


**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.
- Comment on some legal issues that arise when children participate in research.

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**Objectives**

- Examine issues related to medical records, including documentation requirements and protection of confidentiality.
- Review issues associated with access to data, authorship and intellectual property.
- Summarize protections for legal liability of federal employees and non-federal clinical researchers.

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## Informed Consent

- Today we assume that patients have the right to be reasonably informed about, and participate in decisions regarding, their own health care.
- The foundation for the consent requirement in the U.S. arose from the common law tort of battery, i.e., an individual's right to be from nonconsensual touching. Damages were based on the occurrence of the touching, whether or not harm occurred as a result.
- In 1914, Justice Cardozo declared that "every human being of adult years and sound mind has a right to *determine* what shall be done with his own body." Schloendorff v. NY Hospital (1914) (lack of consent for a surgical procedure during an exploratory exam but is "trespass")

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## Informed Consent -- History

- Early legal requirements were reflected in early understandings of medical ethics.
- Writing in the *Journal of the American Medical Association* in 1916, pioneering experimental physiologist Walter Cannon echoed: "there is no more primitive and fundamental right, which any individual possess than that of *controlling the use to which his own body is put.*"

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## Informed Consent -- History

- Nuremberg Code (1947) begins: "The *voluntary consent* of the human subject is absolutely essential." And, to ensure that consent is voluntary, the code states that subjects "should be so situated as to be able to exercise *free power of choice.*"
- Atomic Energy Commission (1947): No human experiments unless "patient give[s] his complete and *informed consent* in writing, and that the responsible next of kin give in writing a similarly complete and informed consent...."

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## Informed Consent -- History

- In 1953, the NIH Clinical Center pioneered informed consent practices and required that all research subjects must “voluntarily,” and “based on informed understanding,” agree to participate in research.
- Around the same time, courts began to treat cases for failure to obtain “proper consent” as negligence/malpractice actions, rather than actions in battery.
- Salgo v. Leland Stanford Jr. University Board of Trustees (1957) is the first case to reference “informed consent” and the first decision finding a separate cause of action when providers fail to disclose a procedure’s nature, purpose, and risks and alternatives.

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## Informed Consent -- History

- Negligence is different from battery. Several specific elements must be proved:
  - The healthcare provider owes a duty to the patient;
  - The duty was breached;
  - Damages resulted; and
  - The damage, unlike in battery, was caused by the breach.
- Courts focus on the “quality” of the consent, finding 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 not distinct.

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## Elements of Informed Consent

- Generally, today, regulatory requirements for informed consent in federally-funded and FDA-regulated research overlap with the elements for a legally effective consent.
- 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.

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### Informed Consent Process

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

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### Informed Consent Process, cont.

- 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.

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### Informed Consent Process, cont.

- Who can consent?
  - A competent adult, or
  - The patient's legally authorized representative.
- What if the person is no longer competent?
  - For Clinical Center patients: you may provide emergency care if you can't obtain consent when the patient lacks the capacity to consent. Other care, particularly new research care, without proper consent is inappropriate.

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## Substitute or Surrogate Consent

- Recall, Justice Cardozo’s admonition: “every human being of *adult years* and *sound mind* has a right to determine what shall be done with his own body.”
- It is well settled that competent adults can consent or refuse to consent to treatment or medical intervention.
  - But, *what happens when an individual lacks capacity to consent?*

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## Advance Directives

- Several high profiles cases have highlighted how courts struggle with decisionmaking for persons who are no longer competent: 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 in 1990 to require hospitals to inform patients about their rights to form advance directives and document patient choices.

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## Advance Directives

- General Types:
  - Living Will: permits an individual to direct in writing that certain life-sustaining measures be 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: allows individual to appoint a surrogate to make decisions in the event he or she becomes incapacitated.

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**Advance Directives, cont.**

- 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.

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**Advance Directives, cont.**

- 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 wishes of the patient if the patients wishes are not known.

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**Advance Directives, cont.**

- What forms are required?
  - Standards, e.g., for witnesses, triggering events, revoking, etc., vary from state to state;
  - Generally, forms must be:
    - Voluntarily executed;
    - Written and signed; and
    - Witnessed by two unrelated people
- Usually, states provide no civil or criminal liability if follow AD in good faith pursuant to reasonable medical standards.

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### Advance Directives, cont.

- As health care practitioners, you need to make yourselves aware of the existence of any ADs and their terms.
- At the Clinical Center:
  - 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 and trusted surrogate making decisions)
  - 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, may require execution of a DPA as a condition of participation.

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### Advance Directives, cont.

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

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### Substituted Consent

- In Maryland, state gives authority to:
  - Spouse
  - Adult child
  - Parent
  - Adult sibling
  - Friend or other relative (with affidavit)

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### Consent & Children in Research

- Children may be required to “assent,” under federal regulations, but they cannot legally “consent” to participate in research.
- Generally, a child requires permission of both parents, or his or her legal guardian, to participate in research (except as provided in 45 CFR Part 46, subpart D).

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### 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.
- For foster children, careful investigation is required. States vary in their requirements and, often, Protective Services and/or a judge is needed. Some states prohibit research with foster children.

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### Research with Children at NIH

- The individual or entity with legal authority to consent should be identified prior to the child’s arrival at the CC. If that person will not accompany the child, procedures need to be in place to procure necessary consents.
  - Consider temporary guardianship in some cases, e.g., pregnant mother and grandmother, or parent unable to travel.

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### If a Parent/Guardian Refuses Consent or is Unavailable

- Unavailable: Emergency care can be provided.
- Refuse research: Choice governs.
- Refuse clinically accepted care: if benefits outweigh risks, state will usually step in. Hospital can seek a court order.

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

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### 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 protocol

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### 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.

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## Medical Records Maintenance

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.

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## Medical Records vs. Research Records

- Medical Records are distinct from “research records,” which are maintained at 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.

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## Medical Records Disclosure

- Disclosures :
  - Rarely without written patient consent
    - Patients may limit consent to certain sections, persons
  - Governed by the Privacy Act of 1974
    - But, Freedom of Information Act relevant also. The Freedom of Information Act (FOIA), 5 U.S.C. 552, 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).

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## The Privacy Act

- The Privacy Act of 1974
  - Bars disclosure of any record maintained in a “system of records,” except pursuant to written consent of individual or for certain other enumerated purposes, e.g. for routine uses.
  - “System of records” – the medical information obtained from and about CC patients that can be retrieved by patient name or other personal identifier.
  - Medical and Research records are maintained in separate systems of records.

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## The Privacy Act

- The Privacy Act of 1974 (cont.)
  - Generally, patient or authorized representative written consent required to release information.
  - Without consent, may verify that individual is a patient (dated of treatment, past or present) and general condition, e.g., “good, fair stable, serious, critical,” with attending physician’s permission.
    - Prohibits releasing confidential information to media without patient consent.
      - » Not apply automatically to records of deceased persons; but, release of presumptive cause of death must comport with wishes of next of kin and have approval of attending physician, IC Directors, Chief CCC, and CC Director.

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## The Privacy Act

- 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;

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## 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;

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## HIPAA Privacy Rule

- 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 partners may be.*
- Applies to all research, regardless of funding
- Generally requires individual authorization for use and disclosure of certain information

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## HIPAA Privacy Rule, 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 compliance:
  - 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.

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## Authorship/Rights in Data

- 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.

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## Data Rights and Intellectual Property

- Data developed in the Clinical Center 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.

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## Patents

- **Patent** (Federal law) encourages inventors by offering right to exclude others from using invention for 20 years from date of filing application (35 USC 101, *et seq.*)
  - Inventions require disclosure that would enable one skilled in the art to practice invention. Data may be needed to support.
  - Remedies for infringement are by civil suit in Federal court. Government can be sued for “reasonable compensation” only in Court of Federal Claims.
- In the United States, Inventor has 1 year from public disclosure to file for patent. Internationally, public disclosure is absolute bar.
- Consult your IC Technology Development Coordinator (TDC) for assistance with filing invention forms.

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## Trade Secrets

- Trade Secrets (Federal law): protects subject matter where patent system may not, e.g., by tort, equity and contract claims.
  - Trade Secrets: “Proprietary Data”, “Limited Rights Data” Information that provides an economic advantage that is kept secret. Unlimited term of protection so long as it’s kept secret.

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## Copyright

- Copyright: (Federal, and some state, law) protects an author’s expression for certain original “works,” e.g. publications, by prohibiting others from using, distributing, etc. (17 USC 102, *et seq.*)
- Secures exclusive right of author to make copies and prepare derivative works of an original work of authorship.
  - Protects the expression of an idea, not the idea itself
  - Vests in the author as soon as the work is created
  - Term varies but is at least the life of the author plus 70 years
  - **Works of U.S. Government employees are not subject to copyright in the U.S.**
  - Government contractors/grantees can copyright, but government retains nonexclusive, royalty-free license to reproduce, publish or otherwise use or authorize others to use for government purposes.

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## 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.

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### 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.

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