



## **QUALITY IMPROVEMENT ACTIVITIES OR PUBLIC HEALTH SURVEILLANCE VERSUS RESEARCH**

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As defined in 45 CFR 46.102(d) and 45 CFR 164.501, research is “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.”

*Generalizable knowledge* is ordinarily regarded in this context as knowledge that can be applied both to the population being studied and possibly to other populations.

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)).

Quality improvement has been described as follows by the National Bioethics Advisory Commission in its August 2001 document titled “Ethical and Policy Issues in Research Involving Human Participants” (page 37):

“These activities, generally referred to as program evaluation or quality improvement, are not intended to have any application beyond the specific organization in which they are conducted. As is true in the area of public health, because populations are the subject of study and because the methods used in program evaluation or quality improvement are the same as those used in research, it is often difficult to determine whether an activity is research that falls under the oversight system.

Definitional issues regarding program evaluation or quality improvement are not limited to health care delivery. They also occur in industrial or educational settings and in social science and operations research. However, if the purpose is to assess the success of an established program, and the information gained from the evaluation will be used to improve that program, the activity should not be considered research involving human participants. Evaluation is a program monitoring tool, and the information gained will immediately benefit the program and/or the individuals involved.

However, when quality improvement involving human participants is undertaken to test a new, modified, or previously untested intervention, service, or program to determine whether it is effective and can be used elsewhere, the activity is human participant research and subject to the oversight system.”

Therefore, it is the DUHS IRB’s position that if an activity is intended to evaluate an existing practice and attempt to improve it, and the data from the evaluation will not be applied to populations other than the population under study, then the activity would not be subject to the research provisions of the Common Rule, the Privacy Rule or FDA regulations.

For example, a quality improvement (QI) activity - such as occurs when members of the Duke University Hospital (DUH) staff conduct an initiative to assess current hospital practice, followed



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by the implementation of a change in the practice that is hypothesized to lead to an improvement in the practice within DUH - does not require DUHS IRB review unless it also meets the above definition of research. Such a QI activity *may be* a systematic investigation designed to improve local practice, but it would not meet the federal definition of research if it is designed to develop or contribute to local knowledge, but not have broader applicability. The local presentation of QI data in an effort to generalize - such as may occur during an in-house conference on hospital management strategies - is also not considered research requiring DUHS IRB review if the process of generalizing is restricted to the specific local setting (such as within the several hospitals of DUHS).

However, if such a presentation were contemplated to occur outside of the local setting, whether in published form or not, such as at a regional meeting on hospital management or in an editorial in a medical or hospital management journal, this contribution to generalizable knowledge using the systematically collected data would meet the federal definition of research, and thus the project would require IRB review. If the material (data) to be analyzed and presented outside of the local setting were to include identifiable private information – information linked to one or more people (for example, patients whose data were included in the QI initiative) – then the research would involve a human subject (45 CFR 46.102(f)) and a DUHS IRB protocol must be submitted and approved before analysis and presentation. If the material (data) were anonymized and de-identified before analysis and presentation and thus did not involve a human subject, then the IRB could declare the research not to be subject to IRB review because the research would not involve a human subject (45 CFR 46.102(f)) and not to be subject to the research provisions of the Privacy Rule (HIPAA) (45 CFR 164.500(a)) or FDA regulations (21 CFR 56.102(c)).

Surveillance for disease, such as occurs through the DUH Infection Control Program or the Duke Tumor Registry, does not meet the above definition of research. Even when identifiable private information is provided to State or federal agencies as a part of their mandated public health surveillance programs, DUHS is not engaged in research. Such activities do not require DUHS IRB approval.

The final determination of whether an activity is research requiring IRB review will be made by the DUHS IRB. To obtain an authoritative determination of whether an activity might meet any of the above definitions of research, investigators and other DUMC/DUHS staff must consult with an IRB Chair, Vice-Chair, or Executive Director.