

QUICK Checklist for Determining HSR, QI or PE

Y or N: Does your project generate new, **generalizable** knowledge through **systematic** scientific methods or practices where you are **interacting** or **intervening** with persons?

- a. **If yes**, this is human subjects research
- b. **If no**, are you aiming to improve internal processes, practices, costs, or productivity for a specific existing intervention? That is, does your project aim to determine how *this* intervention, affected *this* participant group in *this* setting? “This” signifies something unique or specific.
 - i. **If yes**, your project *may* be QI.
 - ii. **If no**, are you aiming to inform decisions and identify improvements about the success of newly developed or existing programs according to predefined goals and objectives?

If yes, your project may *be* PE.

Y or N: Are your research questions asking about personal information ABOUT individuals?

- a. **If yes**, this project *may be* human subjects research.
- b. **If no**, are your research questions designed to assess existing practices or approved procedures that have been shown to be effective in the literature?
 - i. **If yes**, your project *may* be QI.
- c. **If no**, are your research questions designed to evaluate the success of a program based on predefined goals and objectives?
 - i. **If yes**, identify those goals and objectives for PE. This project *may* be program evaluation if you are assessing effectiveness, gathering data to inform future decisions about programming, or increase understanding/knowledge; these activities must be evaluated based on clear goals and objectives established through program development.

Y or N: Will participants be placed at risk during the project?

- a. **If yes**, are these risks due to change in the usual standard of care/intervention or from being exposed to questions regarding sensitive issues and directed at individuals?
 - i. **If yes**, this is human subjects research. Identify the physical and/or emotional risks, including risks to privacy.
 - ii. **If no**, there should be no risks beyond the usual intervention; risks are limited to privacy issues for QI or PE. Protections (e.g., data security) should be in place.

Y or N: Is the data identifiable?

- a. **If yes**, this project is human subjects research.
- b. **If no**, is the data is anonymous or anonymized?
 - i. Your project *may* qualify for QI or PE.
 - ii. Your project *may* qualify for Human subjects research with an exempt status (see exempt categories for HSR).

Y or N: Do your participants reflect the characteristics of the total population that is being studied, or controls are involved?

- a. **If yes**, this may be human subjects research.
- b. **If yes** – solely in regards to the use of controls – are the controls only being used to compare participants for determining success of the program?
 - i. **If yes**, this *may* be PE.
- c. **If no**, will you be using a convenience sample of participants exposed to the practices or procedures under investigation?
 - i. **If yes**, this may qualify for QI.
 - ii. **If no**, does your sample depend on number of program participants and the degree to which it is necessary to determine success of program?

If yes, this may be PE.

Y or N: Will you be using experimental or quasi-experimental design?

- a. **If yes**, what are your methods of analysis? This may fall under human subjects research.
- b. **If yes**, are you using quasi-experimental design only for purposes of gathering data about the program and not about individuals?
 - i. If yes, then this *may* be PE
- c. **If no**, i.e., there are no experimental or quasi-experimental designs, this is QI.