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Legitimate and Ethical: Distinguishing When and How Regulations Apply in Patient-Oriented Research

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We read Schonfeld and colleagues' article "You Don't Know Me But..." with interest. The authors suggest a lacuna in patient privacy and confidentiality falling between protections extended by the HIPAA Privacy Rule and other parts of the Code of Federal Regulations (CFR) addressing research with human subjects and the purview of institutional review boards (IRBs) (a.k.a. the Common Rule), arguing that HIPAA's "preparatory research provisions" permit use of protected health information (PHI) for screening and study recruitment *without patient consent*. Because this period is "preparatory to research," the authors believe it falls before IRB oversight begins and, therefore, that patients' PHI may be used without their consent *and without IRB approval*. However, this suggestion conflates several key distinctions fundamental to understanding regulatory codes that we elucidate here to illustrate how HIPAA and the Common Rule align to provide participant protections in an increasingly broad field of patient-oriented research.

This discussion necessitates a clear distinction between processes of *research* (analysis intended to advance generalizable knowledge in a field) and *quality improvement (QI) or assurance* (analysis intended to improve patient care within a particular setting). Research, as distinct from QI, is intended to be generalizable to other settings. Often this is indicated by intent to publish results through peer review. By this definition, analyses to be disseminated beyond local settings are research, not QI.

This is a means/ends distinction from which follow respective regulatory domains covered by HIPAA and the Common Rule. HIPAA covers the broad domain of PHI created via patient care. The Common Rule sections apply to the narrower domain of research,

overlapping with HIPAA because PHI resulting from patient care may need to be used in patient-oriented research. As Schonfeld and colleagues note, HIPAA delineates “covered entities” that must collect and maintain PHI to provide clinical care (physician practices, managed care corporations, community hospitals, or health plans).

In contrast, most patient-oriented research occurs in academic medical centers and managed care organizations that have developed IRB policy and procedures to address the gap that worries Schonfeld and colleagues. Because these organizations hold patient-oriented research as an explicit organizational mission concurrent with provision of clinical care and recognize that these dual roles carry potential conflicts of interest, they operate with “heightened awareness” concerning risks to patients.¹

IRBs monitor human subjects protection for all *research*, regardless of an investigator’s clinician status. Patients have the right to privacy *from their clinicians* to consider whether to participate in research. This ensures that participation decisions will not affect quality of care received through clinicians. The same rationale underpins requirements that clinicians seek IRB approval before initiating research among their patients. Therapeutic misconception is a key concern in clinical research where patients may incorrectly perceive the purpose of the study to be provision of personalized care rather than contribution to generalizable knowledge through application of uniform research protocols. One way of ensuring patients understand differences between research and care is to distinguish between the role of a clinician conducting research and a clinician providing standard of care. IRB documentation and oversight are designed to monitor these distinctions not only through *content* of consent documents but by *imposing a process* of soliciting informed consent that calls out that difference to patients.

Schonfeld and colleagues suggest that granting an investigator access to information is tantamount to waiving informed consent. We disagree and suggest the authors here conflate Waivers of Consent and Waivers of HIPAA Authorization for Research. Their subsequent discussion of research involving deception is therefore irrelevant, although interesting in its own right. Rather, the important distinction lies between access to retrospective PHI and access to prospective PHI. Granting access to existing PHI held by a covered entity is a defined permission different from waiving the requirement of informed consent to prospective participation in research. In the recruitment context, a Waiver of HIPAA Authorization for Research may be granted precisely because the investigators are not yet able to identify relevant patients *in order to* (1) solicit informed consent for research participation and then (2) access relevant PHI stored as a result of clinical care but that investigators seek to use for research purposes.

To obtain IRB approval to access PHI, investigators must demonstrate that the study they seek to develop is legitimate science and that it will be ethically conducted. Approval to

¹HIPAA explicitly concerns the custodial relationship to patient PHI for various types of organizations. HIPAA is designed to be flexible and to set the *minimum* standard for covered entities. Importantly, PHI refers to data *obtained by a covered entity*, for any purpose. Covered entities that do not routinely conduct research may have privacy boards, rather than IRBs. In QI analyses, staff may access PHI because they already directly engage in patient care or seek to improve it (use, not disclosure). Following Schonfeld and colleagues, we limit our comments to issues of access to patient data examined with the aim of recruitment that therefore cannot be de-identified.

access PHI is conditional on demonstrating investigators' and their supporting team's training and certification in ethical conduct of research and that processes are in place to monitor conduct over the course of research. IRB assessment of the research team, then, addresses Schonfeld and colleagues' concern about extending the patient privacy bubble beyond the treating clinician to affiliated staff. Having determined that a study is legitimate and ethical, the IRB may grant a Waiver of HIPAA Authorization for Research to screen patient data, enabling investigators to determine eligibility so that individual patients can be approached for informed consent. Investigators must demonstrate that *preparatory* research could not be practicably conducted without PHI or the waiver. Investigators must provide an adequate plan to protect and then destroy the PHI at the earliest opportunity and provide assurance that it will not be reused or disclosed for other purposes.

Schonfeld and colleagues' analysis also assumes all clinical research proceeds through the treating clinician, therefore arguing the feasibility of asking patients whether a research staff member can approach them. However, some patient-oriented research is led by nonclinician investigators (e.g., social/behavioral scientists). In many cases, treating physicians may be co-investigators on these studies; in all cases, studies involving patients are developed with the consent of the clinic director, even when clinicians (physicians or nurses) are not part of the study team.

At our institution, any investigator preparing to conduct research who needs access to PHI to screen (identify), approach, and recruit patients must seek IRB approval, whether she or he is that patient's treating clinician or not. Our IRB makes this requirement of all *investigators* rather than of *clinicians* because although many clinicians conduct research, not all patient-oriented researchers are clinicians. A greater level of privacy is sustained by requiring Waivers of HIPAA Authorization for all clinicians and staff involved in dual roles of clinical care and research. Even if clinical staff members would have access to patient records by virtue of their involvement in patient care, they should secure IRB approval and document use of PHI for research recruitment.

In a prior era, when human subjects research was mainly conducted by physician investigators, our institution required that patients only be approached through their treating physician, either in person or through a letter from that physician. In that context, treating physicians approached patients to ascertain interest in a study, referring those who agreed to the study investigator. In many cases, this remains preferred practice where possible.

With increased attention to a broader range of patient-oriented research and an increasing number of nonclinician investigators recruited to the faculty, the fundamental issue for patient privacy is one of parity—treat all researchers as investigators regardless of their roles in providing clinical care. Within the parameters of CFR regulations, it is both the IRB's prerogative and its duty to provide research approval and oversight based on local conditions of the institution and patient populations. Thus, as patient-oriented research at UT Southwestern expanded, our IRB sought education and guidance from social, behavioral, and other faculty to increase awareness of types of studies conducted in these disciplines and explore how different research questions might affect processes of recruitment, sample

selection, and study design. Investigators from these disciplines made presentations to IRB faculty chairs, reviewers, and staff.

An IRB reviews recruitment approaches in protocols to minimize threats to internal and external validity and thereby justify any risks to participants. Nonmedication studies—particularly those from the social, behavioral, and public health disciplines—have raised new issues in sample selection where recruitment through a treating clinician might introduce recruitment bias (nonsystematic sample selection), or even confounding, when provider behavior itself is an outcome variable. Indeed, the research might require treating clinicians to *be blinded to patient study participation*.

These are complex issues that call for dialogue between IRBs and research investigators and ongoing training of both IRB staff and investigators, including clinicians engaging in research. As research methods and information sources such as electronic medical records evolve, it is crucial that these constituencies work together to adapt IRB guidelines that provide appropriate oversight adequately reflecting the range of approaches to patient-oriented research and ensuring best protections for patients.

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References

1. Schonfeld T, Brown JS, Amoura NJ, Gordon B. “You don’t know me, but ...”: Access to patient data and subject recruitment in human subjects research. *American Journal of Bioethics*. 2011; 11(11):31–38.