



مؤسسة حمد الطبية
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HEALTH • EDUCATION • RESEARCH

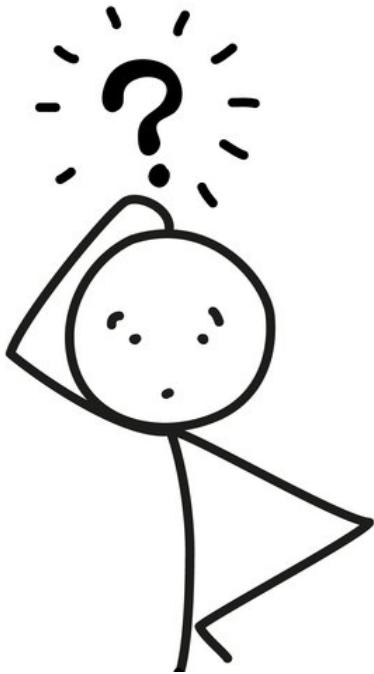
صحة . تعليم . بحوث

Nursing Informatics Department

Research Involving Human Subjects

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Informatics Nurse





**What is the most important part of
the Research?**

**If you will conduct a Research
today, do you know if you're going
to need a consent?**



Objectives

- Introduction
- Basic Principles of Belmont Report
- Protection of Human Subjects
- Vulnerable Samples
- Overview of IRB
- Consent
- Tools for Privacy
- Internet-Based Research
- Investigator's Training



Introduction

- Human subjects have not always been well protected.
- Privacy issues



Brief History

Unethical
Research by
Nazis

Nuremberg
Code

Declaration of
Helsinki

Tuskegee
Syphilis Study
(1932-1971)

The Belmont
report

The Common
Rule



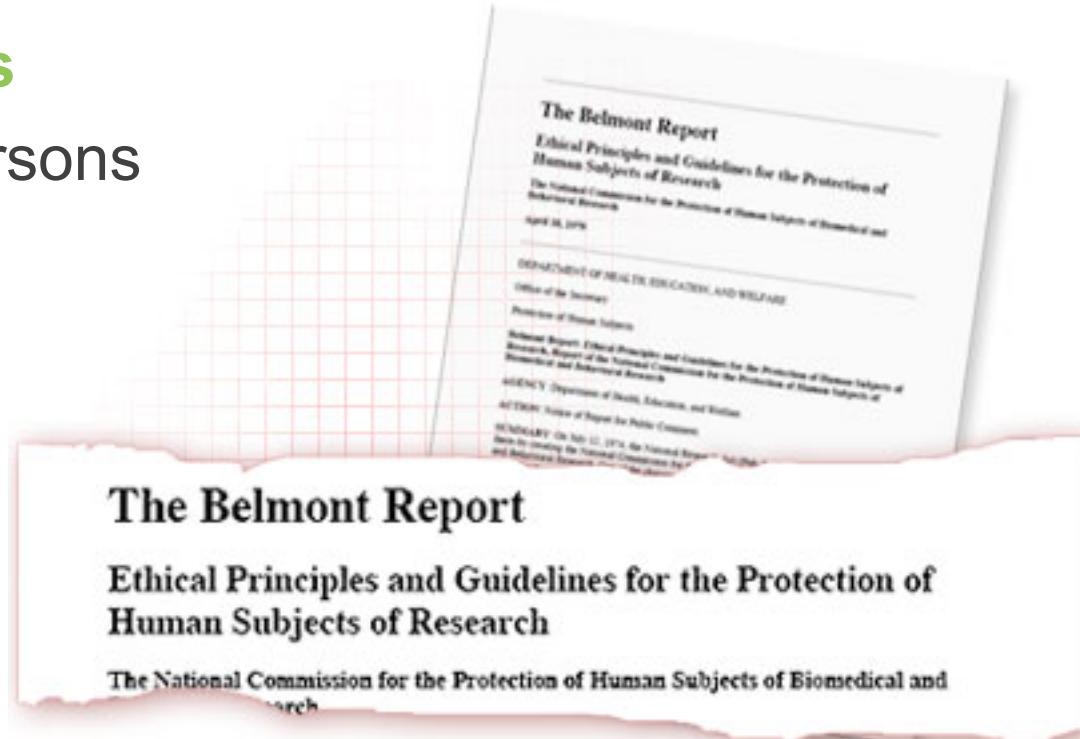
Prisoners Subjected by Nazis to Research



The Belmont Report

Three Principles

- Respect for Persons
- Beneficence
- Justice



When does research require protection of human subjects?

- **Any** study intended to result in publication or public presentation, including classroom projects.
- **Any** activity resulting in publication or public presentation, even though it involves only review of existing data that was collected with no intent to publish.
- **Any** use of an investigational drug or device.

Exempted in Policy of Human Research Subjects

- Employee evaluation
- Program evaluation
- Educational settings (e.g. teaching strategies)
- Taste and food quality evaluation
- or other situations where such evaluation is not designed to lead to generalizable knowledge.

Vulnerable populations

- Children
- Persons with diminished capacity to consent
- Prisoners
- Fetuses and pregnant women
- Terminally ill persons
- Students or employees
- Comatose patients



The Institutional Review Board

- Mandated for all institutions conducting human research.

Role and Responsibility of IRB

- Review research plan to be sure it meets criteria
- Confirm there are no unreasonable risks
- Conduct continuing review
- Assess suspected or alleged protocol violations.



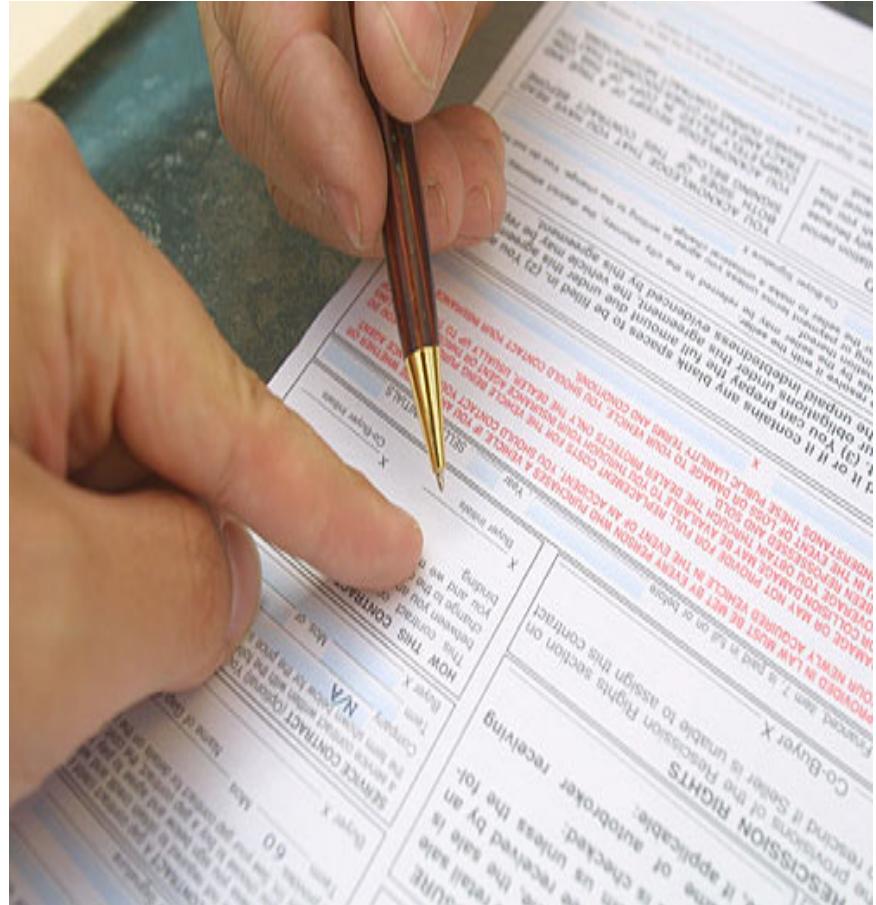
Informed Consent

- A **process** instead of a form. The form is documentation of the process.
- Plan must be reviewed and approved by the IRB before approaching potential subjects.
- There are a number of required elements and standard language that must be used.

Informed Consent

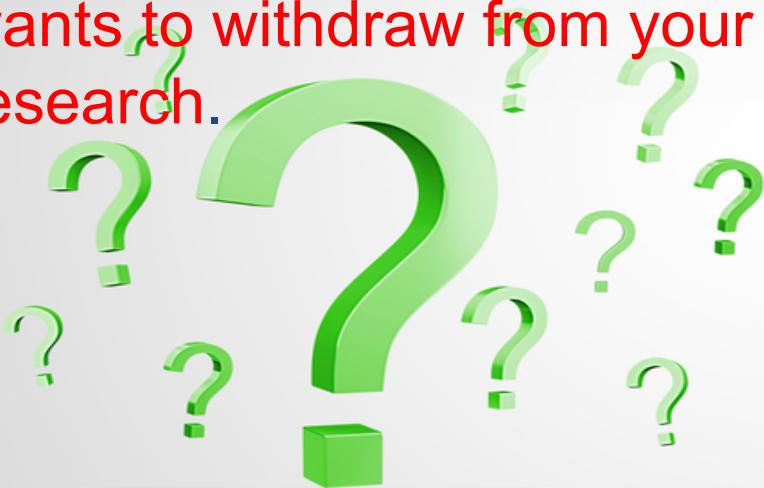
Three Elements

- Information
- Comprehension
- Voluntariness



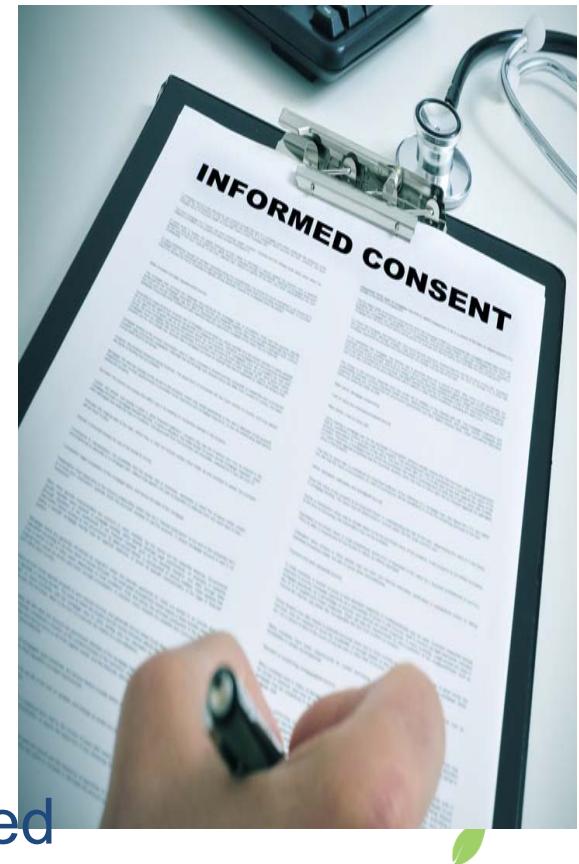
CASE 1:

You are at the final stage of your study, but one of your participant wants to withdraw from your research.



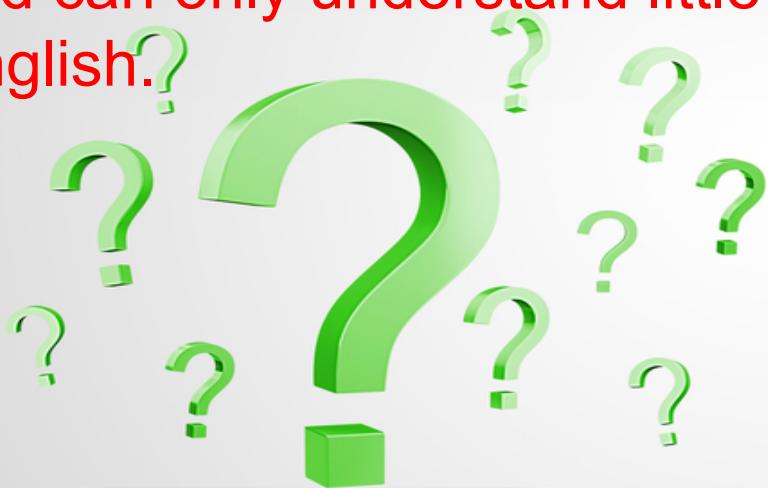
Informed Consent: Contents

- Purpose of the Research
- Qualifications to participate
- Design and Duration
- Right to withdraw
- Risks/ discomforts
- Benefits
- New findings
- Alternative Treatments
- Confidentiality
- Policy regarding Research-Related Injuries
- Contact Information



CASE 2:

Your participant is a Nepali
and can only understand little
English?



CASE 3:

The elder brother agreed and told that he and his wife will participate in the research but the wife looks undecided.



Special Points to remember

- Do you need to give copy of the consent to the participant?
- Do we have deadline in securing the consent?
- If the subject forgot to put the date in the consent?
- Do all the researchers need to be there when taking the consent?
- What level of language should you use?
- Consent is only for the research not with the other procedures included in that study.

CASE 4:

Your participant asked you:

“Is your result going to be
Confidential or Anonymous?”



Tools for Privacy

- Confidentiality
- Anonymity

		Anonymity
Confidentiality	Present	Absent
Present	No way to connect participants' identity to individual data	Researcher lists identities of participants, but only make a group data public
Absent	Report individual participants data, but not divulge participant's identity	Ethics Violation Make Public Subjects' identities and connect to individual identities



CASE 5:

The parent of a 16 y.o minor signed the informed consent and legally allow him for your study BUT the minor doesn't want to participate.



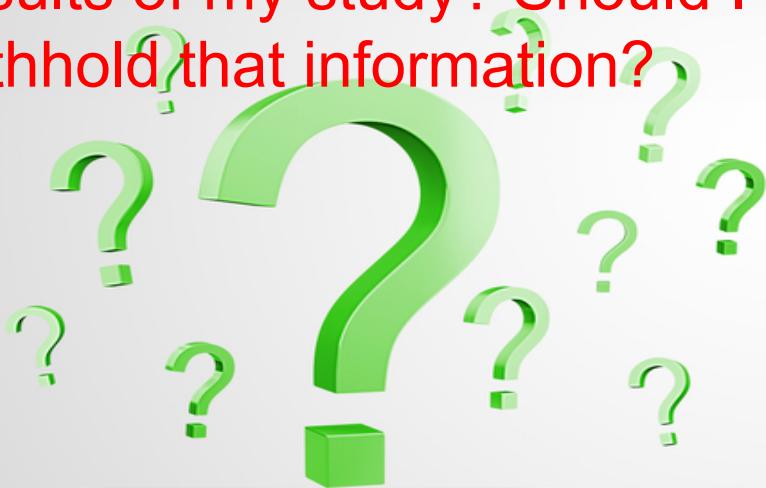
Assent Form

- Similar to consent form.
- To be used with children between age 7 and age 17.
- Should be written at age appropriate level.
- Used in tandem with consent form for parents of participating children.



CASE 6:

What if giving all the information to the participant will affect the results of my study? Should I withhold that information?



Special situation: Internet-Based Research

- Large number of Subjects
- Subjects may be more willing to answer questions via the Internet
- Widely used for obtaining survey information

Internet-based Research Issues

- Social Media: Are they aware?
- How to get consent?
- Is participant who you think he/she is?
- Are vulnerable populations (i.e. children) posing as adults?
- How sure are you about the details of the subject?



What an investigator supposed to do?

- Ethics training
 - CITI Certification (Collaborative Institutional Training Initiative)
 - HIPAA Certification (Health Insurance Portability and Accountability)

CASE 7:

You are to do a study about a new Dell Device. Your father is working in Dell but he will resign next month.



Responsibility of Investigators

- Conduct the project as approved by the IRB
- Declare Conflict of Interest
- Promptly report any revisions or amendments for review and approval by the IRB prior to commencement of the revised protocol.
- Promptly report any unanticipated problems involving risks to subjects or others to the IRB.
- Request an extension prior to the expiration date if data collection is not complete.

CASE 8:

You feel that it is not good for the participant to continue the study but he still wants to continue.





What is the most important part of the Research?

Ethics





**“Innocence of the law
excuses no one”**



References:

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Thank you!

