Legal Issues In Clinical Research

Introduction to the Principles and Practice of Clinical Research Course

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Objectives

- Discuss the history and elements of informed consent for clinical and research care.
- Summarize the evolution and types of advance directives and other surrogate decision making requirements.
- Discuss issues regarding the participation of children in research.

Objectives

- Examine issues related to medical records, including documentation requirements and protection of confidentiality.
- Discuss authorship and rights to research data.
- Summarize protections for legal liability of federal employees and non-federal clinical researchers.

Resources/Background

- HHS – 45 C.F.R. 46, Protection of Human Subjects
  - A – Basic HHS Policy for Protection of Human Research Subjects (Common Rule)
  - B - Fetuses, pregnant women, inc. studies of *in vitro* fertilization
  - C - Prisoners
  - D – Children
  - E – Registration of IRBs (to OHRP)
- FDA - 21 C.F.R. 50, 56, 312, 812
- (NIH Policies)

Resources/Background, cont.

Common Rule

- Advance Notice of Proposed Rulemaking (ANPRM) published in the Federal Register (FR) in July 2011
- Notice of Proposed Rulemaking (NPRM) published in the FR September 8, 2015 – comments due January 6, 2016.

"The NPRM seeks comment on proposals to better protect human subjects involved in research, while facilitating valuable research and reducing burden, delay, and ambiguity for investigators. "

http://www.hhs.gov/ohrp/humansubjects/regulations/nprmhome.html

  - Summary of the proposed changes
  - NPRM text
  - Video or transcript of the October 20, 2015 Public Town Hall Meeting
  - Access HHS webinars on the NPRM
  - Press releases

Informed Consent

- Today we base our practice on the concept that patients have the right to be reasonably informed about, and participate in, decisions regarding, their own health care.

- Not always true….

Informed Consent

- Consent requirement in the U.S. arose from the Common Law tort of battery.
  - Battery claim must prove:
    - Physical touching (regardless of harm)
    - Without consent

- Schloendorff v. NY Hospital (1914) (lack of consent for a surgical procedure during an exploratory exam is "trespass")
  - Supreme Court Justice Benjamin Cardozo declared: "every human being of adult years and sound mind has a right to determine what shall be done with his own body."

Informed Consent

The evolution of medical ethics:

- Nuremberg Code (1947): "The *voluntary consent* of the human subject is absolutely essential." And, subjects "should be so situated as to be able to exercise *free power of choice.*"
- Atomic Energy Commission (DOE) (1947): No human experiments unless "patient give[s] his complete and *informed consent* in writing…."
- NIH Clinical Center (1953): all research subjects must "voluntarily," and "based on informed understanding," agree to participate in research.
- Declaration of Helsinki (1964)

Informed Consent

- Courts too began to evolve.
  - Cases for failure to obtain "proper consent" begin to be viewed as negligence/malpractice actions, rather than actions in battery.

- Negligence is different from battery. Must prove:
  1. The provider owes a duty to the patient;
  2. The duty is breached;
  3. Damages result; and
  4. The damage is caused by the breach.

Informed Consent

- Salgo v. Leland Stanford Jr. University Board of Trustees (1957): finding a distinct cause of action for failing to disclose a procedure's nature, purpose, risks, and alternatives.
  - first U.S. case to reference requirement for "informed consent."

Informed Consent Process

- Courts focus on the "quality" of the consent
  - No legally effective consent unless the patient understands the procedure/treatment and the risks associated with it.
  - The legal standard for consent to research is the same.

- Today, generally, regulatory requirements for informed consent in federally-funded and FDA-regulated research overlap with the court-identified elements for a legally effective consent.

Informed Consent Process

- What must be disclosed?
  - Diagnosis (patient's condition or problem)
  - Nature and purpose of the proposed treatment or intervention
  - Risks and consequences of the proposed treatment or intervention
  - Probability of success (or that it is unknown, if so).
  - Feasible alternatives
  - Prognosis if proposed treatment or intervention is not given.

- By regulation (45 CFR 46.116) research consents include additional information.

Informed Consent Process

- How much information? Concerns often raised about:
  - length of consent forms,
  - whether you need to disclose every risk or consequence,
  - how much science must be explained, etc.
- Clearly, some education of the patient is needed and any communication must be understandable to the patient.
  - Two important parts:
    - Any information that is material to the patient's decision;
    - Risks, i.e., possible or reasonably foreseeable.

Informed Consent Process

- Informed consent should be thought of as a process, not just execution of a form.
  - Allow time for questions; time for patient to consult with others, and, if possible, send form in advance.
  - Ongoing process

Informed Consent Process

- Who can obtain consent?
  - Up to institutional policy
  - Effective communicator with an in depth understanding of the research or procedure.

- Who can consent?
  - A competent adult, or
  - The patient's legally authorized representative.

Surrogate or Substitute Consent

- We know competent adults can consent or refuse to consent to treatment, medical intervention, or research.

- What happens when an individual lacks capacity to consent?
  - You may provide emergency medical care if you can't obtain consent from the patient or their surrogate when the patient lacks the capacity to consent.
  - Other care, particularly new research care, without proper consent is inappropriate.
    - Advance directives/surrogate

Surrogate or Substitute Consent

- Legally appointed guardian
- Advance Directives
  - Living Will
  - Durable Power of Attorney for Healthcare
- Substituted Consent

Advance Directives

- General Types:
  - Living Will: permits an individual to direct in writing that certain life-sustaining measures be given, withheld, or withdrawn if he or she is in a "terminal condition" and does not have the capacity to make decisions.
  - Durable Power of Attorney For Healthcare: allows individual to appoint a surrogate to make decisions in the event he or she becomes incapacitated.

Advance Directives

- What is terminal?
  - Varies from state to state;
  - Generally means a condition from which there can be no recovery (to a reasonable degree of medical certainty), e.g., death within 6 months.
    Increasingly, states adding PVS.

Advance Directives

- Several high profiles cases highlight how courts struggle with decision-making for persons who are no longer competent, e.g., Quinlan, Cruzan, Schiavo.

- Generally, courts favor preservation of life unless clear written statement or appointment of a proxy by the patient.

- Congress passed the Patient Self Determination Act (PSDA) (1990): requires hospitals that accept Medicare/Medicaid to inform patients about their rights to execute advance directives and document patient choices.

Advance Directives

- What are the powers of a surrogate?
  - Varies from state to state;
  - Some states only allow the surrogate to make decisions which are consistent with the patient's wishes.
  - Others, like Maryland, allow the surrogate to make decisions in the best interests of the patient if the patients wishes are not known.

Advance Directives

- What forms are required?
  - Standards vary from state to state, e.g., for witnesses, triggering events, revoking, etc.
  - Generally, forms must be:
    - Voluntarily executed;
    - Written and signed; and
    - Witnessed by two unrelated people.

Advanced Directives

- Usually, states provide no civil or criminal liability if medical providers (researchers) follow AD in good faith pursuant to reasonable medical standards.

- Health care practitioners need to be aware of the existence of any patients' ADs and their terms.

Advance Directives

- At the Clinical Center (CC):
  - DPA: provides for the appointment of a surrogate who is authorized to provide informed consent for participation in research and routine medical care while an individual is at the CC. (preferred; patient need not be terminal)
  - ADs: Recognize if validly executed by the patient.
  - Depending on the nature of the research or the process of the disease to be studied, e.g., Alzheimer's, IRB may require execution of a DPA as a condition of participation in the research study.

- What happens when a patient without a DPA/LW/Guardian becomes mentally incapacitated?
  - If the individual previously expressed wishes which are documented in the medical record, those wishes may be followed.
  - But, without a LW, DPA, or judicially appointed guardian, state law usually authorizes certain individuals to give “substituted consent” for furnishing (not withdrawing) care.

Substituted Consent

- In Maryland, if not competent and no guardian or DPA, state gives authority to:
  - Spouse or domestic partner (July 2008)
  - Adult child
  - Parent
  - Adult sibling
  - Friend or other relative (with affidavit)

- Clinical Center policy follows same hierarchy
- Clinical Center policy on surrogates/substituted consent

Questions?

Consent & Children in Research

Who is a "Child?"

- A person who has not reached the legal age to consent to research treatments or procedures, under applicable law of the jurisdiction in which the research is to be conducted.

- At the Clinical Center: Anyone under the age of 18 and not married or not a parent.

Consent & Children in Research

- Children may be required to “assent,” under federal regulations, but they cannot legally “consent” to participate in research.
- Generally, permission of both parents, or his or her legal guardian, is required for a child to participate in research (except as provided in 45 CFR Part 46, subpart D).
- For foster children, careful investigation is required. State requirements vary.
  - Some states prohibit research with foster children.
  - If permitted, often protective services and/or a judicial order is needed.

Consent & Children

If parents/legal guardians:

- Unavailable: Emergency medical care can be provided.
- Refuse research: Choice governs.
- Refuse standard of care in the clinical context: If benefits outweigh risks, state will usually step in. Hospital can seek a court order.

Mature Minor Exception: Petition the court. Clear and convincing evidence that the minor understands and fully appreciates the consequences of his or her actions.

Children Participating in Research at NIH

- The individual or entity with legal authority to consent should be identified prior to the child's arrival.

- Consider temporary decision-maker in some cases
  - Is the exception, not the rule
  - Consider risk of study and ability to contact parent
  - e.g. parent unable to travel
  - Parent remains involved (e.g., by providing phone consent and directing the decision-maker)

Questions?

Medical Records

Three Basic Rules:

1. Medical records should contain *all diagnostic and clinically relevant information*, including:
   - Physical and psychological examinations,
   - Medical history,
   - Treatment administered,
   - Progress reports,
   - Physician's Orders,
   - Consultation Notes and specialty report.
2. Documentation should be accurate.
3. Entries should be timely.

Medical Records in the Clinical Center

- Medical Records are maintained:
  - To provide a continuous history of the treatment afforded individual patients in the Clinical Center.
  - To provide a data base for the clinical research conducted within the hospital.

- Medical Records serve:
  - To document care to patient
  - To plan and evaluate patient's treatment
    - Support diagnosis
    - Justify enrollment in protocol

Medical Records in the Clinical Center

- Medical records serve (cont.):
  - To facilitate communication among health professionals in and outside of the hospital
  - To support adequate discharge planning

- Failure to document properly may lead to inappropriate treatment and possible patient harm.

Medical Records vs. Research Records

- Clinical Center medical records are distinct from research records, which are maintained at NIH Institutes/Centers (ICs) and with investigators.

- Research Records:
  - Contain data about individuals relevant to a particular research study.
  - Serve to document, track, monitor and evaluate clinical, epidemiologic, and biometric research activities.

Medical Records
Disclosure

- Disclosures :
  - Rarely without written patient consent
    - Patients may limit consent to certain sections, persons

The Privacy Act

of 1974, 5 U.S.C. 552a

- Applies to government records and bars disclosure of any record maintained in a "system of records" to third parties except:
  - With written consent of individual or authorized representative or
  - 12 statutory exceptions notwithstanding lack of consent, e.g. for routine uses.
- System of records – "a group of any records under the control of any agency from which information is retrieved by the name of the individual or by some identifying number, symbol, or other identifying particular assigned to the individual." 5 U.S.C. § 552a(a)(5).
- Applies to disclosure of personally identified information from a medical records in Federal facilities

The Privacy Act

- CC Medical Records Routine Uses include:
  - Responding to Congressional Inquiries for constituents;
  - To community agencies by social work department to assist patients and their families;
  - To referring physicians for care after discharge;
  - To medical or medical record organization or consultants in connection with treatment of patients or to accomplish research purposes of the system for information of diagnostic problems or unusual scientific value.

The Privacy Act

- Research Records Routine Uses include:
  - For research purposes consistent with applicable laws and policies when the research purpose cannot be reasonably accomplished unless the record is provided in individually identifiable form and it is deemed to warrant the risk to privacy and recipient required to comply with certain safeguards;
  - Responding to Congressional Inquiries for constituents;
  - To authorized organizations which provide health services.

The Privacy Act/FOIA

- But Freedom of Information Act (FOIA)(1974) 5 U.S.C. 552 – presumption of disclosure.
  - FOIA provides individuals with a right to access records in the possession of the Federal Government.
  - The government may withhold information pursuant to the nine exemptions and three exclusions contained in the Act.
  - Medical records typically withheld as unwarranted invasion of personal privacy (exemption 6).
    - May continue privacy for family after death of individual.
  - May need to analyze release of records under Privacy Act and FOIA

HIPAA

- Health Insurance Portability and Accountability Act of 1996 (P.L. 104-191) and its implementing regulations - the Privacy Rule (45 CFR 160 & 164, Subparts A and E), the Security Rule (45 CFR 160 & 164, Subparts A and C)(together, "HIPAA")

- Applies, by law, to "covered entities":
  - Health care providers who transmit health information electronically in connection with a transaction for which there is a HIPAA standard
  - Health plans
  - Health care clearinghouses

- *NIH is not a "covered entity," but some NIH research collaborators or partners may be.*

- Generally requires individual authorization for use and disclosure of certain information

HIPAA, cont.

- An individual's written authorization is required for PHI use or disclosure unless waived or excepted.
- Decedent's information is protected.
- Authorization waivers granted by IRBs or Privacy Boards.
- Multiple strategies for HIPAA compliance in research:
  - Elect to incorporate Privacy Rule authorization language into site-specific informed consent forms
  - Develop separate 'stand-alone' authorization documents
  - Seek a waiver or alteration of the authorization requirement.
  - Use limited data sets or de-identified data.

Authorship

- Authorship questions are ordinarily resolved by the research group, Laboratory or Branch, and the primary author.

- No legal requirements governing who may or may not claim authorship, but professional standards and NIH policy require that the designation of authorship be based on a significant contribution to the conceptualization, design, execution, and or interpretation of the study.

- Lesser contributions are often handled by acknowledgement.

Data Rights

- Data developed in the Clinical Center/NIH is, generally, the “property” of the Federal government.
- When NIH supports research in the intramural program certain legal protections exist to protect the inventions of researchers and the government.
- When NIH supports extramural research, data rights will vary.

Legal Liability and Malpractice

- Clinical researchers at the NIH are subject to actions for negligence or malpractice with less frequency than health professionals not involved in research.
- Types of Claims most commonly filed involve allegations of errors or mistakes in treatment or diagnosis, or defects in informed consent.

Federal Tort Claims Act (FTCA)

- The FTCA provides immunity to federal employees from claims of negligence relating to conduct that is within the scope of their employment.
- Health professionals in the Clinical Center who are not federal employees are required to be insured and to maintain professional liability insurance with coverage amounts similar to outside investigators.
- 28 U.S.C. §§ 1346(b), 2401(b), 2671-80

Questions?