

## Reference Guide: Quality Assurance or Research?

### Definition of Quality Assurance

Quality assurance consists of activities—observation, survey, record review or other data collection techniques—that are undertaken to measure a product, process or service against an established standard to determine if an agreed upon level of quality has been met.

#### Steps Common to QA:

- (1) select an established standard;
- (2) measure performance or output to the standard; and
- (3) Implement corrective actions to correct identified deficiencies/shortcomings. Such efforts are usually designed and carried out by personnel with the authority to promptly implement corrective actions, if necessary.

### Definition of Human Subjects Research

A systematic investigation, including research development, testing and evaluation, designed to develop or contribute generalizable knowledge. Research includes collection of data through intervention or interaction with living individuals or identifiable private information about them. Such efforts are designed to benefit society in the future from knowledge gains. 45CFR46.102(e)

### General Characteristics

<u>Quality Assurance</u>	<u>Human Subjects Research</u>
INTENT of the activity is to assess or judge a procedure, process, or program against an established standard.	INTENT of the activity is to generate knowledge—by generating hypotheses, testing them, and answering research questions—to develop new paradigms or untested methods, or establish standards where none are accepted.
DESIGN includes systematic monitoring/measuring to ensure all participants receive standard or best evidentiary care, services, products or instruction, as applicable.	DESIGN may include group comparisons, randomization, control groups, placebo. Some participants may receive non-standard or experimental tests, products or services.
SETTING of the activities undertaken is within the organization or a unit of it.	SETTING of the activities may be within or beyond the organization.
PARTICIPANTS and their data are not used as a representative sample of a broader population outside of the organization.	PARTICIPANTS and their data are selected as a representative sample of a broader population outside of the organization.
RISKS of harm to participants are not anticipated.	RISKS of harm to participants are possible.
INFORMED CONSENT is usually not required as no activity plans to provide less than standard or best evidentiary care, products, services or instruction.	INFORMED CONSENT may be required as research participation is voluntary and may involve non-standard care, products, services or instruction.

**Examples**

**Quality Assurance**

**Human Subjects Research**

**In the Classroom:**

Instructor administers a post-test to determine whether students understood today’s lesson about established steps to follow to solve a quadratic equation. A repeat lesson on the topic is conducted, if post-test results determine its necessity.

Instructor administers post-test to two classes, after providing a different method of instruction on solving quadratic equations to each—a.m. class taught established quadratic formula method/p.m. class taught a new/faster untested method—to determine which method is more effective to solve such equations. Instructor hypothesizes new method will be as accurate and effective as the established method.

**In the Clinic:**

Infection Control (IC) Nurse observes handwashing technique to determine whether unit staff are following the US Center for Disease Control’s (CDC) 5-steps to proper handwashing technique. Corrective on-the-job training is conducted, if results determine its necessity.

IC Nurse instructs Unit 1 staff on CDC’s 5-steps to proper handwashing but instructs Unit 2 staff an unproven 4-step process which reduces time needed to complete steps. IC Nurse observes handwashing technique on both units, hypothesizing staff will be more compliant with 4-step process because it requires less time to complete handwashing; questions of effectiveness remain to be tested.

**In the Community:**

Director audits last 3-months of community health workers’ field notes to assure home assessments have been adequately documented and within the required 10-day timeframe of referral to community residents whose asthma is not well-controlled. Corrective on-the-job-training on timing and completion of Home Assessment to Reduce Asthma Triggers Form is conducted, if audit results determine its necessity.

Director revises the Home Assessment to Reduce Asthma Triggers Form deleting some of the info to be collected and equally divides use of the approved form and revised experimental form to health workers to use. Director hypothesizes that workers using the revised form will meet required 10-day time frame more often because reduced time to complete forms; proof of assessment adequacy remain to be tested.