

Quality Improvement/Program Evaluation/Evidence-based Practice Determination

If your project involves human subjects or information classified as identifiable and/or specimens, but you question if your project might still be classified as Quality Improvement, Program Evaluation, or Evidence-Based Practice/Medicine read on. *For more information, refer to the WVU OHRP website.*

Projects classified as *Quality Improvement, Evidence-based Practice/Medicine, and Program Evaluations* may qualify as **Not Human Subject Research (NHSR)** and may be submitted as NHSR for acknowledgment.

The following questions can help you determine if your project may qualify as NHSR or will require submission as a Human Subject Research study. *When in doubt, contact the WVU Office of Human Research Protections for guidance on your submission.*

1. **My project involves testing an experimental drug, device (including medical software or assays) or biologic.**

YES

NO

Answer: **YES: STOP**—Your project most likely qualifies as Human Subject Research. If needed, contact the WVU Office of Human Research Protections for additional guidance.

2. **My project has received funding to be conducted as human subject research.**

YES

NO

Answer: **YES: STOP**—Your project most likely qualifies as Human Subject Research. If needed, contact the WVU Office of Human Research Protections for additional guidance.

3. **This is a multi-site project.**

YES

NO

Answer: **YES: STOP**—Your project most likely qualifies as Human Subject Research. If needed, contact the WVU Office of Human Research Protections for additional guidance.

4. **This project tests a hypothesis, randomizes subjects, includes a control group, contains observational research or comparative effectiveness research, encompasses comparative research in alternative research paradigms, or otherwise involves a systemic investigation designed to contribute to generalizable knowledge.**

YES

NO

Answer: **YES: STOP**—Your project most likely qualifies as Human Subject Research. If needed, contact the WVU Office of Human Research Protections for additional guidance.

5. **This project will be conducted whether I, or others, benefit from it professionally or not.**

YES

NO

Answer: **NO: STOP**—Your project most likely qualifies as Human Subject Research. If needed, contact the WVU Office of Human Research Protections for additional guidance.

6. **This project is intended to improve or evaluate a practice or process, or a specific program, within the institution.**

YES

NO

Answer: **NO: STOP**—Your project most likely qualifies as Human Subject Research. If needed, contact the WVU Office of Human Research Protections for additional guidance.

7. **The results of this project will be presented, published, or disseminated outside the institution conducting it.**

YES

NO

Answer: **YES: CAUTION**—Intent to publish outside the institution does not automatically constitute Human Subject Research. However, *Program Evaluations*, *Quality Improvement*, and *Evidence-based Practice* projects cannot be described as research when presented. If your other answers indicate that your project may be Human Subject Research and you answered “YES” to this question, your project is most likely Human Subject Research and does not qualify as NHSR.

Basic Definitions:

Quality Improvement (QI) has the primary aim or motive to improve patient care right now or for the next patient seen or improve operations or efficiency. In the non-clinical setting, it's used to evaluate an operational procedure or operational process to determine output, outcomes, and impact.

Evidence-based practice (EBP) is the process of collecting, processing, and implementing research *already conducted and shown to be effective* to improve clinical practice.

Program Evaluations are individual systematic studies conducted periodically or on an ad hoc basis to assess how well a program is working. The purpose of program evaluation is to *improve*, not prove.