turned researcher should clearly indicate to the IRB that the data were originally collected as part of a QI project. The IRB should be prepared to handle this type of review and take the next steps as required of all research projects (e.g., designation of exempt, expedited or full-committee-review, level of consent required).

At our site, after the institutional discussion was commenced related to the definition of research, the IRB developed a close working relationship with the institutional QI committee. The goals for the QI evaluators and the IRB are similar. The QI evaluators want QI projects to be performed with a high standard to protect confidentiality and to ensure that results are applicable. It is important for both entities to know when their review is applicable to a project.

In order to distinguish research from QI, we use the following criteria:

- Primary intent—the intent should be clear in the purpose/aim statement for the specific project. In general, QI projects are aimed at improving local systems of care (nongeneralizable). If the intent is to promote “betterment” of a process of care, clinical outcome, etc., then the project may be considered quality improvement.

If any of the following criteria are met, then the project receives consideration as to whether IRB review is required:

- Generalizability—if the primary intent of the project is to generate generalizable results
- Additional risk or burden—if the project will impose risks or burdens beyond the standard of practice to make the results generalizable
- Design—if a project involves randomization or an element that may be considered less than standard of care

Additional Notes

a. Federal regulators have made it clear that any publication describing a project as “research” must have received prior IRB review and approval. Therefore, projects determined to be QI initiatives should not be published as “research.”

b. Projects considered QI must also maintain the highest integrity of confidentiality possible.

c. Characterizing a project as QI does not necessarily negate the need for informed consent.

Informed Consent

HIPAA allows projects conducted within a covered entity with the intent of obtaining information related to treatment, payment, or health care operations to be conducted without additional patient authorization. Patients should be made aware of these uses of their data via the privacy notice required by HIPAA. A QI project may be appropriately initiated without patient authorization or consent; however, consideration must be given to whether or not health care workers should be aware of and possibly required to consent to the project. These are decisions that must be well thought out by the initiators of the quality improvement teams at the institution.

Research is not covered under the HIPAA “treatment, payment, or health care operations” exemptions, and therefore, if research is being conducted, the requirements for waiving informed consent and/or waiving the requirements for documentation of informed consent must be met. These regulations are described in more detail in other chapters of this book.

Other Activities That Are Not Research

To understand when a project should be classified as research, it is important to understand the major categories of activities that may be appropriately classified as something other than research.

Quality Assessment

Activities that are designed to determine whether aspects of medical practice are being performed in line with established standards are called QA.

Quality Assurance

In New Hampshire, this term is used for the specific instance of the process of reviewing, analyzing, or evaluating patient and/or provider specific data that may indicate (the need for) changes in systems or procedures that would improve the quality of care. The analysis is protected from legal discoverability, and the review is often triggered by predetermined “thresholds/criteria.” This analysis must be conducted with a specific committee structure. The knowledge generated is typically for local, immediate application.

The Case Report or Case Series

A physician requests access to her patient’s medical record to prepare a “case report” for publication in a medical journal. The first step is to determine whether the project contains both of the elements from the regulatory definition of research (a systematic investigation and the intent to contribute to generalizable knowledge). In our opinion, it is not reasonable to suggest that the organization of information for a case report constitutes a systematic investigation to the extent that would be expected of a research project. Because the first element of the regulatory definition of research is not present, this project is not research and, therefore, is beyond the regulatory authority of the IRB. In our opinion, this kind of case report project is most appropriately classified as an educational activity. Care should be taken, however, to distinguish a case report from an “N-of-1” research study in which there is systematic manipulation of an intervention to produce generalizable results.

When discussing the classification of case-report projects, many people ask whether the inclusion of more than one patient requires that the project be classified as research. In our opinion, the number of patients is not a defining factor. Educational activities often involve discussion of the course of a group of patients. It is the use of statistical method such as subgroup comparisons and test for prognostic factors that are the distinguishing features of a systematic investigation. In the absence of the basic elements of a systematic investigation of a scientific question, the case-report project should be classified as an educational activity rather than research, regardless of the number of patients that form the basis for the discussion.
In the event a case report or case series cannot be published or presented without the potential for identifying the patients, permission from the patient(s) must be obtained before use of the data.

**Medical Practice and Innovative Therapy**
A commonly cited definition of medical practice describes an activity that is designed solely to enhance the well-being of an individual patient. A type of medical practice that is often confused with research is a class of activities that has been called “innovative therapy.” Basically, innovative therapy describes an activity that is designed solely to benefit individual patient(s) but in which the ability of the activity to result in the desired outcome is to some degree unproven. Levine has explained that a better term for this class of activity is *nonvalidated practice.*

**Medical Practice for the Benefit of Others**
In some situations, the goal of medical practice is to benefit people other than those directly affected by the health care intervention. Examples of medical practice for the benefit of others include blood donation and some vaccination programs. In terms of the research/nonresearch issue, the critical feature of this form of medical practice is that the goal of the activity is to benefit a well-defined group of people in a predictable way.

**Public Health Practice**
Public health practice is similar to medical practice for the benefit of others in that the activity involves people who do not directly benefit from the intervention. The most common situation in which there is confusion about the distinction between a public health practice and research is with public health practices that require the review of private, identifiable information about health status. Examples of public health practices that often do not involve research include surveillance (e.g., monitoring of diseases) and program evaluation (e.g., immunization coverage or use of clinical preventive services such as mammography).

**Outcome Analysis**
Outcome analysis is a nonspecific term that may be used to describe a variety of projects in which medical records are reviewed to evaluate the outcome of medical treatment or the course of patients with a specific medical condition. Because medical research usually involves a formal analysis of outcome, use of the term *outcome analysis* to describe a nonresearch activity is confusing. Nevertheless, it is common practice for health care providers to perform descriptive analyses of medical outcomes that are appropriately described as something other than research but do not clearly fall into a better defined category. Recognizing that there is no accepted definition of outcome analysis in the context of health care evaluation, the main difference between a nonresearch outcome analysis and a quality-assessment project is that comparison of results to an established standard is not a defining feature of outcome analysis.

**Resource Utilization Review**
Medical record review is often conducted to evaluate the use of resources in a specific health care activity. Terms such as *cost control* are used to describe this class of activity, but the terms *utilization review* or *resource utilization review* are more general and often more accurately reflect the fundamental goal of projects in this category. Although a research project may involve review of resource utilization, the term *resource utilization review* usually refers to a nonresearch activity.

**Education**
The transferring of information from one group of people to another is a common activity in all aspects of society. As we explain later in this chapter, the regulatory definition of research focuses on the desire to develop or contribute to "generalizable knowledge." The reason to mention education in the context of a discussion about the definition of research is that it is important to recognize that the goal of most educational activities is to spread or "generalize" knowledge. The fact that an activity is undertaken for the specific purpose of teaching somebody something does not mean that the activity involves research.

**Conclusion**
To determine whether a project should be classified as research, it is important to understand that nonresearch activities may use scientific methods and produce results that are suitable for publication in a medical journal. The defining characteristic of research is that a fundamental goal of the activity is to learn something that will benefit future patients (not the subjects enrolled in the research study). The following questions facilitate the evaluation of research intent: What is the primary intent of the project? Would the project be conducted as planned if the project director knew that he or she would never receive any form of academic recognition for the project, including publication of results in a medical journal or presentation of the project at an academic meeting?

**References**