



# Quality Assurance, Quality Improvement, & Program Evaluations

*Is it Research?*



# Overview

- Definitions
- Generalizable Knowledge
- About Whom
- Quality Assurance/Quality Improvement
- Program Evaluations
- When and what to submit



# Definitions

## Research [45CFR46.102(l)]

- A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.
  - Systematized - Having or involving a system, method, or plan
  - Investigation - Testing a hypothesis and permitting conclusions to be drawn (i.e., detailed, careful examination)

## Human Subject [45CFR46.102(e)]

- A living individual about whom an investigator (whether professional or student) conducting research:
  - (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
  - (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.



# Generalizable Knowledge

- Generalizable Knowledge means that the purpose or intent of the project is to test or to develop scientific theories or hypotheses, or to draw conclusions that are intended to be applicable and/or shared beyond the populations or situations being studied.
- This may include one or more of the following:
  - Presentation of the data at meetings, conferences, seminars, poster presentations, etc.
  - The knowledge contributes to an already established body of knowledge
  - Other investigators, scholars, and practitioners may benefit from this knowledge
  - Publications including journals, papers, dissertations, and master's theses
- If the project does not meet the definition of research (i.e. is not a systematic investigation or does not contribute to generalizable knowledge), as described above, then the project does not require IRB review and an IRB application is not required.



# Example

*Generalizable knowledge*: Intent of quality improvement project is to inform other organizations of same genre via peer reviewed journal and to impact standard of practice.

*Not generalizable knowledge*: Results of project will be used to improve services within finite group. Publication or presentation may be sought but not intended to impact standards, merely to inform.



# About Whom

- Data collection involving thoughts, feelings, opinions of a person.
- Identifiable private information about a person:
  - *Private Information*: Information about behavior that occurs in a context in which the individual can reasonably expect that no observation or recording is taking place (e.g. person's home, exam room, public restroom, etc.) OR has been provided for specific purposes with a reasonable expectation that it will not be made public (e.g. medical records, student records, employee file, etc.)
  - *Identifiable Information*: The identity of the individual is or may be readily ascertained by the investigator or others either directly or indirectly through the use of codes or a combination of data points.
- If opinion is of subject matter expert on specific topic, *might* not be about whom.



# Example

*About whom*: In depth interviews with teens exploring the impact of social media on their peer groups.

*Not about whom*: Analyzing policies on limitations of social media via interviews with subject matter experts and key stakeholders.



# Quality Assurance/ Quality Improvement





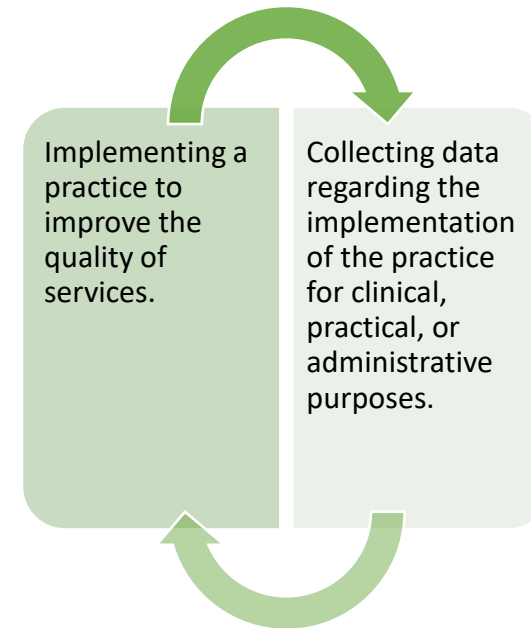
## Quality Assurance/ Quality Improvement (QA/QI)

- Quality assurance/quality improvement initiatives or program evaluations:
  - Are only intended to assess or improve internal practices, programs, or systems AND
  - Are not designed to contribute to generalizable knowledge.
- Does a quality improvement project that involves research need to be reviewed by an IRB?
  - Yes, in some cases. IRB review is needed if the project meets the definition of human subjects research.
- If project involves research and a QA/QI component, submit for review.
  - If you are uncertain if project qualifies as a QA/QI project, please contact the FAU HRPP.



# QA/QI

Do the regulations for the protection of human subjects in research apply to QA/QI activities conducted by one or more institutions whose purposes are limited to?



No, such activities do not satisfy the definition of “research”. 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.



# QA/QI Examples

- Examples of implementing a practice and collecting data for non-research clinical or administrative purposes include:
  - The clinical, practical, or administrative uses for performance measurements and reporting such as helping the public make more informed choices regarding health care providers by communicating data regarding infection rates.
  - Survey to improve services offered by an organization.
  - Assessment of staff education and training.



# QA/QI: How to Know if Review is Required

- PI should make initial determination about the project.
- Use QA/ QI Checklist.
- Use Determination Form (Form 106)
- If still unsure, submit Form 106 to FAU IRB and include:
  - Research details
  - Variables to be analyzed
  - How variables are obtained
  - Documentation from data custodian if data is de-identified

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# Program Evaluations



# Program Evaluations

- As with QA/QI projects, it may depend on intent.
- Broad definition of evaluation is the “examination of the worth, merit, or significance of an object.”
- Almost any organized public health action can be seen as a candidate for program evaluation:
  - Direct service interventions (e.g., a program that offers free breakfasts to improve nutrition for grade school children)
  - Community mobilization efforts (e.g., an effort to improve the economic well-being of farm workers)
  - Research initiatives (e.g., an effort to find out whether health outcome disparities can be reduced)
  - Advocacy work (e.g., a campaign to influence the state legislature to pass legislation)
  - Training programs (e.g., a job training program to reduce unemployment)



# Program Evaluations vs. Research

Focus	Program Evaluation	Research
<p><b>Planning</b></p>	<p><b>Framework for program evaluation</b></p> <p>Engage stakeholders; Describe the program; Focus the evaluation design; Gather credible evidence; Justify conclusions; Ensure use and share lessons learned.</p>	<p><b>Scientific method</b></p> <p>State hypothesis; Collect data; Analyze data; Draw conclusions.</p>
<p><b>Questions</b></p>	<p><b>Values</b></p> <p>Merit (i.e., quality); Worth (i.e., value); Significance (i.e., importance).</p>	<p><b>Facts</b></p> <p>Descriptions; Associations; Effects.</p>
<p><b>Uses</b></p>	<p><b>Feedback to stakeholders</b></p> <p>Focus on intended uses by intended users; Build capacity.</p>	<p><b>Disseminate to interested audiences</b></p> <p>Content and format varies to maximize comprehension.</p>



# Considerations

- Is withholding information always deception?
- Is the deception justified by the scientific value of the study?
- Are other non-deceptive procedures acceptable for data collection?
- Would withheld information affect the subjects decision to participate?
- Is debriefing necessary?





# When and What to Submit



# When and What

## When to Submit

- If study does not meet definition of QA/QI or Program Evaluation exclusively:
  - Submit sooner rather than later.
  - Must submit prior to any research activities taking place.

## What to Submit

- If you are unsure, submit a Determination Form (Form 106);
- If you know, submit a New Study Application via Novelution.
  - Include supporting documents such as data collection tools, and consent document(s).



# Resources

QA/QI Projects: <http://answers.hhs.gov/ohrp/categories/1569>

HHS Regulations:

<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html>

Other agency regulations under “common rule”:

<http://www.hhs.gov/ohrp/humansubjects/commonrule/index.html>

FAU HRPP

[Researchintegrity@fau.edu](mailto:Researchintegrity@fau.edu)