Belmont Report

- Respect for Persons → Informed consent
- Beneficence → Risks and Benefits
- Justice → Selection of Subjects

http://ohsr.od.nih.gov/guidelines/belmont.html
Who is a Participant?

- A Person
- A Medical Chart
- A Blood or Tissue Sample
- A Record about a Person

Example: If a study involves reviewing records, interviewing faculty, and observing students, there are 3 groups of participants.
1. **Minimize Risk**

- Risks to subjects must be minimized
  - Use procedures with sound research design
  - Procedures do not expose participants to unnecessary risk
  - Use standard of care procedures whenever possible
2. **Risk : Benefit Ratio**

- Risk : Benefit ratio must be appropriate
  - Evaluate only the risks from the research, not standard of care
  - Evaluate reasonable benefits, not long-range effects
  - Consider appropriate risk for children
3. Equitable Selection of Subjects

- Consider the purpose and setting of the research.

- Are vulnerable populations included? Should they be included?

- Provisions to include non-English speaking participants.
4. **Informed Consent**

- Informed consent (or assent) must be sought from a participant or an LAR
  - Except when a waiver is appropriate

- Consent documented appropriately
  - Except when a waiver is appropriate

- Consent Process

- Required Elements of Informed Consent
5. Data Monitoring

- Where appropriate, the research plan makes provisions for monitoring the data to ensure the safety of participants.
- Can vary depending on the level of risk.
- All studies are required to report:
  - Unanticipated problems involving risks to participants or others
  - Adverse Events
  - Non-compliance
6. Privacy and Confidentiality

• Privacy of Subjects
  ○ Reportable Diseases
  ○ Genetic Research
  ○ Sensitive Information

• Confidentiality of Data
  ○ Tissue Banking
  ○ Databases and Registries
7. Vulnerable Populations

- More vulnerable to coercion or undue influence

- Additional safeguards should be included
  - Think of the children!
Questions or Comments?
Understanding Consent & Assent Requirements

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Consent for Participants

- Consent must be accounted for with all participants using:
  - A waiver of consent
  - An alteration of consent
  - A waiver of documentation of consent
  - A signed consent document
Waiver of Consent

A waiver of consent is typically used when a PI wants to retrospectively review participant charts or records.
Waiver of Consent

Criteria for a waiver or alteration of consent

1. The research involves no more than minimal risk to the subjects;
2. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
3. The research could not practicably be carried out without the waiver or alteration; and
4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.
Alteration of Consent

- An alteration of consent requests that a consent requirement be altered or removed from the consent form/process.
- The alteration must be justified by the investigator.
- This is used with studies involving deception.
Waiver of Documentation of Consent

● The PI is required to present the consent elements to the participant, but the participant is *not* required to sign a form.

● Examples:
  ● The main risk to the participant would be potential harm resulting from a breach of confidentiality
  ● The procedure is minimal risk and is normally done without a signed consent form
    • A questionnaire cover letter
Consent Process Requirements

- Give the participant enough time to consider being in the study.
  - It may be coercive not to give the participant enough time to decide.

- Minimize coercion and undue influence
  - Power relationships
  - Not just money – Think of the children!
Consent Process Requirements

- In a language the participant understands
  - This is not just getting the consent form translated.
  - A translator is needed to talk with the participants and answer any questions.

- No exculpatory language
  - Waives or *appears* to waive the participant’s legal rights.
  - Releases or *appears* to release the PI, sponsor, or institution from liability.
Consent Process Requirements

- Who can give consent?
  - Only the participant?
  - A legal representative or guardian?
  - Do both parents need to sign?

- Who else needs to be included?
  - Investigator?
  - A witness?
  - A translator?
A consent process and document should contain all of the elements required in the criteria for approval. Requirements are the same for Parental Permission forms.
Consent Form Requirements

Background:

- Does the form state that this is a research study?
- What are the purposes of this research?
Consent Form Requirements

Procedures:

- How long will the participant be in the study?
- What procedures will be done?
- Which procedures are experimental and which are standard?
Consent Form Requirements

Risks:

- What are the risks of participating?
  - Medical risks of procedures
  - Psychological risks of a positive test result, answering sensitive questions, etc.
  - Confidentiality or Privacy risks
  - Reproductive risks to a pregnant woman and/or fetus.
Consent Form Requirements

Benefits:

• What are the *reasonable* benefits of participating?
  
  ○ Sometimes there are no benefits to the participant.
  ○ Compensation is not considered a benefit.
Consent Form Requirements

Alternative Procedures:

- Are there any alternatives to participating in the study?
  - Example: A student can get course credit by participating in the study OR writing a paper.
  - Example: The patient can get experimental treatment A or standard treatment B.
Consent Form Requirements

Confidentiality and Privacy:

- How will the participant’s information be protected?
- How will the participant’s privacy be protected?
Consent Form Requirements

Person to Contact & IRB/ RPA statements:

- Who should the participant contact:
  - Questions, concerns, complaints
  - If he/she is injured or harmed by being in the study

- What if the participant does not feel comfortable contacting the PI?
  - The participant should know that he/she can call the IRB or the RPA.
Consent Form Requirements

Research-Related Injury:

- Is medical treatment and compensation available if the participant is injured by being in the study?
Consent Form Requirements

Voluntary Participation:

- Participation is voluntary.
- The participant can say “no” or stop participating at any time.
- Saying “no” or stopping will not affect normal care and will not cause penalty.
Consent Form Requirements

Costs & Compensation:

- Does the participant have to pay for the procedures?
- Will someone else pay for the procedures?
- Will the participant get paid to be in the study?
Consent Form Requirements

Other considerations:

- Are there any unforeseeable risks?
- Can the PI withdraw the participant from the study? Under what circumstances?
- What are the procedures for withdrawing?
- What if significant new information arises during the research study?
- How many people will be enrolled in this study?
Consent Form Requirements

Possible Signatures:

- Participant
- Parent(s)
- Legally Authorized Representatives
- Person Obtaining Consent
- PI
- Witness
Additional Considerations

- Databases and Registries
- Tissue Banking
- Genetic Testing
- Reportable Diseases
- Placebo Use
Databases & Registries

Participants need to know:

- Where the data will be kept?
- Who has access to the data?
- Will identifiers be recorded?
- Can they withdraw from participation?
- What will the data be used for?
Tissue Banking

- Participants should have a choice about whether or not their tissues can be banked for future research.
- The type of future research should be specific to the type of study, disease, or treatment.
Genetic Testing

- Will results of genetic tests be revealed to the participant?
  - How will results be disclosed (in person, letter)?
  - Who will disclose the results? What is their training?
  - Who will answer questions about results?
  - Are additional services available and who will pay for those services (the participant or the study)?
  - How will associated risks be minimized?
Reportable Diseases

- If a study will be testing for a reportable disease, the consent form should state that positive test results will be reported to the appropriate organization.
- How will results be given to the participant?
- What follow-up medical care will be given?
- Examples of reportable diseases:
  - HIV/AIDS
  - Hepatitis A, B, C
  - Tuberculosis
  - Syphilis
Assent

Is child assent always required when research involves children?

No. The IRB is responsible for deciding whether child assent is required in proposed research activities.
For what age is assent required?

- There is no regulatory defined age. A general guideline is 6 or 7 years old to 17 years old.
- The IRB can decide what type of process and documentation are appropriate for each study.
Points to Consider for Assent

IOM Report 2004:

- Attention should focus on the *process* of requesting parents’ permission and children’s assent.

- In some situations it may not be appropriate to document assent.
Points to Consider for Assent

IOM Report 2004:

- The assent process should
  - Be developmentally appropriate
  - Give children a chance to say “yes” or “no”
  - Clarify what degree of control the parent(s) have over the decision to participate
  - Describe what information will be given to both parent(s) and child, parent only, or child only
Age Appropriate Assent

IOM Report 2004:

- What is the study about? Will it help?
- What will happen and when?
- What discomfort will there be and how will it be minimized?
- Who will answer the child’s questions?
- Does the child have the option to say “no”?
Questions or Comments?

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