JEFFERSON—Office of Human Research

# DECISION TOOL – IS IT QUALITY IMPROVEMENT, HUMAN RESEARCH, OR BOTH?

**Version Date – FOR OHR USE: 3/6/19**

**Instructions:** The Office of Human Research (OHR) considers quality improvement (QI) activities to be a standard part of health care operations and, in general, not subject to IRB oversight. However, there may be instances where a project is both QI and human research and thus would require IRB review. Use this decision tool to determine whether your project requires IRB review. Check the categories below that apply to your project.

While QI projects may employ research methodology, there are key distinctions that can be identified in order to determine whether a project requires IRB review. Jefferson uses the federal definition of research when determining what requires IRB review and oversight. QI projects are defined with the goal to improve institutional processes and delivery of care. An intent to publish or publicly present data is not in and of itself an indicator of the need for IRB review. “Institutional” is defined by the Jefferson IRB as any site included within the Jefferson enterprise.

**DEFINITIONS**

**Research** means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.[45 CFR 46.102(l)]

**Generalizable knowledge** is knowledge specific to a particular research study that is intended for distribution and use by non-Jefferson practitioners to improve medical practice. The typical venues for distribution are publication and public presentation.

**Human subject** – A living individual about whom an investigator: 1) obtains information or biospecimens through intervention or interaction with the individual and uses, studies, or analyzes the information or biospecimens, or; 2) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens. [45 CFR 46.102e(1)]

**QI process description**- A publication or public presentation that describes the structure, model, execution, and/or goals of a QI project without providing the specific clinical outcomes, findings, or patient data. Does not constitute “generalizable knowledge.”

**QUALITY IMPROVEMENT ACTIVITIES**

The following activities fall within the realm of QI and do not require IRB review:

\_\_\_ Activities that focus primarily on improving the performance of local patient-care delivery, staff satisfaction, business systems, and the like, rather than the generation of new scientific knowledge;

\_\_\_ Activities that focus primarily on curricular development or student satisfaction;

\_\_\_ Activities that attempt to consistently implement established best practices based on existing evidence gained from the professional literature and consensus-expert opinion;

\_\_\_ Publication or public presentation of such activities listed above where the intent is to describe the QI process and not the specific data from the project, such that non-Jefferson practitioners may use such a model in their own venues.

**HUMAN RESEARCH**

The following activities fall within the realm of human research that requires prospective IRB review prior to initiation:

\_\_\_ Activities that involve experimental or unproven therapies or procedures (not evidence-based treatment), or prospective evaluation of a drug or device that is not currently approved by FDA for general use (including “off-label” indications);

\_\_\_ Activities that involve a control group, in which therapeutic or study intervention is intentionally withheld to allow an assessment of its efficacy;

\_\_\_ Activities in which subjects are randomly assigned (i.e., through a specific randomization procedure) to competing treatments;

\_\_\_ Activities that impose additional testing burdens (that may or may not represent additional risk to a subject), while not conveying a countervailing potential benefit to that patient;

\_\_\_ Projects funded by a commercial interest with stakes in project results;

\_\_\_ Activities that follow a protocol of fixed procedures with rigid methodology, population, goals and/or time frame;

\_\_\_ Publication or public presentation of data specific to a particular project with the intention that non-Jefferson practitioners will apply this data to improve medical practice, curriculum, business systems, and the like.

**By signing below, the project leader certifies that the entirety of their activities fit into one or more of the above QI categories, and the project does not involve any of the human research categories. If any activities fall into the human research category, the project leader should contact OHR for guidance.**

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Project Leader Date

**WRITTEN DETERMINATIONS**

If a determination is required by a funding agency or sponsor, the investigator may submit a request for written confirmation along with the OHR-36 to the Office of Human Research, which will provide a written response.