

Medically recognized standards of care are treatments or procedures that medical experts consider appropriate and that are commonly used for a given disease or condition. Because adequate knowledge about the effectiveness and risks of standards of care is sometimes lacking, studies designed to evaluate two or more standards of care have become common. Such studies are often referred to as “comparative effectiveness research.” Comparative effectiveness research is conducted to assess differences in outcomes, risks, and benefits between two or more standards of care.

### **Risks of research**

In comparative effectiveness research, there may be uncertainty about which risks should be considered reasonably foreseeable risks of the research and how they should be described to prospective subjects in the informed consent process. The Office of Human Research Protections (OHRP)’s general position is that in research designed to evaluate risks of standards of care:

- the risks of standards of care that at least some subjects would be exposed to by participating in a research study that are different from the risks of therapies the subjects would be exposed to outside the study are risks of the research that the IRB must consider when evaluating the research; and
- the identified risks the research proposes to evaluate as one of the purposes of the study are reasonably foreseeable risks that generally must be disclosed to prospective subjects when seeking their informed consent.

OHRP generally considers the risks of a standard of care being evaluated to be research-related if:

- a standard of care that at least some of the individual subjects will be assigned to receive will be different from the standard of care that they would have received if they were not participating in the study, and
- there might be different risks associated with those standards of care. Therefore, in such studies, the possible differences in risk being evaluated are considered risks of the research.

Research risks do not include those created by subjects’ underlying medical condition or those associated with any available standard of care treatment subjects receive either outside of the research or during the course of an observational study where subjects are assigned to a standard of care based on clinical decision making.

# U-MIC TRANSCRIPT

## Comparative Effectiveness Research

### **Risk evaluation as study purpose**

In comparative effectiveness research, evaluation of the risks posed by one or more standards of care may represent part of a study's purpose. The purposes of research are the aims or objectives that determine a study's design and provide scientific and ethical justification for its conduct. The evaluation of a risk is considered a study purpose when the research is designed and conducted in order to ascertain the existence, extent, or nature of a particular harm. Evaluation of risk that may be identified as a study purpose in comparative effectiveness research should be limited to risks that are sufficiently important to justify the conduct of the study. Outcomes measured as part of the study but not part of the fundamental reasons for its conduct should not necessarily be considered study purposes.

If the evaluation of a particular risk associated with a standard of care is a purpose of the research, OHRP generally considers that risk to be reasonably foreseeable. Such reasonably foreseeable risks must be disclosed as risks in the informed consent process in accordance with regulatory requirements.

Contact the IRB for more information about comparative effectiveness research.

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