

# QUALITY IMPROVEMENT (QI)/IMPLEMENTATION RESEARCH (IR) ETHICS & COMPLIANCE TOOLKIT

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

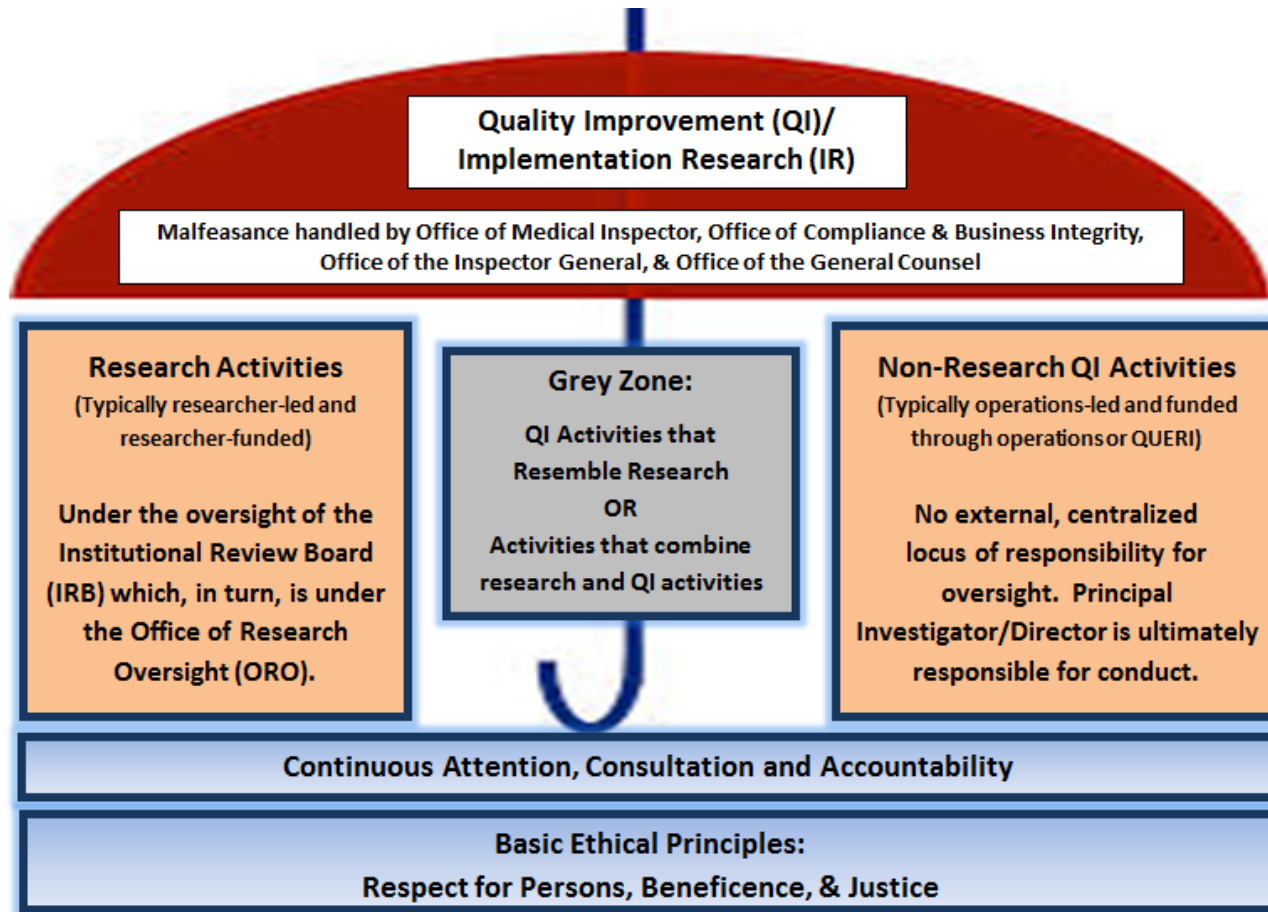
- CIPRS product, created with support from QUERI Program and HSR&D COIN in Los Angeles
- Inspired by local (VA Greater Los Angeles) experience with ethical/regulatory issues in quality improvement projects
- Content reflects conversations with the Office of Research Oversight (ORO) and the VA National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



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



# OVERARCHING ETHICAL/REGULATORY “UMBRELLA” FRAMEWORK



- 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

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

## 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 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.

[Resources](#): A collection of resources, references and tools related to VA QI/IR ethics and compliance accountability of ethical issues.

[FAQs](#): Answers to frequently asked questions about ethical and compliance issues in VA QI/IR projects.

Information about what you will find on this site.

## 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 information on how to determine if a quality improvement (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 manager proactively identify and address potential ethical issues. Note: This worksheet is to be used only for non-research activities.
- ▶ [Ethics & Compliance Project Planning Worksheet](#): This document provides a list of different types of research activities (participants and proximity to research activities), and suggests the level of oversight for the project.

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 to the Discussion Board](#).

\*Note: This board is moderated



[+ new discussion](#)

Post to the **Discussion Board** for questions and/or feedback

# PRINCIPLES

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

## Overarching Ethical Principles

Topic	Discussion points and things to consider	Scenarios/FAQs
<b>Privacy</b> 	<ul style="list-style-type: none"><li>* For projects that involve direct patient interaction, are the patient's wishes to maintain a private personal space considered?</li><li>* The QI team should access or collect only the minimum necessary personally identifiable information needed to complete the aims of the project</li><li>* Consider and respect gender or culturally-specific privacy needs.</li></ul>	<ul style="list-style-type: none"><li><a href="#">Scenario 6: Evaluation vs Privacy</a></li><li><a href="#">FAQ #4: Can I look at and collect electronic patient data?</a></li><li><a href="#">FAQ #5: Can I contact patients for my non-research project?</a></li></ul>
<b>Consent</b> 	<ul style="list-style-type: none"><li>* Create a transparent process of obtaining consent which includes participant's acknowledgement that they have received information about the project.</li><li>* 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.</li><li>* If participants are contacted about involvement in the QI intervention or evaluation, are they provided with information that ensures:</li></ul>	<ul style="list-style-type: none"><li><a href="#">Scenario 1: Patient Privacy and Home Visits</a></li><li><a href="#">Scenario 2: VSN Staff Survey</a></li><li><a href="#">Scenario 6: Evaluation vs Privacy</a></li><li><a href="#">FAQ #7: Do I need informed consent in non-research activities?</a></li></ul>

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

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

# SCENARIOS

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



[Scenario 1: Patient Privacy and Home Visits](#)

[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](#)



## Scenario 1: Patient Privacy and Home Visits

A patient has been enrolled in an intervention that involves home visits. When the project coordinator contacts the patient to schedule the first home visit, the patient says that she does not want anyone to visit her home. The project coordinator explains that she can choose not to allow the visit, but this means that she will not receive any of the benefits of

participation in the intervention. The patient reluctantly consents to the home visit. When an intervention coordinator for the project visits the patient's home to meet with him, the patient claims that she did not consent to the visit. She files a complaint with the VA.

## 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 used?

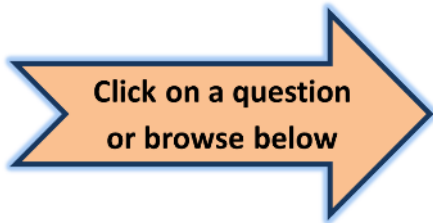
**Patient Care:** Was the patient's care affected by the intervention? Was the patient given to have a personal, familiar to the intervention?

Scenarios (case studies) of how ethical/regulatory issues may present in quality improvement/implementation research activities

Hyperlink to relevant topic on "Principles" page

# FAQs

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



- [2. Who can give me a determination of non-research?](#)
- [3. What local and national resources exist to help me with ethical and compliance-related issues?](#)
- [4. Can I look at and collect electronic patient data?](#)
- [5. Can I contact patients for my non-research project?](#)
- [6. Can I contact providers for my non-research project?](#)
- [7. Do I need informed consent in non-research activities?](#)
- [8. This is a patient intervention. Do I need to obtain the consent of the patient's provider for him/her to participate?](#)
- [9. Can I publish a manuscript based on a non-research project?](#)

## ▶ 1. Is my project considered research or quality improvement?

- A determination of research/non-research/quality improvement may not be static. If the project evolves, the determination may change.
- A project can have components that are research and components that are quality improvement.

As for whether an activity is considered research or non-research/quality improvement.

- The VA Office of Research Oversight (ORO) has created a [decision chart to help determine whether or not a quality improvement activity constitutes research](#). It is available on their website.
- The VA Office of Research & Development (ORD) website has an archive of an [ORO presentation about VHA Handbook 1058.05 - VHA Operations Activities that](#)

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

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

## 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 places 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 only used 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 (HIPAA) identifiers.

### Samples



• **Sample Letter for Officials Authorized to Provide Documentation of VHA Program Office Non-Research Op**

**Activities:** For projects supported by a national program office, this letter from the national program offices listed in the VHA Handbook 1058.00-01, Office Non-Research and/or Human Subjects Research.

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

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