

Informed Consent

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Origins of Informed Consent in a clinical setting

- Defense to the tort of battery based on unauthorized therapy
- The words “informed consent” do not appear in any cases until 1957
- State law with considerable influence from the civil rights movement—a reaction to what was viewed as medical paternalism

Informed Consent in a Clinical Setting

- Must be a failure in informed consent, and that failure must cause the injury
 - Typically that injury must be physical—or at least not a “dignitary harm”
- Basis of liability
 - Administration
 - Disclosure

Informed Consent Clinical Setting

- Canterbury v. Spence (DC Circuit 1972)
- “patient-focused standard”
 - May be the “specific patient” or may be a “reasonable patient”
- “reasonable practitioner standard”
- Both of these are objective standards

Informed Consent Clinical Setting

- Objective Standard
 - Protects against patients' hindsight regrets
 - Limits jury speculation as to individual idiosyncrasies
- May not apply for some elective surgeries—
e.g. cosmetic surgery

Informed Consent Clinical Setting

- A document or a process?
- Exceptions (AMA 1981)
 - Emergent situations where patient is incapacitated
 - Where disclosure poses a serious psychological threat and non-treatment would create direct and immediate harm

Informed Consent (Clinical Setting)

- Required documentation?
 - Typically only for invasive procedures
 - State law mandates (genetic testing)
 - Boilerplate

Informed Consent Research Setting

- There is a general, but not universal, view that different standards and considerations should apply to informed consent in a research context

Antecedents of Informed Consent in a Research Context

- Principles of Autonomy developed in reaction to (what came to be viewed as) unethical research
 - Nuremberg Code and Belmont
 - Nazi experimentation
 - Tuskegee (and others)
- Voluntary Consent Essential

Research Context

- There is an implicit conflict of interest in research; researchers are committed to both the real present people involved and to abstract future patients
- This tends to objectify the real present subject
- Researchers *need* the person to enroll
- Research *can* do harm
- Protocols may require specific procedures that may not be the best alternative
- Researchers may be blinded to potential alternatives
- Therapeutic misconception

Informed Consents in Research Context

- In research, there may be an ethical requirement, if not a legal requirement, to use a subjective approach
- The question becomes what would *this* person want to know before deciding whether to participate

Informed Consent Documentation

- Both a legal document and an ethical document
 - For sponsored protocols; sponsor may have a legal agenda
 - Institutional legal agenda
 - Regulatory agenda

Consent Form Documentation

- Summary of the clinical trial
- Purpose
- Procedures
- Risks and Benefits
- Alternatives
- Privacy Rights
- Rights as a Participant

Consent Form Process

- This is the place to address subjective concerns
 - There may be a duty to elicit those concerns
- Recognize that the consent process continues for as long as the subject continues to participate

Consent Form Process

- Recognize that different people require different kinds and different levels of information
 - This may be based on gender, education, personality or cultural norms
- If a sponsor will permit, consider additional educational material

Literacy Issues

- Consents must be in language that can be understood by the general subject population
 - Default 5th grade level
- Cognition research is in its infancy
- Legal concerns can actually make consents longer and more complex
- Consider Charts

Literacy Issues

- Separate out clinical treatment from experimental treatment—don't confuse the clinical risks with the experimental risks

Literacy Issues-Risks

- Often very valuable to list risks as
 - Very likely
 - Less likely
 - Rare

Risks

- When death is a possibility, i.e. >1%, it needs to be acknowledged

Benefits

- Avoid the temptation to overstate; researchers may be captured by the potential promise of their own research
- Boilerplate may create confusion
- Phase 1 studies

Alternatives

There is evidence that researchers are less creative in positing alternatives than they would be in clinical settings

Researchers frequently fail to state the availability of the study treatment outside of the

Placebos

- Therapeutic Misconception
- Subjects need to know that the placebo arm may actually be the “luckier” arm of a study

Privacy Risks

- Not discussing HIPAA today!
- It is often very difficult to determine, never mind articulate, what kind of privacy risks may be involved.
- For some studies, e.g. genetic studies, remember that *unknown* risk is not the same as *no* risk.

Payment

- May be used to show that this isn't therapeutic
- That message may be too subtle

Children

- Have their own autonomy
- Assent
- Issues of parental consent

Waiver

- Because of the ethical constraints, waiver should not be sought because of convenience
- Extremely difficult for FDA studies
- For non-FDA
 - Minimal risk
 - Consent not be practicable (means that it can't be done otherwise)
 - Will not adversely affect rights and welfare
 - Pertinent information must be provided later