## Effect of the HIPAA Privacy Rule on Health Research

Since the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule was implemented by the U.S. Department of Health and Human Services (HHS) in April 2003, health researchers have asserted that the Privacy Rule has had a negative effect on researchers' abilities to conduct meaningful research. The purpose of this chapter is to review the currently available evidence on the effect of the Privacy Rule on research, including surveys as well as other types of studies to measure impact. The chapter begins with an overview of several surveys that examined health researchers' personal experiences with and opinions about the Privacy Rule. Many issues identified by survey respondents were also the focus of other types of studies, so the remainder of the chapter consists of a topical review of the available evidence regarding the effect of the Privacy Rule, and its interpretation, on health research. The following issues are reviewed in detail: (1) selection bias, (2) research efficiency, (3) abandoned research, (4) deidentified information. (5) the authorization process, and (6) concerns about potential legal consequences.

#### OVERVIEW OF SURVEY RESULTS

As noted in previous chapters (Chapter 1 in particular), the information gained by opinion surveys has limitations. The potential for bias exists because of the way the questions are worded and framed, and respondents may have self-motivated reasons for responding in a particular fashion. For example, individuals responding to surveys conducted by professional societies may be more likely to have encountered difficulties with the Privacy

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