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

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

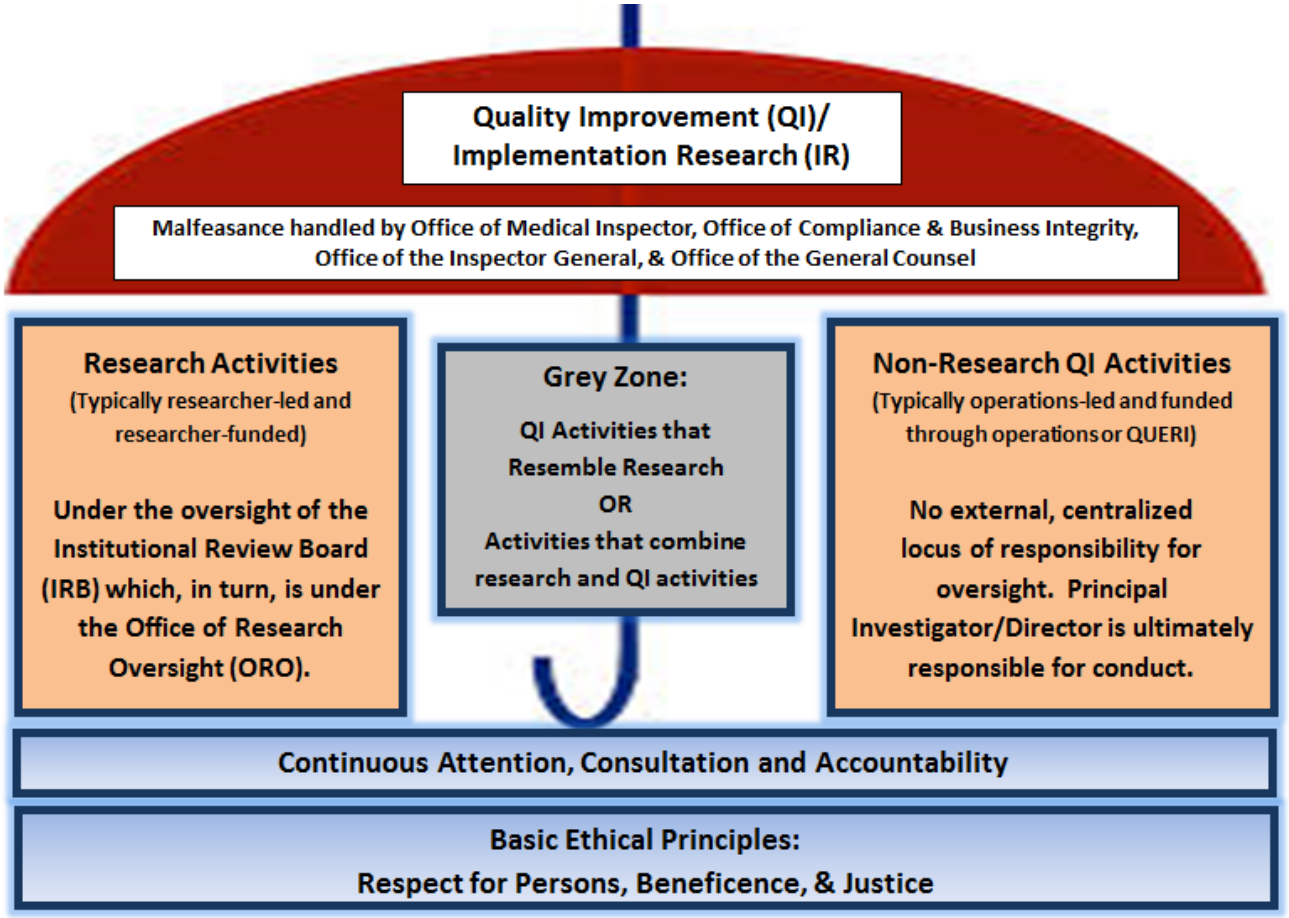
- CIPRS product, created with support from QUERI Program and HSR&D COIN in Los Angeles
- Inspired by local (VA Greater Los Angeles) experience with ethical/regulatory issues in quality improvement projects
- Content reflects conversations with the Office of Research Oversight (ORO) and the VA National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

CIPRS Center for Implementation Practice and Research Support

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

VA QUERI Quality Enhancement Research Initiative

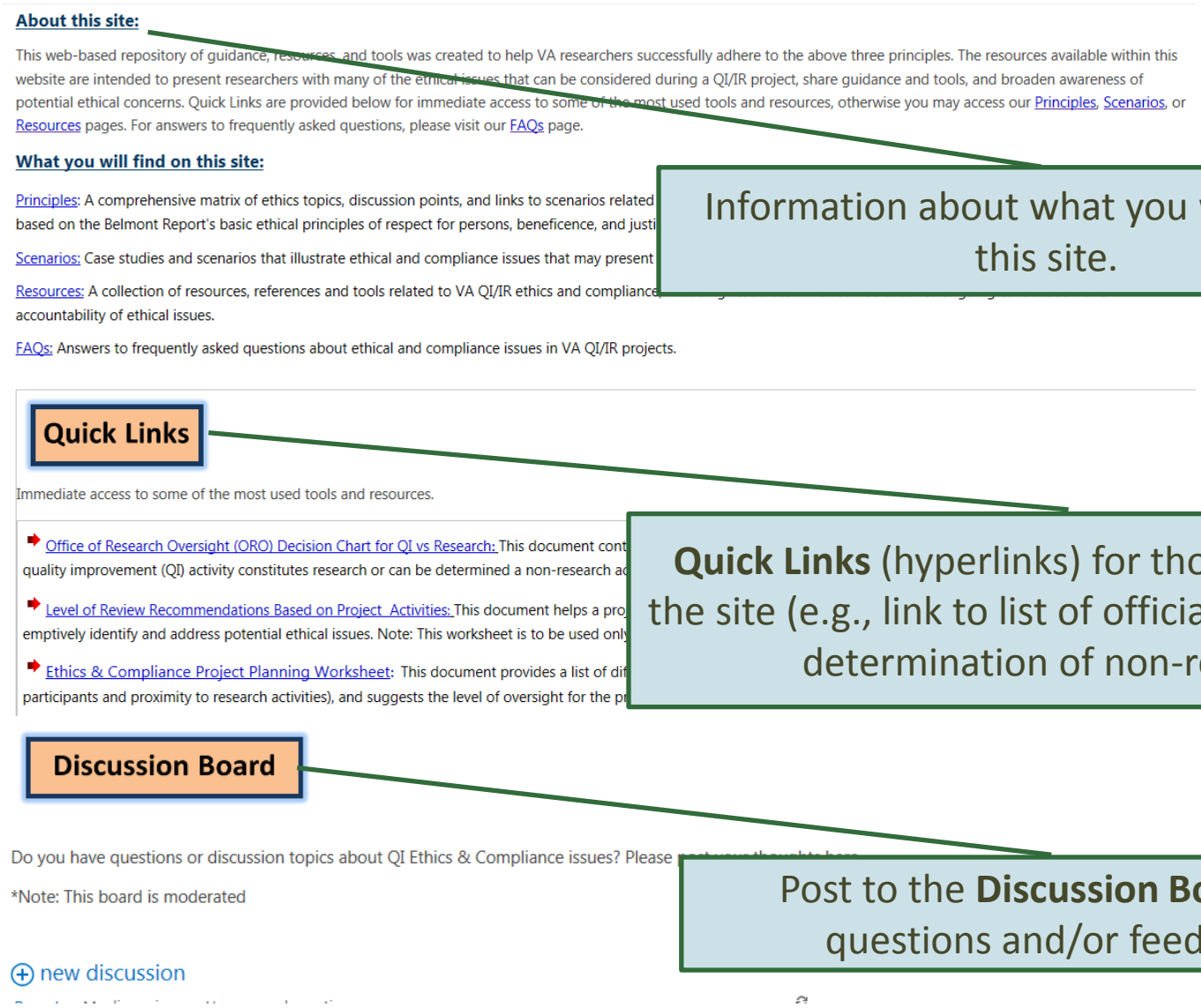
Overarching Ethical/Regulatory "Umbrella" Framework



- 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



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)

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

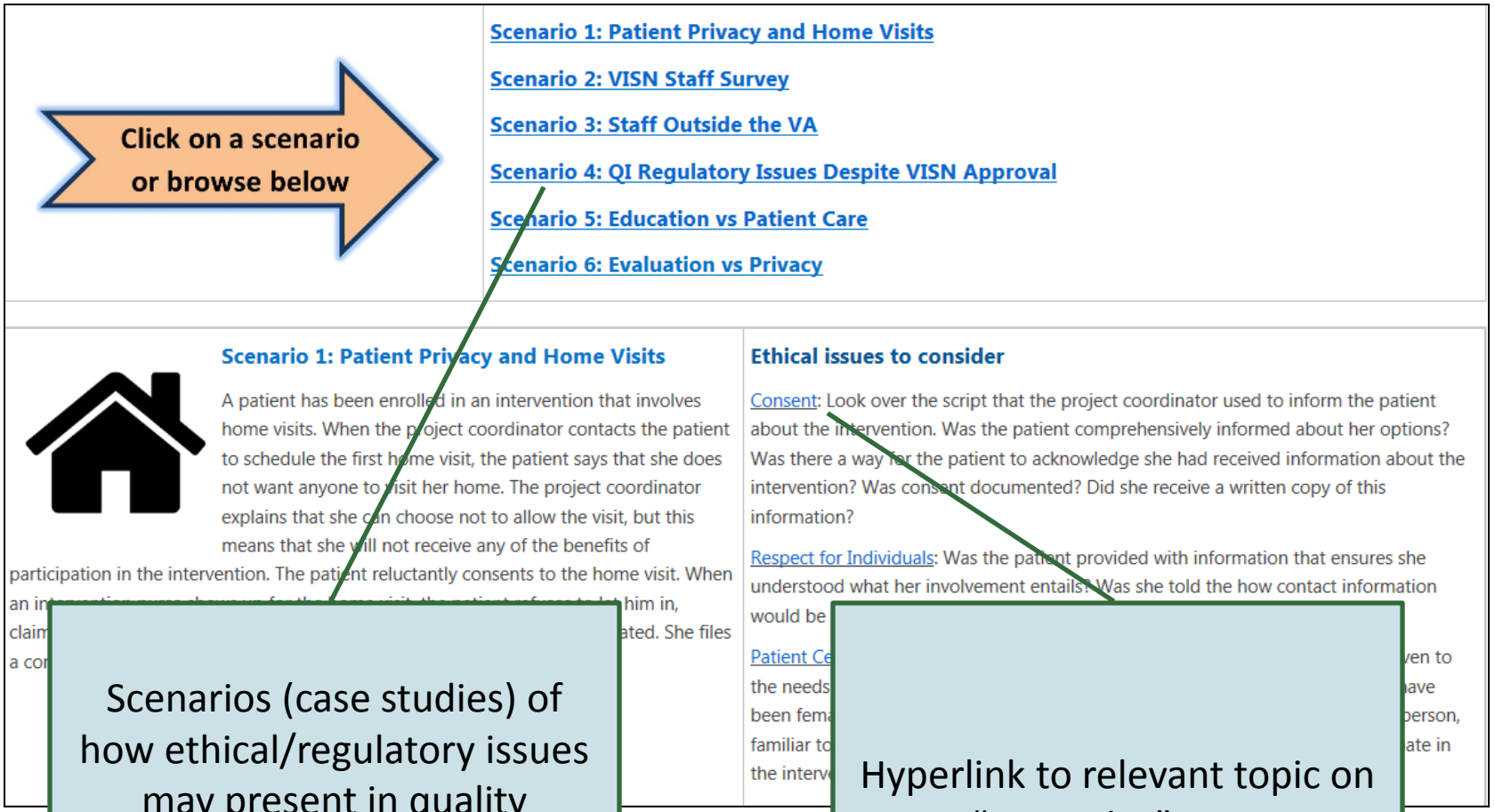
Topic	Discussion points and things to consider	Scenarios/FAQs
Privacy 	* For projects that involve direct patient interaction, are the patient's wishes to maintain a private personal space considered? * The QI team should access or collect only the minimum necessary personally identifiable information 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: ement in the proje mstances data the ed or disclosed to	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?

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

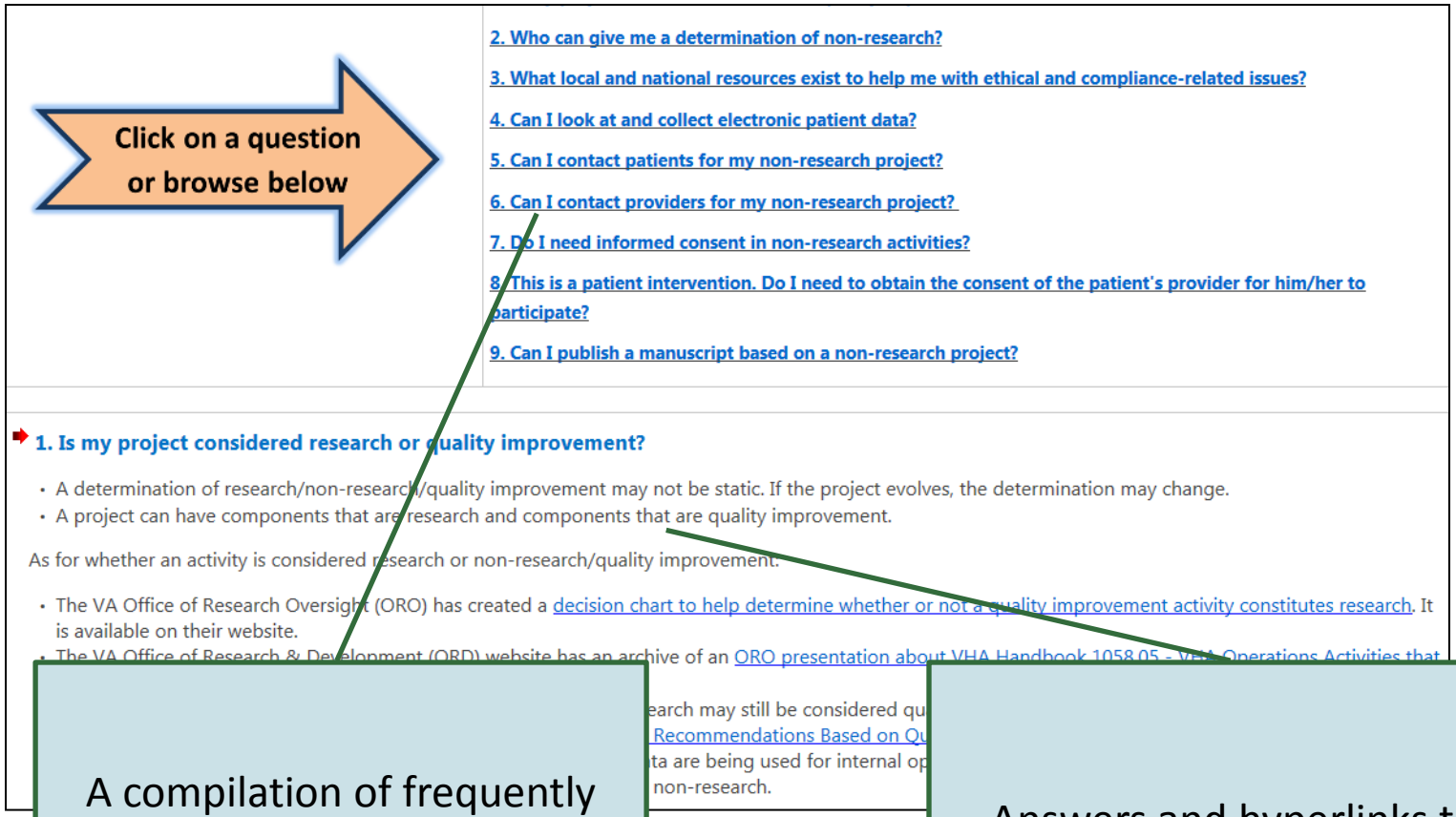


Scenarios (case studies) of how ethical/regulatory issues may present in quality improvement/implementation research activities

Hyperlink to relevant topic on "Principles" page

FAQs

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

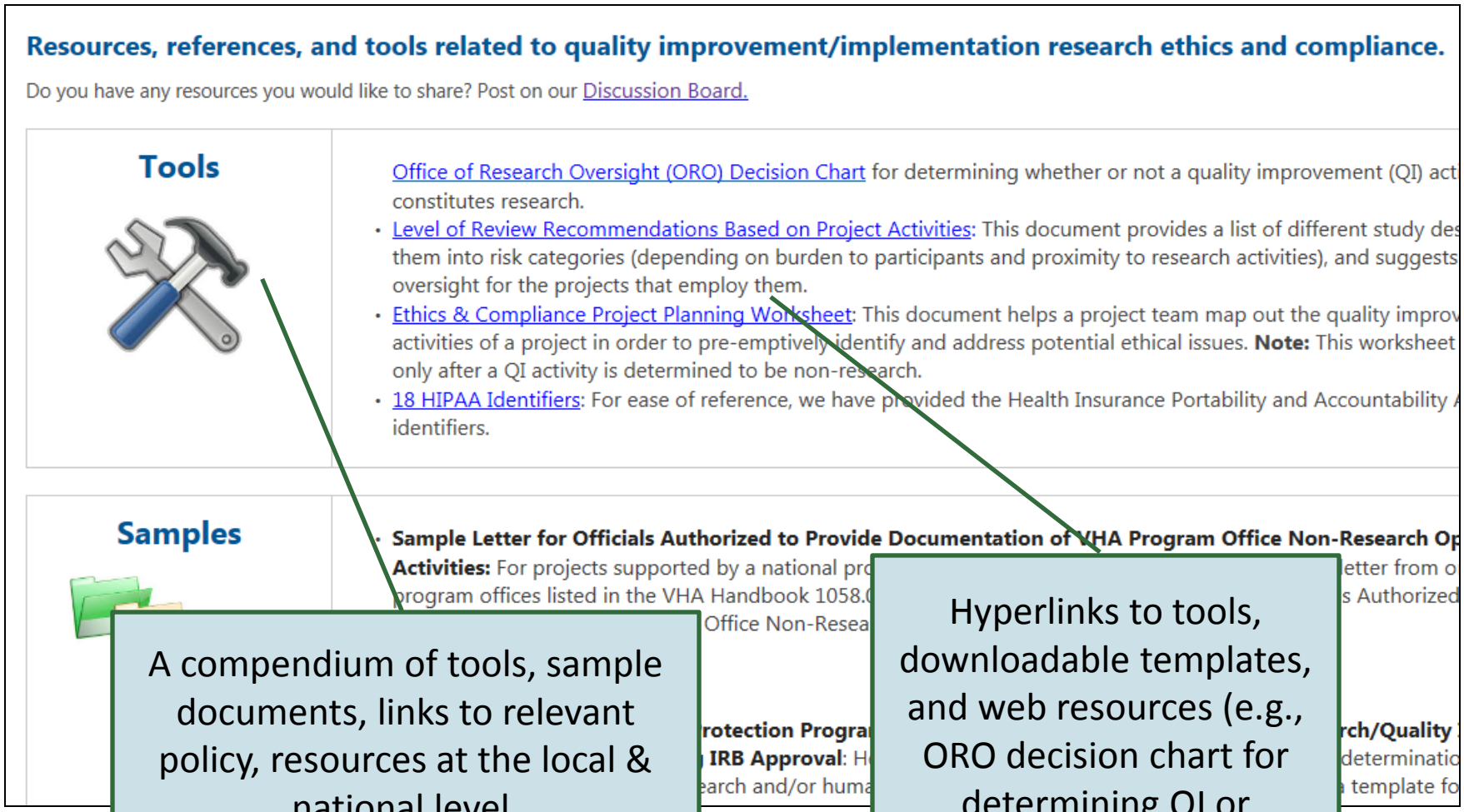


A compilation of frequently asked questions (e.g., is my project considered QI or research?)

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



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)