**GUIDANCE 27E**

**GUIDANCE FOR QUALITY CONTROL AND QUALITY IMPROVEMENT**

**1.14 Definition of non-human subject research for quality improvement activities (QIA)**

When quality improvement activities (QIA) are not done for research purposes, they may not be considered as human subject research. Examples:

A. Implementing a practice to improve the quality of patient care or administrative performance

B. Collecting patient or provider data regarding the implementation of the practice for clinical, practical, or administrative purposes delivering healthcare or academic activities.

**1.15 QIA Projects considered as human subject research (**<https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/quality-improvement-activities/index.html>)

A. Activities such as measuring and reporting provider performance data for clinical, practical, or administrative uses to carry out a quality improvement project and publish the results.

B. Data that are not individually identifiable, such as medication databases stripped of individual patient identifiers, for research purposes.

C. 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

D. QIA projects that involves research require IRB review at full board or expedited review levels depending upon the level of risk to subjects and private information

E. QIA projects that are research must also meet all of the HIPAA requirements when participant’s protected health information is used.

For further information on Quality Improvement Activities, go to <http://www.firstclinical.com/regdocs/doc/?db=OTH_OHRP_Quality_Improvement>.