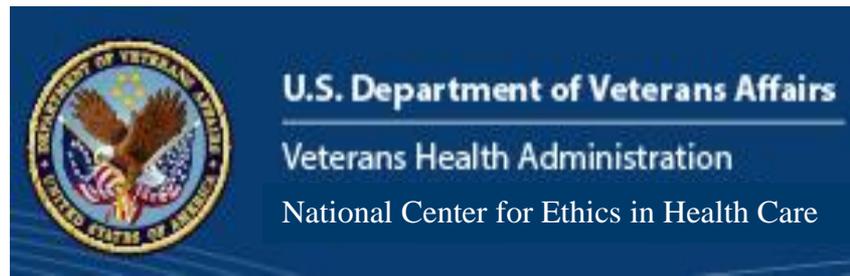


VHA's Moral Obligation to Quality Improvement: Ethics and The Common Rule Within A Learning Health Care System



December 3, 2015

QUERI Implementation Network



Opening Remarks

- Amy Kilbourne, PhD, MPH, Director, QUERI

Panelists

- Melissa Bottrell, PhD, Chief, IntegratedEthics, VA National Center for Ethics in Health Care
- Tom Puglisi, PhD, Chief Officer, VA Office of Research Oversight
- Nina Smith, MPH, Communication & Dissemination Coordinator, CIPRS

Objectives

- Discuss current thoughts re: Common Rule in learning health care systems
- Provide an overview of VA policies that govern research and quality improvement (QI) activities
- Provide information about the QI Ethics & Compliance Toolkit
- Answer frequently asked questions in this area
- Provide resources for additional concerns in this area

What is the common rule?

- Outlines the basic provisions for IRBs, informed consent, and Assurances of Compliance.
- For VA, the Common Rule is encoded through Title 38 Code of Federal Regulations Part 16 (38 CFR 16)
- The Office of Research Oversight (ORO) (10R) has the authority and responsibility to enforce the Common Rule for VA research

Common rule & learning healthcare systems

“... the mechanism developed to govern ethical conduct in one important area - human subjects research - could have the perverse, if unintended, consequence of interfering directly with an equally important ethical imperative in another area - that is, unceasing efforts by health care professionals to make clinical care safer and more effective. The current state of uncertainty about what is ethically and legally required to safeguard participants in QI activities has already become a disincentive to engage in QI, making it more difficult to bring about the system transformation urgently needed if health care is to be made better and safer for patients.” (Hastings Center Report 2006)

Common rule & learning healthcare systems

“... health care institutions have a moral obligation to become learning organizations that continually improve the quality, value, and efficiency of care in support of a just health care system.... [However] the traditional distinctions between research and clinical practice - distinctions that for almost forty years have provided an ethical and regulatory framework for our current human research protection system - have become blurred from a moral perspective and outmoded from a practical perspective.” (Puglisi in Hastings Center Report 2013)

Ethical requirements for protection of human participants in QI activities

From Hastings Center Report 2006: The ethics of using QI methods to improve health care quality and safety.

Social or scientific value

The gains from a QI activity should justify the resources spent and the risks imposed on participants.

Scientific validity

A QI activity should be methodologically sound— properly structured to achieve its goals.

Fair subject selection

Participants should be selected to achieve a fair distribution of the burdens and benefits of QI.

Ethical requirements for protection of human participants in QI activities (contd)

Respect for participants

- A QI activity should be designed to protect the privacy of participants through confidentiality
- Participants in a QI activity should receive information about findings from the activity that are clinically relevant for their own care.
- All patients and workers in a care delivery setting should receive basic information about the program of QI activities.
- QI results should be freely shared with others in the health care system, with participant confidentiality protected by putting results into nonidentifiable form or obtaining specific consent to sharing.

Informed consent

- Patients should give background consent to inclusion in minimal risk QI activities as part of consent to receive treatment.

Ethical requirements for protection of human participants in QI activities (contd)

Informed consent [contd]

- Patients should be asked for informed consent to be included in a specific QI activity if the activity imposes more than minimal risk.
- The risk-harm ratio for patients is measured relative to the risk associated with receiving standard health care.
- Workers (employees or nonemployee professionals who provide care within an organization) are expected to participate in minimal risk QI activities as part of their job responsibilities.
- Workers should be asked for their informed consent to inclusion in a QI activity that imposes more than minimal risk
- The risk to workers is measured relative to the risk associated with the usual work situation and does not include any risk to economic security that might result if a QI activity reveals that the worker is incompetent or that the organization can provide quality care with fewer workers.

Ethical requirements for protection of human participants in QI activities (contd)

Independent review

Accountability for the ethical conduct of QI should be integrated into the system of accountability for clinical care. Each QI activity should receive the kind of ethical review and supervision that is appropriate to its level of potential risk and project worth.

VA Implementation of Common Rule

VHA Handbook 1058.05: VHA Operations Activities that may Constitute Research

VHA Handbook 1200.05, Requirements for the Protection of Human Subjects in Research

- Created a risk-appropriate protection system that establishes accountability not only for research activities but also non-research health care operations activities.
- Establishes oversight accountability and documentation requirements for activities that do not constitute research
- Provides a mechanism for publishing results of nonresearch activities

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

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

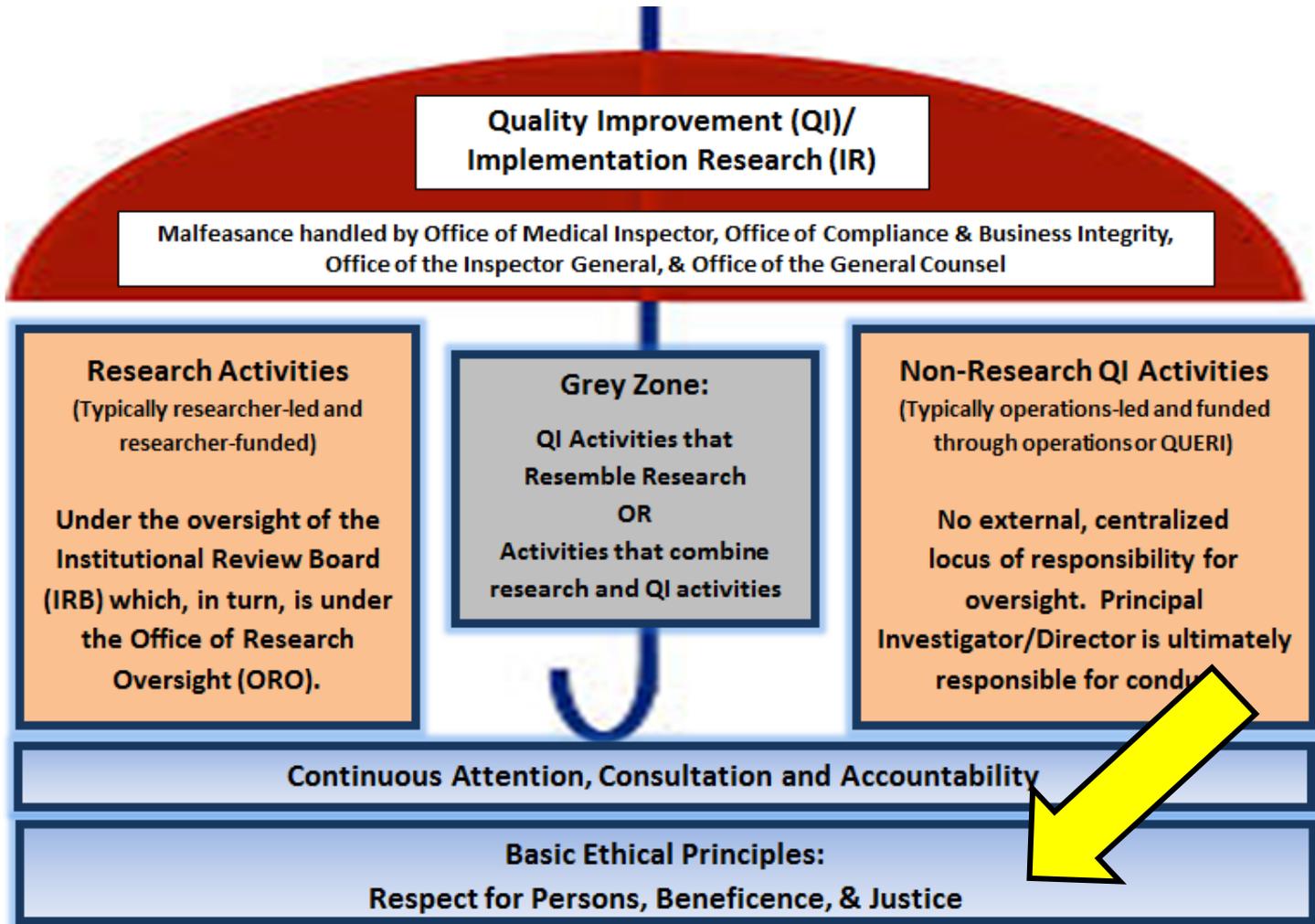
- CIPRS product, created with support from QUERI Program and HSR&D COIN in Los Angeles
- Inspired by QUERI & local (VA Greater Los Angeles) experience with ethical/regulatory issues in quality improvement projects
- Content reflects conversations with the Office of Research Oversight (ORO), the VA National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



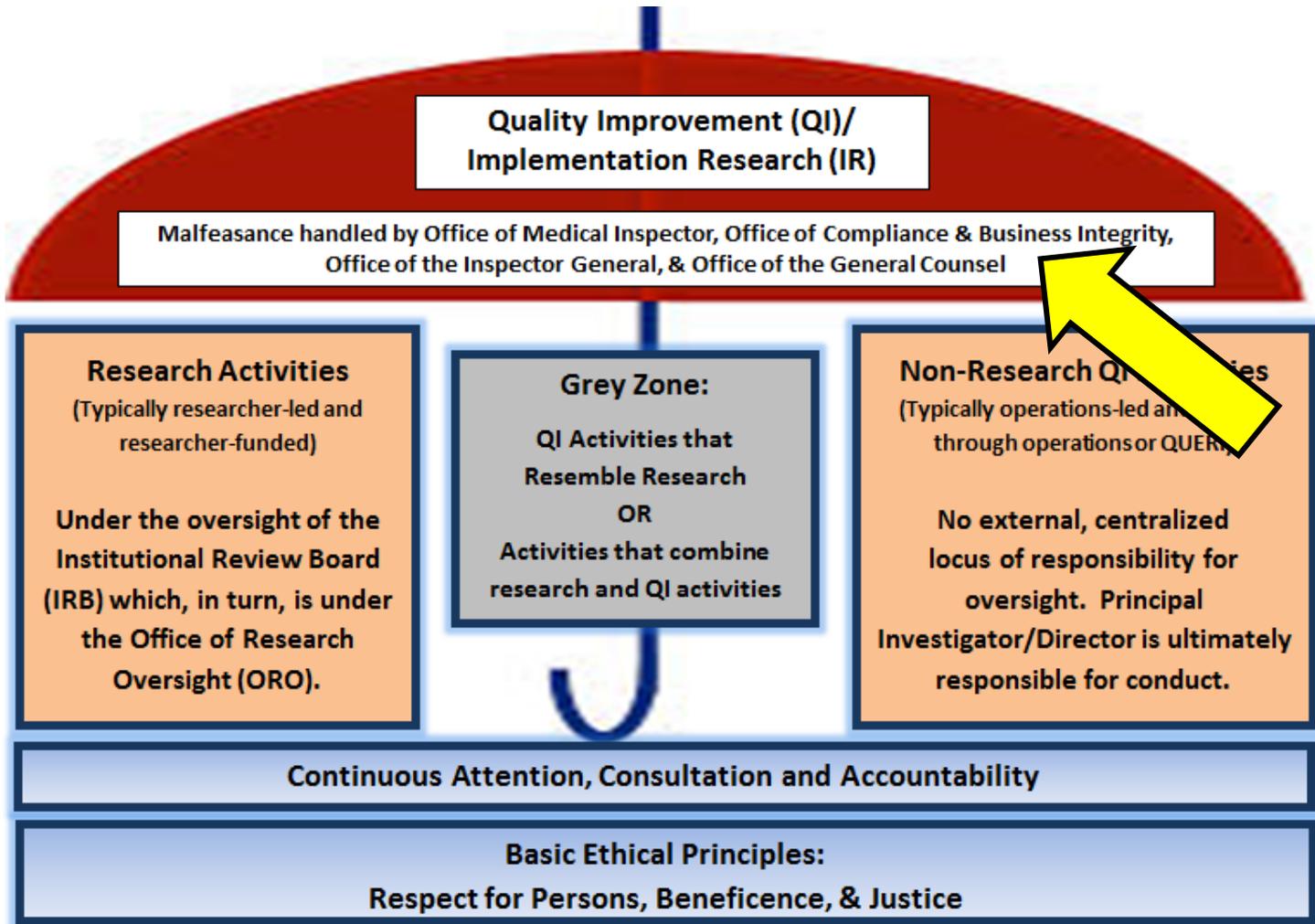
CSHIIP
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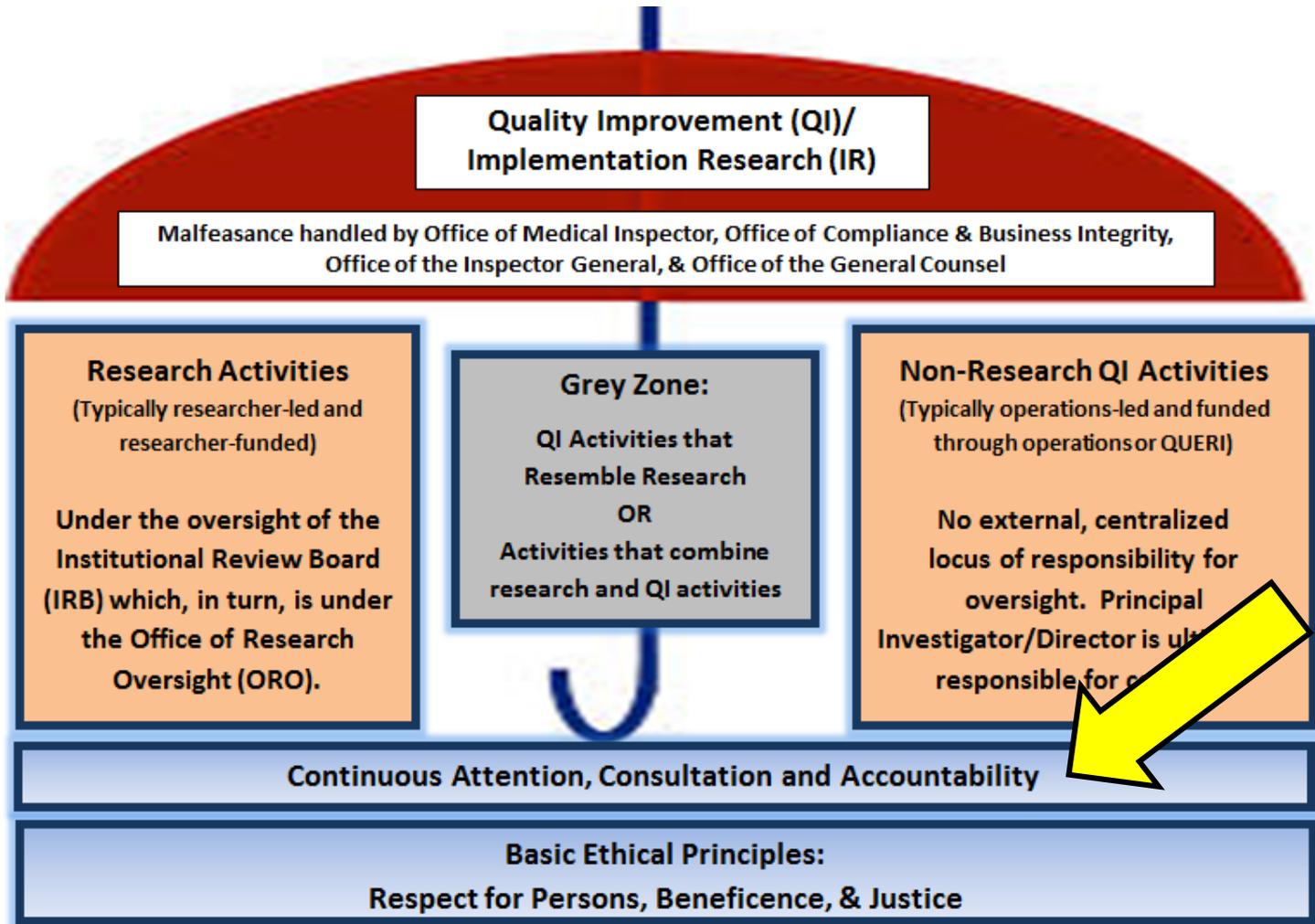
Ethics & Regulation in VHA



Ethics & Regulation in VHA



Ethics & Regulation in VHA



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, e.g.,

<p>Privacy</p>  <p>PRIVACY POLICY</p>	<p>Consent</p> 	<p>Fairness and Disparities</p> 
<p>Patient Centeredness</p> 	<p>Conflicts of Interest</p> 	<p>* Provide staff with, and train them on the use of, protocols for responding to distress or identified needs required to ensure patient safety and security. This is relevant at all times, but especially in the case of working with vulnerable populations or when asking sensitive questions.</p> <p>NOTE: What is a vulnerable population? The Belmont Report notes that those with limited or compromised autonomy should be protected. The Common Rule specifically lists pregnant women, fetuses or neonates; prisoners; and children as specific vulnerable populations. IRBs have also noted that the following populations require, when appropriate, additional safeguards: Veterans, persons with mental disabilities or economical disadvantages, educationally disadvantaged persons, and employees and students.</p>

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 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 nurse shows up for the home visit, the patient refuses to let him in, claiming that she never agreed to the visit and that her privacy is being violated. She files a complaint with the Office of the Inspectors General.

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 Centeredness and Vulnerable Populations: Was there proper attention given to the needs of women participants? Could the Project Clinician for the home visit have been female instead of male? Could arrangements have been made for another person, familiar to the patient, to be present at the home visit? Could the patient participate in the intervention without having the home visits?

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?

- For projects involving a local facility or VISN, the facility or VISN Director or his/her designee can provide a letter documenting QI status. However, many facilities designate their Institutional Review Board (IRB) or Research and Development Committee to provide documentation for projects considered QI. You can review the [Research vs QI Determination](#) section for more details.
 - The "[Resources](#)" section of this site has Sample Requests for Human Research Protection Program Determination of Non-Human Research/Quality Improvement or Other Activity not Requiring IRB Approval. These samples can be downloaded for your editing.
- Some VHA program officials are authorized to provide documentation of QI status. The [Office of Research Oversight \(ORO\)](#) has a list of program officials who have this authority (on their website). It is helpful to provide these officials with a letter for them to review and sign, if appropriate.
 - The "[Resources](#)" section of this site has Sample Letters for Officials Authorized to Provide Documentation of VHA Program Office Non-Research Operations Activities. These samples can be downloaded for your editing.
- If you have a project that crosses organizational levels, e.g., multi-VISN projects:
 - It is advisable to inform all levels of the organization about the project.
 - The project lead should keep a copy of the determination of non-research/quality improvement and be ready to furnish it at any point.

Resources (References and Tools)

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

Samples



- **Sample Letter for Officials Authorized to Provide Documentation of VHA Program Office Non-Research Operations Activities:** For projects supported by a national program office, QI status must be documented via a letter from one of the VHA program offices listed in the VHA Handbook 1058.05. Here are several examples of Letters for Officials Authorized to Provide Documentation of VHA Program Office Non-Research Operations Activities:
 - [Sample 1](#)
 - [Sample 2](#)
 - [Sample 3](#)
- **Request for Human Research Protection Program (HRPP) Determination of Non-Human Research/Quality Improvement or Other Activity not Requiring IRB Approval:** Here we provide two versions of forms to request a determination whether an activity/project is considered research and/or human subjects' research. These forms can be used as a template for similar determination from other Institutional Review Boards.
 - [Sample from the VA Greater Los Angeles Healthcare System](#) (version dated Sept 1, 2015)
 - [Sample from the VA's Central Institutional Review Board](#) (go to link for Form 118: Request for Determining Whether an Activity/Project is Research and/or Human Subjects Research)
- **ORO Sample Format for Documentation of Non-Research Activities** for:
 - [Peer-Reviewed & Other Publications](#)
 - [Intramural & Extramural Presentations](#)

Links to Policy



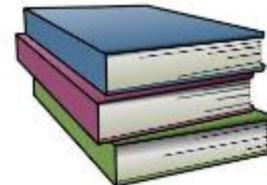
Local Resources



National Resources



Bibliography



Resources: Tools

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, groups them into risk categories (depending on burden to participants and proximity to research activities), and suggests the level of 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 (HIPAA) identifiers.

Resources: Tools

○ Ethics & Compliance Project Planning Worksheet

- Answer a series of questions about the project, e.g.,
 - Will providers and staff be involved in this QI intervention?
 - Will patients be involved?
 - Do you plan to interview or survey patients or invite patients to focus groups?
 - Do you plan to interview or survey providers?
- Lists issues to consider when planning and conducting quality improvement projects, e.g.,

Resources: Tools

○ Level of Review Recommendations Based on Project Activities

- List of different study designs
- Groups them into risk categories (depending on burden to participants and proximity to research activities)
- Suggests the level of oversight for the projects that employ them

Resources: Tools:

Level of Review Recommendations Based on Project Activities

Project activities include only minimal burdens or risks and/or are usually considered to be non-research operations activities

Review Level Recommendation:

- Submit to the IRB for a determination of non-research.
- Review the [Ethics & Compliance Project Planning Worksheet](#) to identify any potential ethical or regulatory concerns.

- Retrospective or current reviews of existing data *NCE 2002*
- Patient or provider satisfaction or experience surveys *1058.05(5)a; NCE 2002*
- Population-based activities related to improving health, ensuring safety, or reducing health care costs; and case management and care coordination. *1058.05(4)b*
- Reviewing the competence or qualifications of health care professionals, evaluating provider performance; training health care and non-health care professionals *1058.05(4)b*

Educational interventions designed to promote evidence-based practices, and

- related evaluation activities, as long as they are designed and/or implemented for internal VA purposes only. *NCE 2002; 1058.05(4)e*
- Performance evaluations *1058.05(5)a*
- Root cause analyses *1058.05(5)a*
- Quality assessment and quality improvement activities designed for internal VA purposes only
- Medication Use Analysis *1058.05(5)a*
- Policy and guideline development and related evaluation activities *1058.05(5)a*

Frequently Asked Questions

How can I tell if my project is research or QI?

How should I contact patients for my QI project?

Do I need to document informed consent in a QI project?

How should I contact providers for my QI project?



How can I tell if my project is
research or QI?

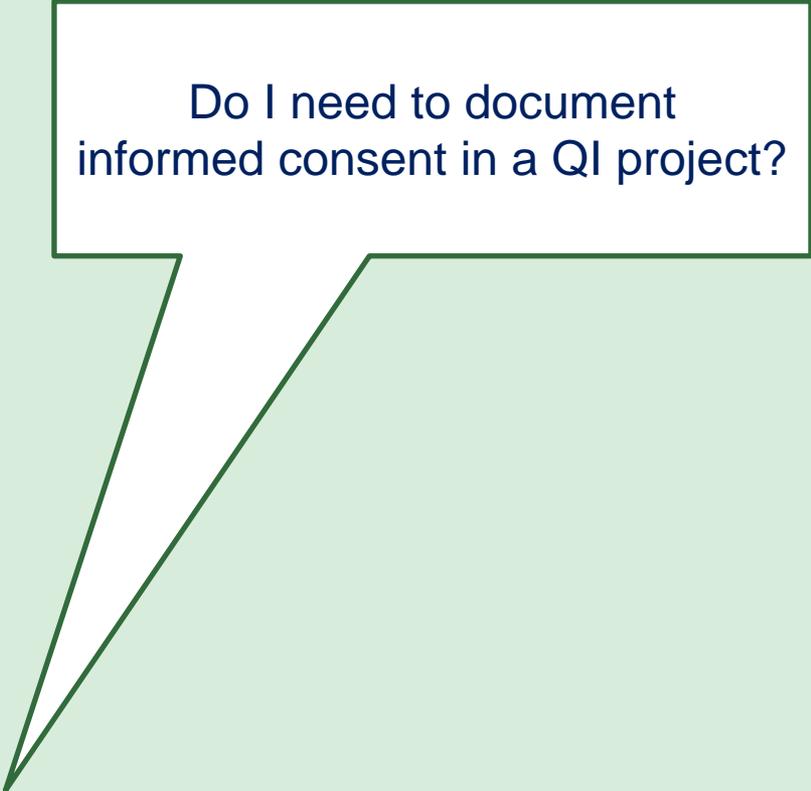
How can I tell if my project is research or QI?

Through the Institutional Review Board (IRB), determine if your project will obtain an IRB determination of non-research, or VA's administrative documentation of non-research. This is recommended for multi-site or complex projects and required by many journals prior to publication (check journal websites for specific requirements).

In order to be determined QI, your project should meet both of the following criteria:

- The project is intended to improve VA processes or care.
- The project is not intended to contribute to generalizable knowledge in a scientific field or discipline.

A determination of research/non-research/quality improvement may not be static. If the project evolves, the determination may change.



Do I need to document
informed consent in a QI project?

Do I need to document informed consent in a QI project?

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.

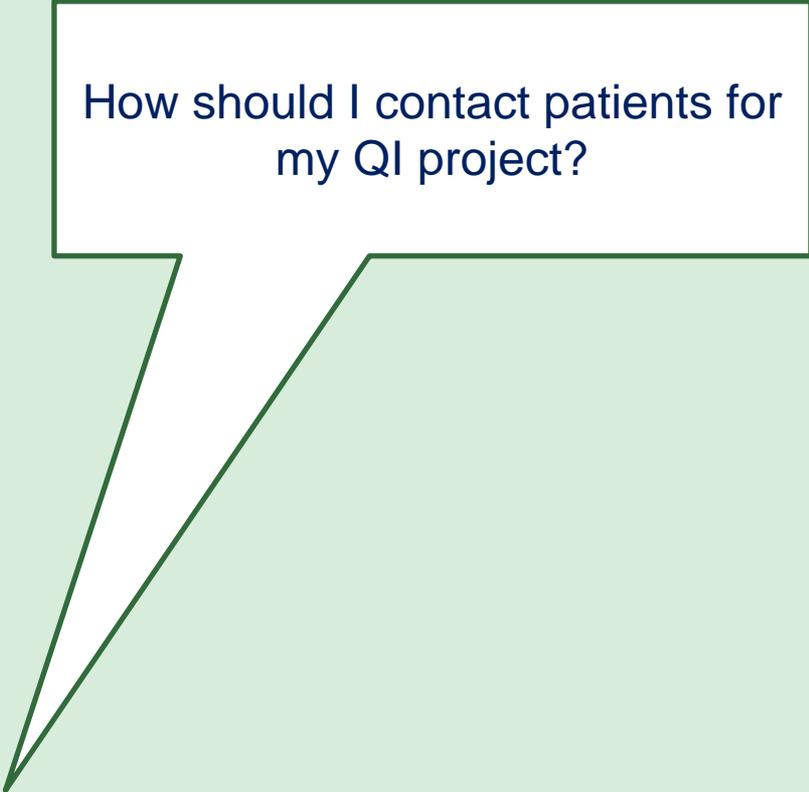
If participants are contacted about involvement in the QI intervention or evaluation, are they provided with information that ensures:

- They understand what their involvement in the project entails.
- They understand under what circumstances data they provide or information about them will be used or disclosed to providers or others.

Do I need to document informed consent in a QI project? (contd)

As applicable, adequate information should be provided to individuals so that they understand:

- If participation is voluntary.
- If they will be compensated
- Whether or not they are likely to derive direct benefit.



How should I contact patients for
my QI project?

How should I contact patients for my QI project?

Collections of information from more than 9 patients in a 12 month period should be submitted to QUERI to determine whether documentation is needed for OMB review under the Paperwork Reduction Act. A collection is considered to count towards the maximum of 9 if the information being collected is similar to, or will be compared or analyzed with, other data collected during that 12-month period, e.g., the differences introduced by adapting a questionnaire or guide to apply to different subsets of the patient population is not considered substantial enough to count each patient subset as a new 9-person collection in the same year.

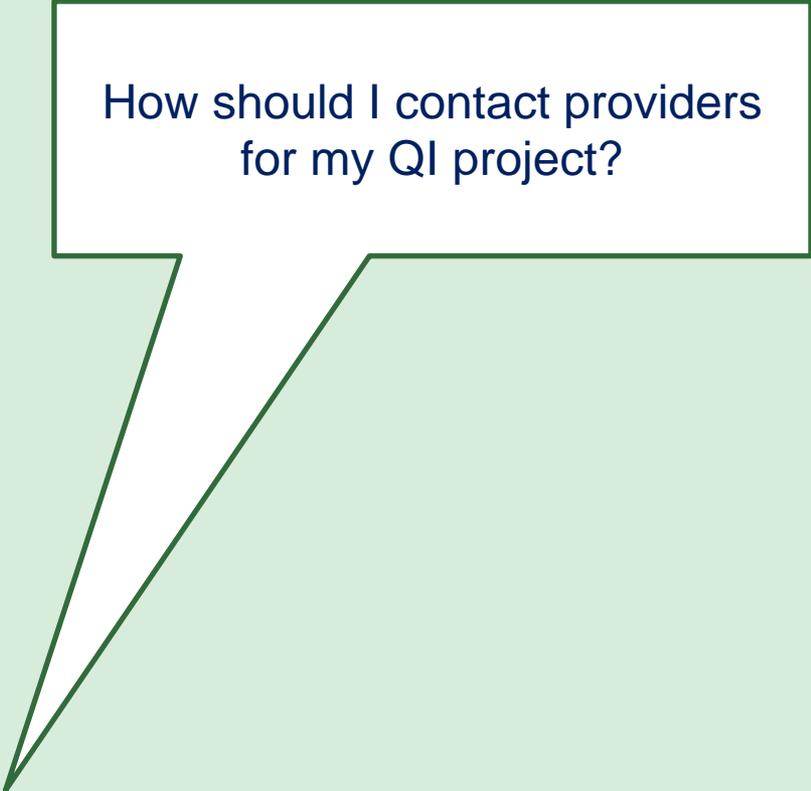
Your project may be exempt if it addresses treatment or prophylaxis. There is a list of possible exemptions on page 7 of the [Memorandum re: Information Collection under the Paperwork Reduction Act \(Generic Clearances/OMB review exemption\)](#), dated April 7, 2010.

How should I contact patients for my QI project? (contd)

Keep in mind that every effort should be made to respect a patient's privacy. For example, a patient may not want to discuss matters within earshot of others. Also keep in mind that the patient may have gender or culturally-specific privacy preferences.

Remember that the reason why we work in the VA is to serve the Veteran. As such, all interactions should reflect this patient-centered principle. Also, keep in mind that the patient may have gender or culturally-specific privacy and communication preferences.

When working with vulnerable populations or when asking sensitive questions, make sure that project staff have and follow protocols for responding to distress or identify needs required to ensure patient safety and security.



How should I contact providers
for my QI project?

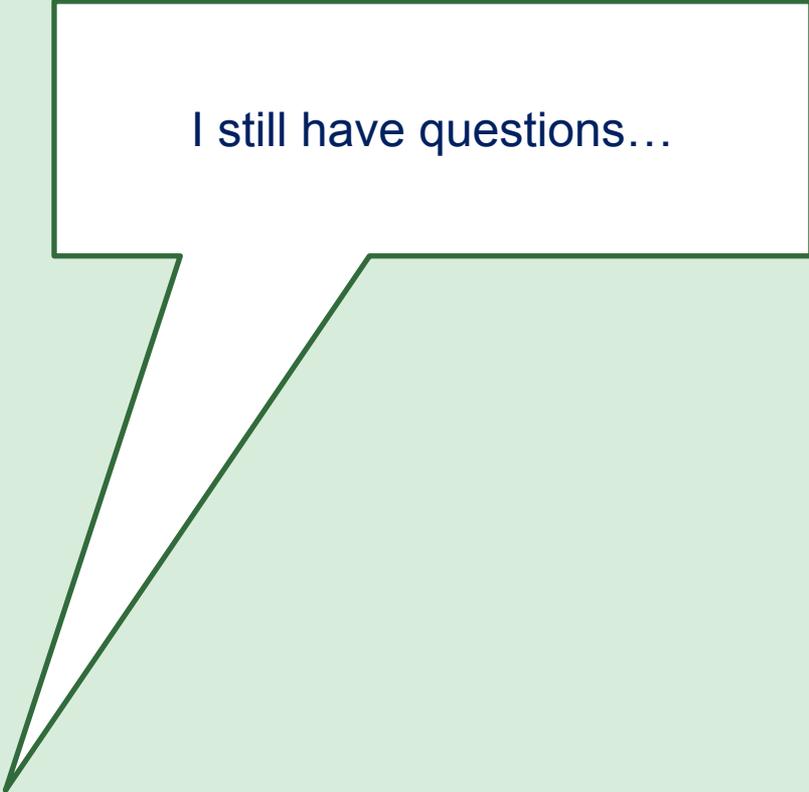
How should I contact providers for my QI project?

It is important to keep in mind how the activity will impact Staff Resources and how to, as much as possible, decrease Burden on staff resources to prevent burnout or overload. Keep in mind not only the burden from your particular quality improvement activity, but also from other competing/prior activities involving the providers.

It is best to encourage Leadership Support and Stakeholder Involvement in the project by keeping provider leadership and providers informed about the project and ideally involving them in planning and implementing the project. This encourages support for the project and the project's chances for successful implementation.

How should I contact providers for my QI project?

Labor unions are also project stakeholders. Unions at the VA have negotiated the right to be notified prior to commencing data collections involving employees. The requirement is a 2-4 week notification period, depending on the unions. During that period, the union may contact the project lead with questions. You may need to contact a site's Human Resources (HR) representative for information on who to contact and how to proceed. Senior investigators who have worked in different sites could also, potentially, provide advice. If surveying providers in multiple VISNs, the project will need to go through the Organizational Assessment Sub-Committee (OASC) Review and National Union Notification process. Information about this process exists on the national VA Office of Research & Development (ORD) website.



I still have questions...

I still have questions...

- Sponsor of the quality improvement project
- [QI Ethics & Compliance Toolkit](#)
- [Office of Research Oversight Publication & Guidance website](#)
- ORORCEP@va.gov: Office of Research Oversight (10R) Research Compliance & Education Program (RCEP)
- VHAethics@va.gov: [VA National Center for Ethics in Health Care](#)

References

- Baily MA, Bottrell M, Lynn J, Jennings B, Hastings Center. The ethics of using QI methods to improve health care quality and safety. *Hastings Cent Rep.* 2006 Jul-Aug;36(4):S1-40.
- Puglisi T. Reform within the common rule? Commentary. *Hastings Cent Rep.* 2013 Jan-Feb;Spec No:S40-2.