QA/QI v. Human Subjects Research

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This training should help students and their faculty mentors to:

Determine if their proposed projects meet the QA/QI criteria *or* meet the definition of human subjects research that must go through the TU IRB review process.

A project must meet the federal definitions of both:

1. *"Research"* and

2. *"Human Subjects"*

to be considered, *"Human Subjects Research"*

DHHS Regulations define **research** as "a systematic investigation, including research development, testing and evaluation, *__designed to develop or contribute to generalize knowledge__*." (45 CFR 46.102(1) Common Rule).

Human subject is defined as 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. (45 CFR 46.102(e)(1) Common Rule).

*Additionally, the FDA regulates research involving a drug, device or biologic, and all research involving data that will be submitted to or held for inspection by the FDA (21 CFR 56.102(c)).

The 2018 Common Rule defined certain scholarly activities as 'not' human subjects research. QA/QI projects were one of those activities.

What are QA/QI Projects?

QA and QI activities — clinical or procedures: Systematic, data-guided activities designed to implement promising ways to improve clinical care, patient safety and health care operations. The activity is designed to bring about immediate positive changes in the delivery of health care, programs or business practices in the local setting.

QA and QI activities —non-clinical: Data collected with the limited intent of evaluating and improving existing services and programs or for developing new services or programs.

*QI/QA activities meeting the following definitions
do <u>not</u> require IRB review, as long as these activities *DO NOT*:

Pose significant risk to patients *and;*

Include testing the safety and efficacy of a drug, device or biologic in a human subject.

Sometimes a project can be *both* QA/QI AND HSR.

*The TU IRB Office will continue to review QA/QI submissions to confirm that your proposed projects ONLY meet the QA/QI criteria and that TU IRB review in not needed.

Some Examples of QA/QI and NOT HSR:

Implementing a practice (e.g., a no-interruption process to improve some quality of patient care);

Collecting provider/patient data to evaluate program implementation, satisfaction, or effectiveness;

Collecting admin. data related to a practice; and

Measuring and reporting provider/staff performance for clinical or admin. purposes

Comparing HSR and QA/QI

Study Design Element	Human Subjects Research	QA/QI Project
Purpose	Gather facts to test a hypothesis and develop or contribute to generalizable knowledge.	Improve and understand specific, local processes or practices commonly related to cost, productivity, operations, quality, or patient experience.
Starting point	Answer a question or test a hypothesis that can be applied to a more general population.	Improve performance in a specific unit or population (patient or provider) in an organization.
Design	Systematic design with strict adherence to a protocol that does not change throughout the process. May involve randomization or a placebo arm.	Adaptive design that may or may not be systematic. Usually does not involve randomization or a placebo arm.
Who Benefits?	Clinician, researcher, scientific community, and occasionally the subject benefit. Results do not directly benefit institutional practice or programs.	Intended for the immediate benefit of patients, staff, providers, and institution.

QA/QI CITI Training Course

- On your CITI main page, click on "**View Courses** for The University of Tulsa" and then click on, "**Learner Tools**" and then click on **"Add a Course".**

- Go to **Question 1: Human Subjects Research Courses.**

- Select the course, "**Conducting Classroom Projects or Quality Assurance/Quality Improvement (QA/QI) Projects",** and submit.

- The complete the added course to **"My Courses"** section, "**Conducting Classroom Projects or Quality Assurance/Quality Improvement (QA/QI) Projects".**
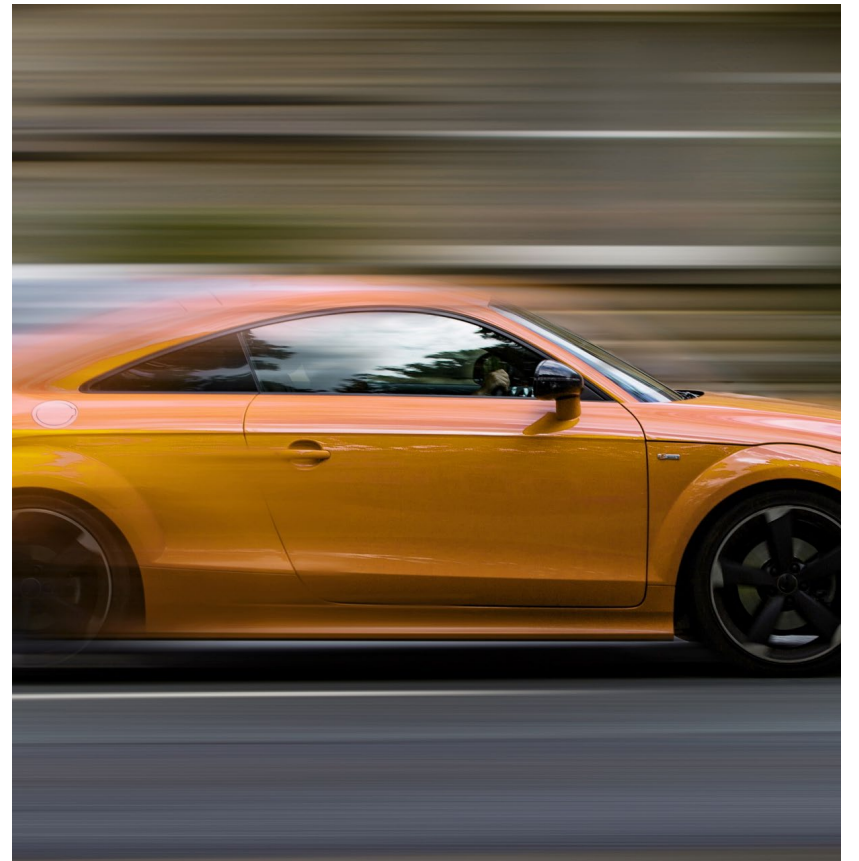
Who is your audience when filling out the QA/QI Form???

Key to a Speedy Review…

- Use the correct QA/QI form on the TU IRB webpage (WORD doc.)

- Signatures of all Students and Faculty Mentor (sign page can be PDF)

- Include separately: CITI training certificates & site approval(s)

- Enough detail to make a determination of HSR or not HSR

Additional Information :

TU IRB web page: https://utulsa.edu/research/office-research/research-compliance/irb-protection-human-subjects/

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7122260/

https://irb.ucsf.edu/quality-improvement-qi-and-quality-assurance-qa

Questions?