

Informed Consent Around Electronic Exchange of Health Records

What is informed consent?¹

Informed consent is fundamentally a matter of protecting and enabling autonomous or self-determining choice by patients and subjects and that final authority for making decisions about medical treatment or research participation properly rests with patients and subjects, not physicians or research scientists.

How do we provide patients with informed consent around the exchange of electronic health records?

- HIPAA
- Verbal disclosure to patients about
 - Electronic health record design and purpose
 - Privacy regulations
 - Protections to prevent risks

Elements of Informed Consent:

(1) Disclosure of relevant information

- description of proposed action
- risks
- potential benefits
- an assurance that choice is the individual's to make with no fear of repercussion
- etc

(2) Comprehension

- an effort is taken to ensure that the individual can understand the info disclosed

(3) Voluntariness

- choice must be voluntary
- free of pressure from doc/researcher/system.

Levels of Disclosure²

How do you know when you have said enough about a certain decision? Most of the literature and law in this area suggest one of three approaches:

- **reasonable institution standard:** *what would a typical institution say about this intervention?* This standard allows the institution to determine what information is appropriate to disclose. However, it is probably not enough, since most research in this area shows that the typical institution tells the patient very little. This standard is also generally considered inconsistent with the goals of informed consent as the focus is on the institution rather than on what the patient needs to know.
- **reasonable patient standard:** *what would the average patient need to know in order to be an informed participant in the decision?* This standard focuses on considering what a patient would need to know in order to understand the decision at hand.
- **subjective standard:** *what would this patient need to know and understand in order to make an informed decision?* This standard is the most challenging to incorporate into practice, since it requires tailoring information to each patient.

¹ Beauchamp T, Faden R. Encyclopedia of Bioethics

² Basic Definition of Informed Consent. University of Washington School of Medicine. Available electronically at: <http://depts.washington.edu/bioethx/topics/consent.html#ques1>