OBTAINING INSTITUTIONAL REVIEW BOARD APPROVAL

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"I didn't know anything about the research process when I started my research project. We were given templates of the documents that needed to be filled out to obtain IRB approval, but I didn't really understand what I was filling out or why I needed to fill it out. A thorough understanding of the IRB process is fundamental to a successful research project."

—Former PGY2 Ambulatory Care Resident

LEARNING OBJECTIVES

- Describe regulations and requirements that govern institutional research.
- Differentiate between exempt, expedited, and full review Institutional Review Board (IRB) submissions.
- Identify strategies for successful IRB submissions.
- Create a list of key elements and specific language that should be included in an IRB submission.
- Compare and contrast quality improvement and research activities, and illustrate when a performance improvement project might require IRB or other institutional oversight.

INTRODUCTION

This chapter aims to demystify the process of obtaining ethical approval for your project through an Institutional Review Board (IRB) or other institutional committees, such as a Privacy Board. This can often be an overwhelming process for residents and practitioners due to the variable

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processes among institutions, but it is a required component that must be completed prior to conducting research, especially if you hope to publish your findings in the peer-reviewed literature. This chapter will outline the regulations related to human subjects research detailed in the Code of Federal Regulations (45 CFR 46). This Federal Policy for the Protection of Human Subjects was updated with a delayed January 21, 2019 effective date for what are called the "2018 Requirements" or Revised Common Rule.[1]

There are other types of regulations to keep in mind, including those published by federal agencies (e.g., Food and Drug Administration [FDA] and Department of Defense), federal statutes such as the Family Educational Rights and Privacy Act, and international organization guidelines (e.g., ICH E6 Guideline for Good Clinical Practice). A detailed explanation of these regulations is outside the scope of this chapter. You should consult your IRB and find out which regulations apply before you begin your project. Secondly, this chapter focuses solely on research conducted within the United States. If you are planning to implement a project within another country, this guidance will not apply to country-specific requirements for approval and conduct of research involving human subjects outside the United States.

HUMAN SUBJECTS RESEARCH

To determine whether an activity constitutes human subjects research, you must answer two questions:

1. Does the activity involve human subjects?
2. Is the activity research?

Let us begin by defining the term *human subject*. According to the Common Rule (a federal policy regarding the rule of ethics concerning biomedical and behavioral research involving human participants), a human subject is defined as a living individual about whom an investigator (whether professional or student) conducting research (1) obtains data through an *intervention* (e.g., physical procedures, manipulation of a subject's environment) or *interaction* (i.e., communication or interpersonal contact) with the individual; or (2) obtains *identifiable private information*. Identifiable private information is present any time the identity of an individual may be easily determined by an investigator or is associated with the collected data.[2]

Many institutions that conduct research extend this definition of human subjects to include deceased individuals as the Health Insurance Portability and Accountability Act of 1996 (HIPAA) regulations use this expanded definition. Whether an activity is considered research hinges on the definition of *research* as "a systematic investigation designed to develop or contribute to generalizable knowledge."[3] A *systematic investigation* is an activity that involves a prospective plan that incorporates data collection, either quantitative or qualitative, and data analysis to answer a question; *generalizable knowledge* is knowledge that is expressed in theories, principles, or statements of relationships that can be generally applied to our experiences.[4] If the answer to both of the above questions is *yes*, then your project meets the criteria for human subjects research.

Many important pharmacy research questions can be answered without human subjects research. Common examples of non-human subjects research would be the use of administrative data that does not include any personally identifiable information (PII) (e.g., protected health information [PHI], personal data of students, employees, or consumers) or analysis of data extracted from electronic databases, such as an electronic medical record, claims data warehouse, or compilation of survey results. These data must be stripped of all PII before being obtained by the study team, so the researchers cannot re-identify any individual(s) included in the sample. The FDA Adverse Events Reporting System Public Dashboard, containing almost 17 million MedWatch reports, is a publically accessible database that can be used for research without IRB approval for that reason (see **https://www.fda.gov/drugs/questions-and-answers-fdas-adverse-event-reporting-system-faers/fda-adverse-event-reporting-system-faers-public-dashboard**).