

Criteria for Approval of Research

Ann Johnson, M.P.H.
IRB Administrator, University of Utah

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Belmont Report

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

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

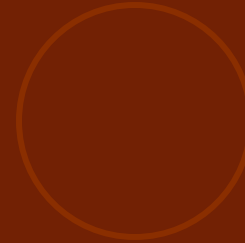
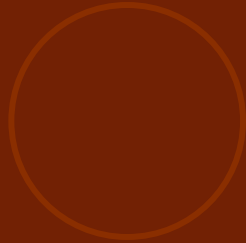
- Where appropriate, the research plan makes provisions for monitoring the data to ensure the safety of participants.
- Can vary depending on the level of risk.
- All studies are required to report:
 - Unanticipated problems involving risks to participants or others
 - Adverse Events
 - Non-compliance

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?

Consent Documents

- A consent process and document should contain all of the element required in the criteria for approval.
- Requirements are the same for Parental Permission forms.



Consent Form Requirements

Background:

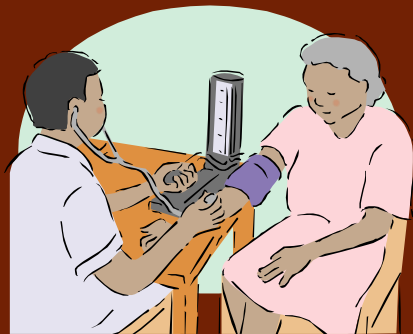
- Does the form state that this is a research study?
- What are the purposes of this research?



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 statement:

- 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.



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.

Assent



- **Child assent is required, except in the following three circumstances:**
 1. the capability of some or all of the children is so limited that they cannot reasonably be consulted;
 2. the intervention or procedure involved in the research holds out the prospect of direct benefit to the health or well-being of the children and is available only in the context of the research;
 3. the research meets the same conditions as those for waiver or alteration of informed consent in research involving adults.

Assent



- Additional considerations if parental permission is to be waived:
 - How will researchers encourage each adolescent to seek the support of a parent or another adult prior to participation?
 - What is the procedure to allow adolescents to seek assistance on a confidential basis after completing surveys containing questionnaires that may raise issues for which adolescents may desire further information or assistance?

Assent



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

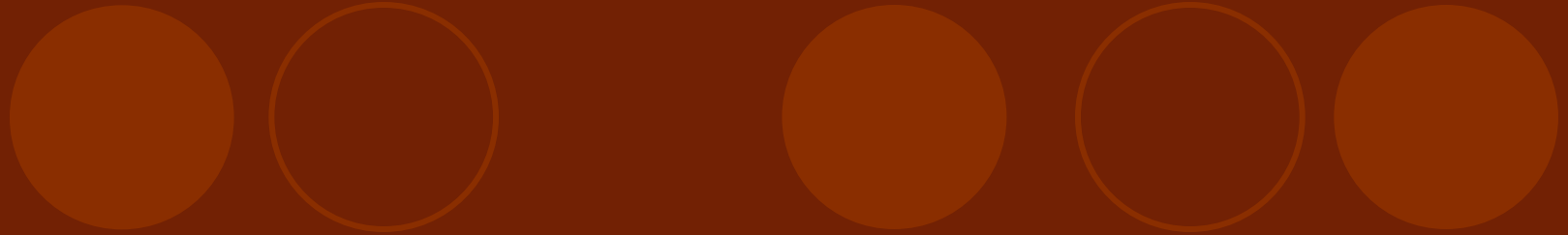
IOM Report 2004:

- 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?

ann.johnson@hsc.utah.edu

www.research.utah.edu/irb