or organizations | Scenario 1: Patient Privacy and Home Visits  
Scenario 2: VISN Staff Survey  
Scenario 6: Evaluation vs Privacy  
FAQ #7: Do I need informed consent in non-research activities? |
Scenarios (case studies) of how ethical/regulatory issues may present in quality improvement/implementation research activities.

Scenario 1: Patient Privacy and Home Visits

Ethical issues to consider

Consent: Look over the script that the project coordinator used to inform the patient about the intervention. Was the patient comprehensively informed about her options? Was there a way for the patient to acknowledge she had received information about the intervention? Was consent documented? Did she receive a written copy of this information?

Respect for Individuals: Was the patient provided with information that ensures she understood what her involvement entails? Was she told the how contact information would be handled?

Patient Choice: Did the patient have the opportunity to make a choice? Did the patient’s decision to participate in the intervention have been factored in, rather than the needs of the study?

Respect for Autonomy: Did the patient have the opportunity to freely participate in the intervention?

Scenario 2: VISN Staff Survey

Scenario 3: Staff Outside the VA

Scenario 4: QI Regulatory Issues Despite VISN Approval

Scenario 5: Education vs Patient Care

Scenario 6: Evaluation vs Privacy

Hyperlink to relevant topic on “Principles” page
FAQs

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

A compilation of frequently asked questions (e.g., is my project considered QI or research?)

Answers and hyperlinks to relevant resources, materials, and pages on the site
Resources, references, and tools related to quality improvement/implementation research ethics and compliance.

Do you have any resources you would like to share? Post on our Discussion Board.

### Tools

- **Office of Research Oversight (ORO) Decision Chart** for determining whether or not a quality improvement (QI) activity constitutes research.
- **Level of Review Recommendations Based on Project Activities**: This document provides a list of different study designs and classifies them into risk categories (depending on burden to participants and proximity to research activities), and suggests oversight for the projects that employ them.
- **Ethics & Compliance Project Planning Worksheet**: This document helps a project team map out the quality improvement activities of a project in order to pre-emptively identify and address potential ethical issues. **Note**: This worksheet is to be used only after a QI activity is determined to be non-research.
- **18 HIPAA Identifiers**: For ease of reference, we have provided the Health Insurance Portability and Accountability Act identifiers.

### Samples

- **Sample Letter for Officials Authorized to Provide Documentation of VHA Program Office Non-Research Activities**: For projects supported by a national program office, a request letter from one of the program offices listed in the VHA Handbook 1058.403d or the VHA Handbook 1058.603d.

Hyperlinks to tools, downloadable templates, and web resources (e.g., ORO decision chart for determining QI or research)

A compendium of tools, sample documents, links to relevant policy, resources at the local & national level, and a bibliography

Resources:

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