

The Ethics of Research: Elements of Informed Consent

Presented for Perspectives in Assistive
Technology

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Ethical Principles & Regulations for Human Subjects Research

- The Belmont Report
- The “Common Rule”
(45 CFR 46)
- FDA Regulations
(drugs/devices)
- HIPAA (Protected health information)
- State Law



The Belmont Report

- Published in 1979
- Filled a void of ethical oversight for human subjects research
- Became the “Ethical principles and guidelines for the protection of human subjects of research”
- Consists of three basic principles
- Foundation of later regulations

Three Basic Principles Belmont Report

- Respect for Persons
 - Individuals to be treated as autonomous agents
 - Persons with diminished autonomy are entitled to protection
- Beneficence
 - Do no harm
 - Maximize possible benefits & minimize possible harms
- Justice
 - The distribution of burdens and benefits:
to each person (1) an equal share, (2) according to individual need, (3) according to individual effort, (4) according to societal contribution, and (5) according to merit

Application of the Three Belmont Principles

Respect for Persons



Informed Consent

- Obtain & document informed consent
- Voluntariness/coercion
- Protect privacy
- Consider additional protections for those with limited autonomy

Beneficence



Risks & Benefits

- Procedures with least risk
- Risks reasonable in relation to benefits
- Maintain confidentiality
- Monitor data for more than minimal risk research

Justice



Enrollment

- Select participants equitably
- Avoid exploitation of vulnerable or convenient populations

Charge of the IRB

- Review and approval **human subject research**
- Authority vested through FWAs (Federal wide Assurances)
- Our FWA covers research conducted at:
 - Stanford University, Stanford Hospital and Clinics, LPCH, VA and PAIRE

Defining HS Research

- **Human Subject** - A *living* individual about whom an investigator (whether professional or student) conducting research obtains:
 - Data through *intervention* or *interaction* with the individuals, or
 - *Identifiable private information*
- **Research** - A *systematic investigation* designed to develop or contribute to *generalizable knowledge*

IRB Approval for HS Research

- All research involving human participants (subjects) must be reviewed and approved by an Institutional Review Board (IRB) **before participants can be recruited, enrolled, or study interventions begun**
- **IRBs** = Administrative Panels on Human Subjects in Medical and Non-medical Research

The Process of Informed Consent

- Consent does not begin with a research protocol nor does it end with the signature on the consent form
- Study the elements of informed consent with the research consent form in New Course on Assistive Technology utilizing a hypothetical protocol

Identifiers on the Consent Form

- Title , P.I., Dates
- Adult or Minor
 - Assent for minors ages 7-17
- Subject in other research studies

Introduction to Research Studies

- Patient controlled implantable device used to manage intractable hiccups
- *“Banish the Belcher”*
- Selection of subjects
 - inclusion & exclusion criteria
- Duration of Study Involvement

Procedures

- Blinding
- Placebo control
- “Sham” or deception
- Cohorts
- Disclosure

Possible Risks, Discomforts & Inconveniences

- Every conceivable one must be listed
 - Physical
 - Psychological
 - Social
 - Financial

Potential Benefits

- How significant is the problem in relationship to the risks?
- No expectation of treatment
- May be a “control” or receive a “placebo”
- Altruism of the subject

Subject's Rights & Alternatives

- Freedom to participate
- Restriction from other therapeutic options
- Updated on progress of the research

Confidentiality

Use & Disclosure of P.H.I.

- Personal information
- Possible impact of revealing information
- Who may see the research records?
- P.I. must be careful about revealing patient specific data
- Time line of authorization
- Large type font

Financial Considerations & Conflict of Interest

- Reimbursements for incidental expenses
- Receiving payment for participation as an incentive
- Billing for costs (insurance payments)
- Potential commercial interests
- Financial ties of the P.I.

Withdrawal from Study & Compensation

- Subject initiated
- Investigator initiated
- Withdrawal cannot jeopardize medical care
- Legal responsibilities & disclosures

Contact Information & Human Subject Bill of Rights

- Emphasis on safety & disclosure
- Signatures
 - Subject (assent for minor)
 - Legally authorized representative
 - Person obtaining consent

Conclusion

- Well written protocol with realistic objectives
- Detailed research design
- Resources need for implementation
- Ethical subject involvement
- The risk of research is commensurate with the benefit of knowledge