

Human Subjects Research - Major Revision Planned

October 26 Deadline for Public Comments

The Food and Drug Administration (FDA) plans to make sweeping changes to federal regulations on human subjects research. [The deadline for public comments is Wednesday, October 26.](#)

The [federal notice](#) (ID # HHS-OPHS-2011-0005) notes the impossibility of protecting patient identities from disclosure, but proposes to write a new rule to:

- expand researcher access to private patient data and biospecimens.
- exempt research and analysis that interferes with the patient-doctor relationship from the definition of “research” — and customary research oversight requirements.
- lessen legal contracts for protecting patients and patient data.
- centralize oversight and review of human subjects research.
- eliminate consent requirements for researcher access to deidentified, *but identifiable* patient tissues, body parts, and DNA.

In 1991, the “Common Rule” — a uniform set of rules for the protection of human subjects in *federally-funded* research — was adopted by 15 federal agencies. However, the FDA’s “Advance Notice of Proposed Rulemaking” now states, “The intent is to revise the Common Rule.”

There are no proposals recognizing individual ownership and meaningful patient control over storage, sharing and use of medical records, body parts and DNA. The notice includes an incredible 165 questions to the public from the FDA. Consider just six of the major proposals under consideration for public comment:

1. No Consent - Not requiring written consent for research using patient medical records or biospecimens collected for purposes *unrelated* to a proposed research study — such as for clinical care (leftover blood, removed organs, discarded tissues) — if the researcher does not obtain identifying information about the patient. (pp. 44519/44527) *See quotes on identifiability below.*
2. Not “Research” - Exempting from the definition of “research” government and health plan use of private patient data to interfere in treatment decisions and patient care. Thus, patient and doctor profiling, tracking patient outcomes, using patient data to create government treatment protocols, electronic medical record surveillance, birth defect registries, “quality” monitoring, imposing penalties on physicians who fail to comply with government treatment protocols (pay-for-performance), obesity monitoring, and government cancer registries and other research would be allowed without patient consent. (p. 44521)
3. Centralization - Expanding the number of studies exempt from review and approval, and mandating that a single centralized Institutional Review Board at one of the sites oversee all

multi-site research requiring review and approval. This will shift oversight to an entity far from many of the patients who are subjects of the research study. (p. 44522)

4. All Research - Requiring organizations that receive any funding for research to follow the revised “Common Rule” for all research, not just federally-funded research. (p. 44522)
5. Loophole - Deeming patient consent requirements for certain secondary use and analysis of patient medical records and/or biospecimens to be “impracticable” and thus waived. (p. 44524)
6. No Contract - Allowing the elimination of written contractual “data use agreements” between the institutions sharing patient data and biospecimens (e.g. hospitals) and the researchers analyzing them. The proposal would simply require all researchers to adhere to the HIPAA Security Rule, including encryption, audit trails, and breach notifications as well as a prohibition on attempting to reidentify the subject. (p. 44526)

Privacy, security and unidentifiability of records and specimens cannot be assured.

The U.S. Department of Health and Human Services recently [reported 7.8 million breaches](#) of patient data from 2009 through 2010. Furthermore, the FDA’s notice clearly states the *impossibility* of protecting or limiting access to the identity of individuals:

[W]e recognize that there is an increasing belief that what constitutes “identifiable” and “deidentified” data is fluid; rapidly evolving advances in technology coupled with the increasing volume of data readily available may soon allow identification of an individual from data that is currently considered deidentified. In this sense, much of what is currently considered de-identified is also potentially identifiable data. . . . (p. 44524)

Furthermore, none of these statutes [the HIPAA privacy Rule, the Privacy Act of 1974, etc.] was written with an eye toward the advances that have come in genetic and information technologies that make complete de-identification of biospecimens *impossible* and re-identification of sensitive health data easier. . . . [*emphasis added*] (p. 44525)

Regardless of what information is removed, it is possible to extract DNA from a biospecimen itself and potentially link it to otherwise available data to identify individuals. Consequently, we are considering categorizing all research involving the primary collection of biospecimens as well as storage and secondary analysis of existing biospecimens as research involving identifiable information. . . . (p. 44525)

DEADLINE for public comments: Wednesday, October 26 at 11:59 p.m. EDT

To comment online, [click here](#) and enter ID# HHS-OOPHS-2011-0005.

Specifically: The FDA notice requests the public’s comments on their proposals, any one or more of the 165 specific questions and any other general concerns, including comments “about circumstances in which the protections provided by the current system might be inadequate and in need of supplementation or change in order to make sure that subjects are receiving appropriate protections.” (p. 44529)

Let Us Know: Please send a copy of your comments to info@cchfreedom.org. Thank you!