PARTICIPANT RIGHTS AND PRIVACY

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Presentation Outline

- By the end of this presentation, you will have an understanding of:
  - The history which lead to current regulations
  - The entities (Board and Regulatory agencies) serving to protect participant rights
  - The basic rights of a research participant
  - The informed consent process
  - The evolution of regulations

Events contributing to the rules of today

- Nazi War Crimes - WWII (1935-'45)
- Jewish Chronic Disease Hospital Study - 1963
- Willowbrook Hepatitis Study - 1963-1966
- "Tuskegee" Syphilis study - 1932-1972
- San Antonio Contraceptive Study - 1970s
- Havasupai Tribe - 2005

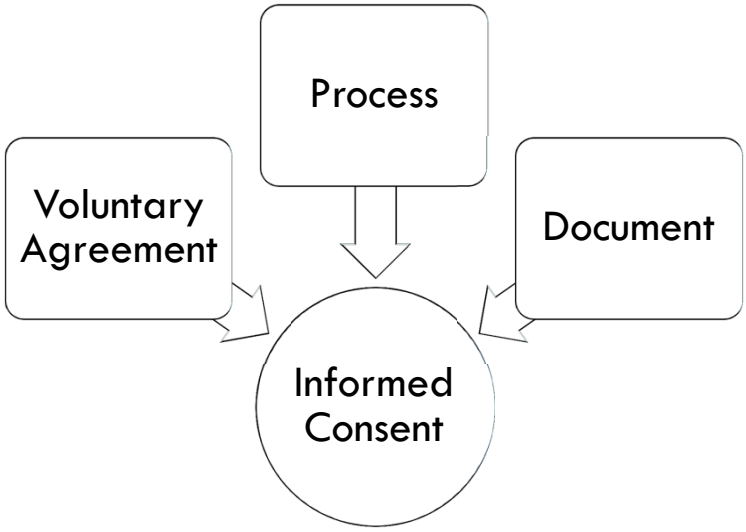
Resulting Regulations / Ethical Principles

- Nuremberg Code – 1947
- Declaration of Helsinki – 1964
  - Right to informed decisions
  - Welfare of subject takes precedence
  - Increased considerations for vulnerable populations
- IRB approval requirements – 1966 and 1974
- Belmont Report – 1979
  - Respect for Persons
  - Beneficence
  - Justice
- The Common Rule (45 CFR 46, et al) – 1981
  - Codified in 1991

Regulatory Bodies

- Office of Human Research Protection (OHRP)
- Office of Research Integrity (ORI)
- Department of Health & Human Services (HHS)
- National Institute of Health (NIH)
- Food & Drug Administration (FDA)
- Office for Civil Rights (OCR)
- Centers for Medicare & Medicaid Services (CMS)
- International Conference on Harmonization Good Clinical Practice (ICH-GCP)
- Institutional Review Board (IRB)

Informed Consent



Required Elements of Informed Consent

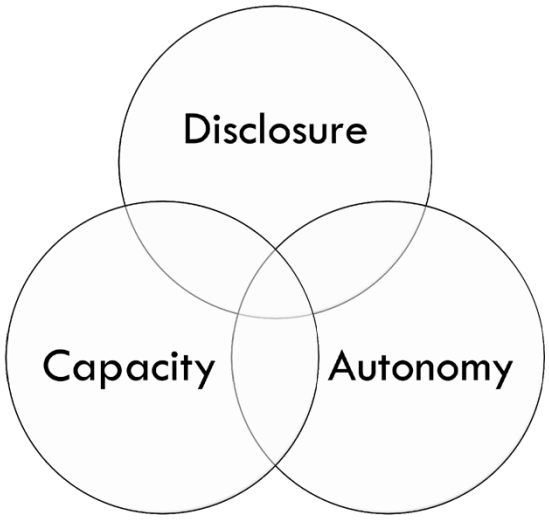
Research Participants have the right to …

- Know why the research is being done and what you can expect
- Understand the risks, side effects, or pain that may occur
- Understand the benefits of this research study
- Be made aware of alternative treatment options
- Know how your information will be used and kept confidential
- Know if payment will be involved in the study
- Provide opportunity to ask questions and know who to contact
- Make decisions without pressure, coercion, force or undue influence (voluntary).

Addt'l Elements of Informed Consent

- Understand that the particular tx may involve risk which is unforeseeable
- The investigator may terminate participation without the subject's consent
- Understand if any additional costs may result from participation
- Understand the consequences of a subject's decision to withdraw and procedures for orderly termination
- Understand if new findings will be shared with the participant
- Be aware of the number of total participants in the trial.

Key Aspects of Informed Consent



HIPAA's Impact on Research

- Health Insurance Portability and Accountability Act (HIPAA)
  - Two rules:
    - Privacy Rule
    - Security Rule
- Establishes national standards for protecting patient's protected health information (PHI).
- An authorization must be obtained from the individual unless an exception exists.
  - May be combined with the Informed Consent form

HIPAA Elements

- Description of the information to be used or disclosed
- Names or identification of individuals authorized to use or disclose information
- Names or identification of individuals authorized to use and receive information
- Description of each purpose
- Expiration date
- Individual signature and date
- Other Specific statements

Research Exceptions-45 C.F.R 164.512

i. Waiver of Authorization
ii. Preparatory to Research
iii. Research on Decedents Information
iv. De-Identified Information
v. Limited Data Sets
    i. Data Use Agreements
vi. Accounting of Disclosures

Changes to HIPAA

- New rule maintains greater flexibility for research
  - Compliance date – September 23, 2013
  - New provisions permit the following:
    - Compound authorizations
    - Authorization to use and disclose PHI for future research
- Intended Benefits:
  - Harmonization with the Common Rule
  - Reduce redundancy (separate authorizations not longer required)
  - Removal of barriers to develop and use data/tissue repositories

Compound Authorizations

- Permits Compound Authorizations which combine conditional and unconditional consent/authorization
  - Must clearly differentiate between the two (opt-in)
  - Consider revocation for each component
  - Exception - psychotherapy Notes

Future Research

- Authorization do not need to be study specific where they pertain to future research
- Per HHS (OHRP & FDA) covered entities, researchers, and Institutional Review Boards (IRBs) have flexibility in determining how best to describe a future research purpose.

Practical Applications

- Align all documents
  - Policies
  - Templates
  - Checklists

IRB/Covered Entity Considerations

- Distinguish between conditional and unconditional requests for consents/authorizations
- Determine when it is appropriate to use a single form
- Are distinctions clearly conveyed when a combined authorization is used?
- Can the participate revoke just a part of the combined authorization?
  - How is that managed?
- State Law Considerations
- Setting appropriate boundaries for unspecified research taking into account:
  - Sensitivity of information
  - Nature/extent of identifiable PHI
  - Whether the research involves bio-specimens or only data
  - Whether the research is in the same institution or a unrelated party
  - Expiration Date/Event

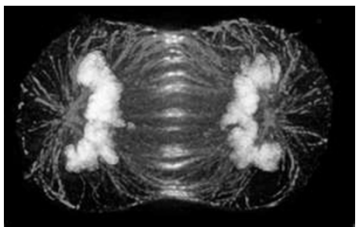
Certificate of Confidentiality

- Researchers can apply for an extra layer of privacy protections through NIH.
- Protects "sensitive information" against subpoenas
- Eliminates discrimination against participants (e.g. insurability, employability, etc.)

- http://grants.nih.gov/grants/policy/coc/faqs.htm

Genetic Information Nondiscrimination Act - GINA

- Restricts disclosure of genetic data
- Prohibits discrimination in health coverage (e.g. rates, coverage) and employment (e.g. hiring, firing, promoting) based on genetic information.
- Genetic tests include analysis of human DNA, RNA, chromosomes, proteins, etc.



Courtesy of Paul D. Andrews

Proposed Changes to Common Rule

- Streamlining IRB review of multi-site studies
- Improving informed consent
- Strengthening data protections to minimize information risks.
- Ensuring risk-based protections

Summary

- The history which lead to current regulations
- The entities (Board and Regulatory agencies) serving to protect participant rights
- The basic rights of a research participant
- The informed consent process/elements
- HIPAA elements / new regulations
- Certificate of Confidentiality
- GINA
- ANPRM – Common Rule

Questions?

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