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Don't take your EHR to heaven, donate it to science: legal and research policies for EHR post mortem

Vojtech Huser, MD, PhD[1], James J. Cimino, MD[1,2]
[1]Laboratory for Informatics Development; NIH Clinical Center
[2] National Library of Medicine, Bethesda, MD, USA

Abstract

Electronic Health Records (EHR) represent a valuable research source. We explore legal and research policies governing EHR use after a patient's death. We describe how the EHR is used after patient's death and how deceased status impacts laws and regulations governing such record. We explore the patient consent mechanism that would support creation of a separate deceased subject integrated data repository (dsIDR) and discuss potential benefit of such repository in comparison with existing query tools, such as the i2b2 cohort estimation query tool, which operate under IRB exemption for reviews preparatory for research. Governance of dsIDR data is compared to regulatory frameworks governing post-mortem management of tissues, organs and corpses as well as digital afterlife of non-healthcare private data.

Background: The policy governing access to EHRs is the *HIPAA Privacy Rule* (HPR) regulation included in the Health Insurance Portability and Accountability Act (HIPAA). The HPR distinguishes between access to the record for medical reasons (e.g., same diagnosis in offspring), administrative and legal reasons (e.g., life insurance claim) and research use. Patient data that are subject to HIPAA are often released to use in research during patient's life (*ante mortem*) by having patients sign project-specific informed consent forms. Per HPR regulation, HIPAA authorization forms, which allow named individuals access to EHR for medical reasons, expire after patient's death. *Post mortem*, the data are subject to different sets of rules. No federal legal policy explains whether research use of ante mortem consented data may continue after patient's death; however, several published studies indicate that local IRBs did approve such continuation of use.

Post mortem research use of organs and corpses: After death, organs can be donated for research. In order to increase their research utility, some patient information (e.g., gender, age at death, or comorbidities) are stored together with the organ or other specimen. The federal Uniform Anatomical Gift Act governs organ donations after death for the purpose of transplantation, as well as making of anatomical gifts of one's cadaver to be dissected in the study of medicine. The law prescribes the forms (declaration of intent) by which such gifts can be made. It also provides that in the absence of the intent form, a surviving spouse or specific relatives can make the gift. For example, in Virginia, the state department of Health runs a State Anatomical Program and patients make body donations by mailing a signed intent form to the state authority and giving a copy to a relative, physician, pastor or a close friend. A parallel could be made between post mortem use of biological artifacts for medical and research purposes and post mortem use of digital EHR artifacts.

Human subject research: The *Common Rule* (Title 45 CFR 46) classification into human and non-human subjects research renders research utilizing deceases subjects' EHR as non-human subject research. The less restrictive regulations related to non-human subject research prompted a Vanderbilt University team to proposed a category of *human non-subjects* research. We argue that dsIDR-based research would warrant a further category of *deceased human non-subjects* research.

Deceased patient warehouse: Numerous institutions offer cohort estimation query tools to researchers and have streamlined processes for empowering researchers. In some cases, governance of such query tools is under a separate IRB protocol that is updated regularly. In a typical cohort estimation query tool, researchers can perform simple searches on any medical record by using an IRB exemption usually granted to such use of the query tool. More detailed data queries and analyses, however, require topic-specific IRB approval. We envision a separate research cohort within IDRs that would only involve deceased subjects (dsIDR). This repository (possibly paraphrased as "clinical data cemetery") would operate under a separate IRB protocol and hold a similar exemption for research queries by interested researchers. It would allow greater access to the EHR records of deceased patients (e.g., individual lab values, de-identified text reports). The Social Security Death Index is viewed as an acceptable source to verify deceased status.

Conclusion: With the growth of accumulated EHR data, the use of the EHR records of deceased patients represents a significant body of data. A separate warehouse with only deceased subjects could represent a useful addition to tools available to a researcher and we hope to initiate a public policy debate around EHR digital afterlife.