What is Quality Improvement (QI)?

What is Human Subjects Research (HSR)?

Comparing QI and HSR

Practical Application: Case Studies

OHRP QI FAQs

Other Notes

SQUIRE Guidelines (Standards for Quality Improvement Reporting Excellence)

References
WHAT IS QUALITY IMPROVEMENT (QI)?

- a **systematic, data-guided activity** designed to bring about immediate improvements in health care delivery in particular settings

- an **intrinsic part of good clinical care**, in which **data from clinicians’ own settings guide them in improving their practices**

**Continuous quality improvement is part of the mission of health care professionals and health care managers.**

**Health-care QI activities are considered part of health-care operations** [45 CFR 164.506(c)(4)].
WHAT IS HUMAN SUBJECTS RESEARCH?

1. **Research** means a **systematic investigation**, including research development, testing and evaluation, **designed to develop or contribute to generalizable knowledge**

2. **Human subject** means a **living individual** about whom an investigator (whether professional or student) conducting research **obtains**
   - **Data through intervention or interaction** with the individual, or
   - **Identifiable private information**

45 CFR 46.102 (d & f)
**QI activities and Human Subjects Research can overlap**

- **QI**
  - QI activities
  - QI involving human data sources
  - Nonexempt QI/HuSR

- **Research**
  - Research on QI
  - Research on HuSR

- **Human Subjects Research (HuSR)**
  - Exempt HuSR

- **Activities Involved**
  - Activities involving human data sources
  - Clinical & Managerial Innovation & Adaptation

- **Classification**
  - Activities: not research
  - QI
  - Exempt
  - Human Subjects Research
  - Expedited
  - Research: not human subjects research
<table>
<thead>
<tr>
<th>Purpose</th>
<th>Human Subjects Research</th>
<th>designed to develop or contribute to generalizable knowledge</th>
</tr>
</thead>
<tbody>
<tr>
<td>Starting Point</td>
<td>knowledge-seeking is independent of routine care and intended to answer a question or test a hypothesis</td>
<td></td>
</tr>
<tr>
<td>Design</td>
<td>follows a rigid protocol that remains unchanged throughout the research</td>
<td></td>
</tr>
<tr>
<td>Benefits</td>
<td>might or might not benefit current subjects; intended to benefit future patients</td>
<td></td>
</tr>
<tr>
<td>Risks</td>
<td>may put subjects at risk</td>
<td></td>
</tr>
<tr>
<td>Participant Obligation</td>
<td>no obligation of individuals to participate</td>
<td></td>
</tr>
<tr>
<td>Endpoint Analysis</td>
<td>answer a research question statistically prove or disprove hypothesis</td>
<td></td>
</tr>
<tr>
<td>Adoption of Results</td>
<td>little urgency to disseminate results quickly</td>
<td></td>
</tr>
<tr>
<td>Publication/Presentation</td>
<td>investigator obliged to share results</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Quality Improvement</th>
<th>designed to implement knowledge, assess a process or program as judged by established/accepted standards</th>
</tr>
</thead>
<tbody>
<tr>
<td>Starting Point</td>
<td>knowledge-seeking is integral to ongoing management system for delivering health care</td>
</tr>
<tr>
<td>Design</td>
<td>adaptive, iterative design</td>
</tr>
<tr>
<td>Benefits</td>
<td>directly benefits a process, system or program; might or might not benefit patients</td>
</tr>
<tr>
<td>Risks</td>
<td>does not increase risk to patients, with exception of possible patients' privacy or confidentiality of data</td>
</tr>
<tr>
<td>Participant Obligation</td>
<td>responsibility to participate as component of care</td>
</tr>
<tr>
<td>Endpoint Analysis</td>
<td>improve a program, process or system compare program, process or system to established standards</td>
</tr>
<tr>
<td>Adoption of Results</td>
<td>results rapidly adopted into local care delivery;</td>
</tr>
<tr>
<td>Publication/Presentation</td>
<td>QI practitioners encouraged to share systematic reporting of insights</td>
</tr>
</tbody>
</table>
Characteristics of a QI-HSR activity

Testing of issues that go beyond current knowledge based on science and experience, such as new treatments.

Random allocation of patients into different intervention groups to enhance confidence in differences that might be obscured by nonrandom selection (but not randomization for equitable allocation of a scarce resource).

Deliberately delayed or ineffective feedback of data from monitoring the implementation of changes, especially if this is done to avoid biasing the interpretation of data.

Involvement in key project roles of researchers who have no ongoing commitment to improvement of the local care situation, even if others in the team do have professional commitments to it.

Funding, sponsorship, or substantial participation by parties outside the clinical setting or organization in which the activity takes place.
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.

Favorable risk/benefit ratio
A QI activity should be designed to minimize risks and maximize potential benefits, and to ensure that risks to an individual human participant are proportionate to benefits to the participant and to society.

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.

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.

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.
Case Study 1

### Fact Pattern

- Catheter-related bloodstream infections cause ~28k deaths/year in the US

- A practicing anesthesiologist/critical care physician successfully **developed and implemented a checklist intervention** (washing hands, disinfecting patient’s skin before insertion of catheter) **to reduce catheter-related bloodstream infections at a medical center**

- The **checklist intervention became part of a QI initiative** (with federal funding), with 67 sites (103 ICUs), and **collected data on catheter-related bloodstream infection rates** and **included two de-identified AHRQ surveys completed by staff (perceptions of the culture of safety in the ICU)** and the survey will be used to inform hospital staff/officials about their own hospitals; the data was published in the NEJM, reporting a reduction of infections by up to 66% in an 18-month period.

### Final Analysis

1. The **implementation of the checklist** does **not** meet the definition of **research** because:
   - None of the parties involved are implementing the program as a research intervention in order to evaluate its effectiveness.
   - The program is being implemented solely for the purpose of improving the quality of care.

2. The **analysis of the aggregate data about the rate of catheter-related infections, combined with the data drawn from the two anonymized surveys**, does meet the definition of **research**, **not human subjects research** because:
   - Identifiable data was not collected about living individuals
   - There is no intervention/interaction with living individuals for research purposes

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### Case Study 2

#### Fact Pattern

- **Performed under a medicare contract**, the End Stage Renal Disease (ESRD) network conducted a quality improvement project aimed at improving end dialysis measures of adequate blood cleaning through better compliance with dialysis prescriptions.

  - The CMS Scientific Officer stated “as a CMS-directed QI project, it was not subject to oversight by the university’s IRB.”

- The QI project **reviewed routinely collected data for all dialysis centers in the state** (Pennsylvania).

#### Final Analysis

1. The design of the quality improvement project **met** the definition of human subjects research.
**Fact Pattern**

*Parent satisfaction Survey with Fast Track Clinic*

- Purpose of the survey is to **determine the parents’ satisfaction** with the staff, healthcare provider, and care.

- Providers will note the child’s diagnosis, time spent for the visit, and comment on whether or not the child met the “Fast Track Clinic” criteria.

- The **intent is to improve** triage of patients and to improve parent satisfaction with care (today).
Case Study 4

Fact Pattern

*Impact of Streamlined Documentation Tools*

- Conduct focus groups with clinicians working in outpatient settings to *optimize* the electronic health record (EHR)
- Plan to develop and implement problem lists and other tools to *improve* experience of working with EHR
- Conduct second round of focus groups to *determine the impact* of tools on satisfaction with EHR
## Fact Pattern

**Improving the Process of Tacrolimus Drug Monitoring**

- **Objectives are to decrease** the rate of clotted or insufficient samples for outpatient blood tests. **The intent is to improve** family satisfaction by decreasing the need to repeat lab tests.

- Plan to look at existing and prospective records to examine the timing of procedures and method of blood draw (i.e., finger stick or needle stick).
Case Study 6

Fact Pattern

**Trial to Improve Outpatient Asthma Care**

- Practices will be cluster randomized to multipart intervention including education, EHR decision support, and receipt of spirometers.

- The **objectives are to determine if the intervention improves patients’ asthma outcomes**

- Data from all physicians’ patients with asthma meeting age criteria will be included.
An iterative process will be implemented with an objective of preventing missed opportunities for vaccination (training, feedback).

Plan is to implement the intervention and measure change with each PDSA cycle.

Conduct surveys to learn providers’ impressions of the program.

Plan to publish to help inform other MOC projects.
Does 45 CFR 46 (HSR) apply to QI activities conducted by one or more institutions whose purposes are limited to: a) implementing a practice to improve the quality of patient care, and b) collecting patient or provider data regarding the implementation of the practice for clinical, practical, or administrative purposes?

No - such activities do not satisfy the definition of “research” under 45 CFR 46.102(d), which is “...a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge...” …there is no requirement under these regulations for such activities to undergo review by an IRB, or for these activities to be conducted with provider or patient informed consent.

Examples

- A radiology clinic uses a database to help monitor and forecast radiation dosimetry. This practice has been demonstrated to reduce over-exposure incidents in patients having multiple procedures. Patient data are collected from medical records and entered into the database. The database is later analyzed to determine if over-exposures have decreased as expected.

- A group of affiliated hospitals implements a procedure known to reduce pharmacy prescription error rates, and collects prescription information from medical charts to assess adherence to the procedure and determine whether medication error rates have decreased as expected.

- A clinic increasingly utilized by geriatric patients implements a widely accepted capacity assessment as part of routine standard of care in order to identify patients requiring special services and staff expertise. The clinic expects to audit patient charts in order to see if the assessments are performed with appropriate patients, and will implement additional in-service training of clinic staff regarding the use of the capacity assessment in geriatric patients if it finds that the assessments are not being administered routinely.
Does 45 CFR 46 (HSR) apply to QI activities if their purposes are limited to: a) delivering healthcare, and b) measuring and reporting provider performance data for clinical, practical, or administrative uses?

**No** - such quality improvement activities do not satisfy the definition of “research” under 45 CFR 46.102(d), which is “…a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge…” …there is no requirement under these regulations for such activities to undergo review by an IRB, or for these activities to be conducted with provider or patient informed consent.

**Example**

- The clinical, practical, or administrative uses for such performance measurements and reporting could include, for example, helping the public make more informed choices regarding health care providers by communicating data regarding physician-specific surgical recovery data or infection rates.
- Other practical or administrative uses of such data might be to enable insurance companies or health maintenance organizations to make higher performing sites preferred providers, or to allow other third parties to create incentives rewarding better performance.
Can I analyze data that are not individually identifiable, such as medication databases stripped of individual patient identifiers, for research purposes without having to apply 45 CFR 46 (HSR)?

Yes - whether or not these activities are research, they do not involve “human subjects.”

The regulation defines a “human subject” as “a living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information….Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.”

Thus, if the research project includes the analysis of data for which the investigators cannot readily ascertain the identity of the subjects and the investigators did not obtain the data through an interaction or intervention with living individuals for the purposes of the research, the analyses do not involve human subjects and do not have to comply with the HHS protection of human subjects regulations.
Are there types of QI efforts that are considered to be research that are subject to HSR?

**Yes** - in certain cases, a quality improvement project may constitute non-exempt human subjects research conducted or supported by HHS or otherwise covered by an applicable FWA.

For example, **if a project involves introducing an untested clinical intervention for purposes which include not only improving the quality of care but also collecting information about patient outcomes for the purpose of establishing scientific evidence to determine how well the intervention achieves its intended results**, that quality improvement project may also constitute nonexempt human subjects research under the HHS regulations.
If I plan to carry out a QI project and publish the results, does the intent to publish make my QI project fit the regulatory definition of research?

No - the **intent to publish** is an insufficient criterion for determining whether a **quality improvement activity involves research**.

The regulatory definition under 45 CFR 46.102(d) is “Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.”

Planning to publish an account of a quality improvement project does not necessarily mean that the project fits the definition of research; people seek to publish descriptions of nonresearch activities for a variety of reasons, if they believe others may be interested in learning about those activities. Conversely, a quality improvement project may involve research even if there is no intent to publish the results.
If a QI project involves non-exempt research with human subjects, do I always need to obtain informed consent from all subjects (patients, and/or providers) involved in the research?

No - the HHS regulations protecting human subjects allow an IRB to waive the requirements for obtaining informed consent of the subjects of the research when:

- the risk to the subjects is minimal,
- subjects’ rights and welfare will not be adversely affected by the waiver,
- conducting the research without the waiver is not practicable, and
- if appropriate, subjects are provided with additional pertinent information after their participation (45 CFR 46.116(d)).

Other applicable regulations or laws may require the informed consent of individuals in such projects independent of the HHS regulations for the protection of human subjects in research.

Note: Because QI is an essential part of normal health care, it is necessary –and acceptable– to have consent to receive health care include consent to a reasonable level of cooperation with QI activities.
If a QI project is HSR requiring IRB review, do I need to obtain separate IRB approval from every institution engaged in the project?

**No - not if certain conditions are met.**

The HHS protection of human subjects regulations allow one IRB to review and approve research that will be conducted at multiple institutions.

An institution has the option of relying upon IRB review from another institution by designating that IRB on its FWA and submitting the revised FWA to OHRP, and having an IRB Authorization Agreement with the other institution.
1. HIPAA allows projects conducted within a covered entity with the intent of obtaining information related to treatment, payment, or health care operations to be conducted without additional patient authorization. Patients should be made aware of these uses of their data via the privacy notice required by HIPAA.

A QI project may be appropriately initiated without patient authorization or consent; however, consideration must be given to whether or not health care workers should be made aware of and possibly required to consent to the project.

Research is not covered under the HIPAA “treatment, payment, or health care operations exemptions, and therefore, if research is being conducted, the requirements for waiving informed consent or documentation of informed consent must be met.

More examples:
https://www.healthit.gov/sites/default/files/exchange_health_care_ops.pdf
http://www.hhs.gov/blog/2016/02/12/understanding-some-hipaaas-permitted-uses-and-disclosures.html

2. When in doubt, complete and submit the Non-Human Subjects Determination (NHSRD) form to the IRB for review/documentation.

Most journals require documentation of whether a research activity required IRB approval or not. If your project is a QI project, the completed NHSRD will serve as documentation from the IRB.

3. Projects considered QI must also maintain the highest integrity of confidentiality possible.

4. Characterizing a project as QI does not necessarily negate the need for informed consent.

5. An easier interpretation: The discriminating factor between a QI activity and QI-research depends on whether the activity is designed to contribute to generalizable knowledge. A more narrow definition of generalizable, such as “widely applicable,” is more appropriate.

One exception: When the research is regulated by a US federal agency, or a country outside of the US, the law is clear that the regulator has the final authority over whether research is subject to regulation. [45 CFR 46.101(c)]
<table>
<thead>
<tr>
<th>Text Section</th>
<th>Section or Item Description</th>
</tr>
</thead>
</table>
| Title and abstract| Did you provide clear and accurate information for finding, indexing, and scanning your paper?  
1. Title:                                                                                                      
   a. Indicates that the article concerns the improvement of quality (broadly defined to include the safety, effectiveness, patient-centeredness, timeliness, efficiency, and equity of care)  
   b. States the specific aim of the intervention  
   c. Specifies the study method used (for example, “A qualitative study,” or “A randomized cluster trial”)  
2. Abstract:                                                                                                      
   Summarizes precisely all key information from various sections of the text using the abstract format of the intended publication |
| Introduction       | Why did you start?                                                                                                                                                                                                        |
| 3. Background knowledge | Provides a brief, nonselective summary of current knowledge of the care problem being addressed and characteristics of organizations in which it occurs |
| 4. Local problem   | Describes the nature and severity of the specific local problem or system dysfunction that was addressed                                                                                                                   |
| 5. Intended improvement | a. Describes the specific aim (changes/improvements in care processes and patient outcomes) of the proposed intervention  
   b. Specifies who (champions, supporters) and what (events, observations) triggered the decision to make changes, and why now (timing) |
<p>| 6. Study question  | States precisely the primary improvement-related question and any secondary questions that the study of the intervention was designed to answer                                                                                   |</p>
<table>
<thead>
<tr>
<th>Methods</th>
<th>What did you do?</th>
</tr>
</thead>
<tbody>
<tr>
<td>7. Ethical issues</td>
<td>Describes ethical aspects of implementing and studying the improvement, such as privacy concerns, protection of participants’ physical well-being, and potential author conflicts of interest, and how ethical concerns were addressed</td>
</tr>
<tr>
<td>8. Setting</td>
<td>Specifies how elements of the local care environment considered most likely to influence change/improvement in the involved site or sites were identified and characterized</td>
</tr>
</tbody>
</table>
| 9. Planning the intervention | a. Describes the intervention and its component parts in sufficient detail that others could reproduce it  
b. Indicates main factors that contributed to choice of the specific intervention (for example, analysis of causes of dysfunction; matching relevant improvement experience of others with the local situation)  
c. Outlines initial plans for how the intervention was to be implemented: what was to be done (initial steps; functions to be accomplished by those steps; how tests of change would be used to modify intervention), and by whom (intended roles, qualifications, and training of staff) |
| 10. Planning the study of the intervention | a. Outlines plans for assessing how well the intervention was implemented (dose or intensity of exposure)  
b. Describes mechanisms by which intervention components were expected to cause changes, and plans for testing whether those mechanisms were effective  
c. Identifies the study design (for example, observational, quasi-experimental, experimental) chosen for measuring impact of the intervention on primary and secondary outcomes, if applicable  
d. Explains plans for implementing essential aspects of the chosen study design, as described in publication guidelines for specific designs, if applicable (see, for example, www.equator-network.org)  
e. Describes aspects of the study design that specifically concerned internal validity (integrity of the data) and external validity (generalizability) |
| 11. Methods of evaluation    | a. Describes instruments and procedures (qualitative, quantitative, or mixed) used to assess the effectiveness of implementation, the contributions of intervention components and context factors to effectiveness of the intervention, and primary and secondary outcomes  
b. Reports efforts to validate and test reliability of assessment instruments  
c. Explains methods used to assure data quality and adequacy (for example, blinding; repeating measurements and data extraction; training in data collection; collection of sufficient baseline measurements) |
| 12. Analysis                 | a. Provides details of qualitative and quantitative (statistical) methods used to draw inferences from the data  
b. Aligns unit of analysis with level at which the intervention was implemented, if applicable  
c. Specifies degree of variability expected in implementation, change expected in primary outcome (effect size), and ability of study design (including size) to detect such effects  
d. Describes analytic methods used to demonstrate effects of time as a variable (for example, statistical process control) |
<table>
<thead>
<tr>
<th>Results</th>
<th>What did you find?</th>
</tr>
</thead>
<tbody>
<tr>
<td>13. Outcomes</td>
<td>a. Nature of setting and improvement intervention</td>
</tr>
<tr>
<td></td>
<td>i. Characterizes relevant elements of setting or settings (for example, geography, physical resources, organizational culture, history of change efforts), and structures and patterns of care (for example, staffing, leadership) that provided context for the intervention</td>
</tr>
<tr>
<td></td>
<td>ii. Explains the actual course of the intervention (for example, sequence of steps, events or phases; type and number of participants at key points), preferably using a timeline diagram or flow chart</td>
</tr>
<tr>
<td></td>
<td>iii. Documents degree of success in implementing intervention components</td>
</tr>
<tr>
<td></td>
<td>iv. Describes how and why the initial plan evolved, and the most important lessons learned from that evolution, particularly the effects of internal feedback from tests of change (reflexiveness)</td>
</tr>
<tr>
<td></td>
<td>b. Changes in processes of care and patient outcomes associated with the intervention</td>
</tr>
<tr>
<td></td>
<td>i. Presents data on changes observed in the care delivery process</td>
</tr>
<tr>
<td></td>
<td>ii. Presents data on changes observed in measures of patient outcome (for example, morbidity, mortality, function, patient/staff satisfaction, service utilization, cost, care disparities)</td>
</tr>
<tr>
<td></td>
<td>iii. Considers benefits, harms, unexpected results, problems, failures</td>
</tr>
<tr>
<td></td>
<td>iv. Presents evidence regarding the strength of association between observed changes/improvements and intervention components/context factors</td>
</tr>
<tr>
<td></td>
<td>v. Includes summary of missing data for intervention and outcomes</td>
</tr>
<tr>
<td>Text Section</td>
<td>Section or Item Description</td>
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</tr>
<tr>
<td>Discussion</td>
<td>What do the findings mean?</td>
</tr>
</tbody>
</table>
| 14. Summary          | a. Summarizes the most important successes and difficulties in implementing intervention components, and main changes observed in care delivery and clinical outcomes  
                        b. Highlights the study’s particular strengths                                                                                                                                                                                                                                                                                                                                                                       |
| 15. Relation to other evidence | Compares and contrasts study results with relevant findings of others, drawing on broad review of the literature; use of a summary table may be helpful in building on existing evidence                                                                                                                                                                                                                                                                                                                                                           |
| 16. Limitations      | a. Considers possible sources of confounding, bias, or imprecision in design, measurement, and analysis that might have affected study outcomes (internal validity)  
                        b. Explores factors that could affect generalizability (external validity), for example: representativeness of participants; effectiveness of implementation; dose–response effects; features of local care setting  
                        c. Addresses the likelihood that observed gains may weaken over time and describes plans, if any, for monitoring and maintaining improvement; explicitly states if such planning was not done  
                        d. Reviews efforts made to minimize and adjust for study limitations  
                        e. Assesses the effect of study limitations on interpretation and application of results                                                                                                                                                                                                                                                                                          |
| 17. Interpretation   | a. Explores possible reasons for differences between observed and expected outcomes  
                        b. Draws inferences consistent with the strength of the data about causal mechanisms and size of observed changes, paying particular attention to components of the intervention and context factors that helped determine the intervention’s effectiveness (or lack thereof), and types of settings in which this intervention is most likely to be effective  
                        c. Suggests steps that might be modified to improve future performance  
                        d. Reviews issues of opportunity cost and actual financial cost of the intervention                                                                                                                                                                                                                                                                                       |
| 18. Conclusions      | a. Considers overall practical usefulness of the intervention  
                        b. Suggests implications of this report for further studies of improvement interventions                                                                                                                                                                                                                                                                                                                         |
| Other information    | Were there other factors relevant to the conduct and interpretation of the study?                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| 19. Funding          | Describes funding sources, if any, and the role of the funding organization in design, implementation, interpretation, and publication of the study                                                                                                                                                                                                                                                                                                                                                           |

*These guidelines provide a framework for reporting formal, planned studies designed to assess the nature and effectiveness of interventions to improve the quality and safety of care. It may not always be appropriate or possible to include information about every guideline item in reports of original studies, but authors should at least consider every item in writing their reports. Although each major section (Introduction, Methods, Results, and Discussion) of a published original study generally contains some information about the items within that section, information about items from one section (for example, Introduction) is also often needed in other sections (for example, Discussion).*
Agency for Healthcare Research and Quality (AHRQ): 2015 Webinar – IRB Challenges in QI and Research


Health Resources and Services Administration (HRSA). Quality Improvement. April 2011.


