

# How to Distinguish Research From Quality Improvement

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Dear Practical Ethicist,

Within our hospital, there are several projects conducted that some of our IRB members think should be coming to the IRB for review. Others argue that these projects are not research, they are quality improvement initiatives. But sometimes the people running the projects want to make their results public—publish them or present them at national conferences. And even more complicated, sometimes they say initially that they don't plan to publish the results—but when the project is over, they decide that they do! We have endless discussions at IRB meetings about this issue. Can you help?

Signed,

Quality Inquisitor

Dear QI,

It is important to get definitions straight when distinguishing between research and quality improvement. There is a regulatory definition of research, but no regulatory definition of quality improvement. Research is “a systematic investigation . . . designed to develop or contribute to generalizable knowledge.”<sup>1</sup> Quality improvement projects may or may not meet the definition of research. Therefore, the real question is whether a quality improvement activity is, or is not, research.

We can probably agree that if a quality improvement activity is worth doing, it is a systematic investigation. It is an investigation in that it is a searching inquiry for knowledge or truth. A quality improvement investigation is systematic in that it should follow a pre-defined method or plan. A quality improvement systematic investigation is designed to develop or contribute to knowledge that is relevant to the organization or process that is the target of the quality improvement activity. Therefore, the discrimination between a quality improvement activity that is research and a quality improvement activity that is not research depends on whether the activity is designed to contribute to *generalizable* versus non-generalizable knowledge.

Research is a behavior, not an outcome. Research represents the actions that investigators undertake that are directed at developing or contributing to generalizable knowledge. A systematic investigation designed to develop or contribute non-generalizable knowledge that also happens to develop generalizable knowledge is serendipity, not research. A systematic investigation designed to develop or

contribute generalizable knowledge that does actually result in any generalizable knowledge is failed research, but it was still research.

The interpretation of “generalizable” is the hardest part of deciding whether a quality improvement activity is research. Publication or other dissemination of results does not retrospectively turn activity that was not research into research, and the absence of publication does not retrospectively turn a behavior that was research into non-research. A lot of research never gets published and a lot of publications do not involve research (e.g., Stephen King or the *New York Times*). It is a similar consideration with regard to adding to generalizable knowledge. A lot of research does not work out (pilot studies fail, studies have to be stopped due to poor enrollment and never answer the research question) and the result does not add to generalizable knowledge. At the same time, lots of activities that are not research add to generalizable knowledge (consider Newton watching an apple fall from a tree or Fleming observing penicillin-contaminated petri dishes). There is a difference between activities *designed* to develop or contribute to generalizable knowledge and activities that develop or contribute to generalizable knowledge. The former is about behavior, and the latter is about outcome, and the thing that counts is behavior.

We can look to dictionaries for assistance in interpreting the term *generalizable*. Dictionaries define the term *generalizable* with wide a range of meanings. There are broad definitions, such as “inferring from the few to the many,” to narrow definitions, such as “widely applicable.” “Inferring from the few to the many” results in nonsensical decisions. For example, consider polling college students on their satisfaction with the cafeteria food. This is clearly not research, yet such a poll invariably requires sampling in which the poll taker must infer the opinions of many people from the responses of a few (the sampled students). Therefore, a more narrow definition, such as “widely applicable,” is more appropriate.

In the end, distinguishing whether quality improvement is research is a difficult task—and one best assigned to an individual within the institution, but not one that should be determined by the convened IRB. Like an umpire deciding whether to call a pitch at the edge of the strike zone, you have to use your best judgment and call it like you see it. In some cases, people will disagree with your opinion. If you cannot be comfortable with that uncertainty and criticism, someone else should make the decisions.

There is one exception to the rule of “call them like you see them.” When the research is regulated by a U.S. federal agency and sometimes when the research is regulated by a country outside the United States, the law is clear that the regulator has the final authority over whether research is subject to regulation.<sup>2</sup> Any decision you make, no matter how reasonable, can be overruled by the regulators. In addition, governmental agencies, such as National Institutes of Health (NIH), that fund research think that everything they fund meets their regulatory definition of research. So, if there is federal oversight, ask the regulators. If no regulatory body can second guess you, call them as you see them. The Office for Human Research Protections (OHRP) has addressed this issue in a series of Frequently Asked Questions, available online.<sup>3</sup>

In summary, we can use the regulatory definition of research to make an analytical decision about whether quality improvement is research. However, these are just words that are limited. On the other hand, people who oversee research intuitively know when a quality improvement is research based on what we expect people to do in the quality improvement field. When our intuition and analysis are at odds, it is time to consider whether our intuition should inform our analytical thinking. As much as we can bring our intuition and analytical skills to bear, some decisions about whether quality improvement is research will be fuzzy. Be like an umpire. Know that you need to make the call. Do your best and call them like you see them.

## Notes

1. 45 CFR §46.102(d): Definition of “research.”
2. 45 CFR §46.101(c): Department or agency heads retain final judgment as to whether a particular activity is covered by this policy.
3. <http://www.hhs.gov/ohrp/policy/faq/quality-improvement-activities/index.html>

P. Ethicist

## Author Biographies

**Dr. Practical Ethicist**, in real life, is a collaboration of two experts: Jeffrey A. Cooper and Lindsay McNair. They can be reached at JCooper@wcgclinical.com and LMcNair@wcgclinical.com.

**Jeffrey A. Cooper**, MD, MMM, is a physician, basic science investigator, clinical investigator, and manager with many years of ethical review experience as a member and chair of an IRB. He left medical practice in 2002 to help start the Association for Accreditation of Human Research Protection Programs, Inc. (AAHRPP), where he was responsible for the development and operation of the accreditation process. He is currently vice president for Global Consulting at WIRB-Copernicus Group.

**Lindsay McNair**, MD, MPH, MSBioethics, is a physician, clinical investigator, and former academic IRB member who has spent most of her career working in clinical research for the pharmaceutical and biotechnology industry, with a specific interest in ethical drug development research. She is an adjunct faculty member at Boston University and is currently the chief medical officer and president of Consulting Services for the WIRB-Copernicus Group.