

CHAPTER 3

The HIPAA Privacy Rule's Impact on Patient Recruitment

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Objectives

- Identify areas where the HIPAA Privacy Rule will have an impact on recruiting efforts.
 - Understand how to use protected health information for patient recruitment under the HIPAA Privacy Rule.
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Introduction

Both government and industry are trying to increase public awareness of clinical trials and trust in the clinical trial process through the targeted, strategic dissemination of information. The comprehensive registry of all clinical trials for serious illness mandated by Congress in 2000 and the proliferation of web sites providing information about the clinical trials process and the ability for patients to self-refer are examples of these efforts.

Traditionally, recruitment and retention efforts have been dependent on individual investigative site efforts to develop and place advertisements, pre-screen callers, manage patient databases, schedule appointments, provide appointment reminders and other services that help patients attend study visits. These methods depend exclusively on research sites and their resources for successful recruitment and retention. The increasing challenges are motivating new strategies involving centrally orchestrated recruitment campaigns and retention services.

To positively impact the enrollment of patients for clinical trials, marketing or advertising agencies specializing in patient recruitment are blending advertising with public relations and other novel marketing initiatives, including the Internet. This current trend shifts the patient recruitment focus from the individual investigator to centralized patient recruitment campaigns.

This chapter will discuss the basics of the HIPAA Privacy Rule (Privacy Rule), its impact on the recruitment of patients as clinical research subjects and will provide guidance on the current methods for recruiting and retaining patients under the Privacy Rule.

HIPAA Privacy Rule “Personal Health Information” (PHI)

The Privacy Rule's regulations apply to “personal health information” (PHI), which is (1) “health information” that is (2) “individually identifiable” and is (3) created or received by a “covered entity.” Health information is “individually identifiable” under HIPAA if it directly identifies an individual or could be used to identify an individual. Health information directly identifies an individual if it includes any of eighteen (18) direct identifiers specified by HIPAA (see Table 1).

Items 1-17 in Table 1 describe demographic information that directly identifies an individual (“direct identifiers”). Item 18 is a catchall category that covers any identifier that HIPAA did not specify in Items 1-17 that could be used to identify an individual. Importantly Item 18 includes an “identifying code.” Under HIPAA, an identifying code is one that is derived in some way from the data set or an individual's identification. An example would be the last four digits of a person's social security number. Such a code is an “indirect identifier” that renders the data set “identifiable” because the code could possibly be used to re-identify the individual. In contrast, a non-identifying code is one that is not derived from the data and could not feasibly be used to re-identify the individual.

In summary, individually identifiable health information (IIHI) has two components: health information and identifying demographic information. The latter could include direct identifiers (Items 1-17 in Table 1) and/or an indirect identifier (an identifying code, Item 18 in Table 1).

HIPAA Privacy Rule: The Basics

The most significant impact of the HIPAA Privacy Rule for investigators is in the area of patient recruitment. In an update to the Privacy Rule, effective August 14, 2002, the HHS clarified that recruitment of subjects for research