Informed Consent

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Lecture Overview

I. Principles of Informed Consent

II. Basic information to provide subjects in the consent process

III. Final Issues

*I. PRINCIPLES OF INFORMED CONSENT**

- A) Information Elements
  1. Disclosure of Information
  2. Comprehension of Information

- B) Consent Elements
  3. Voluntary Consent
  4. Competence to Consent

* follows Beauchamp & Childress, *Principles of Biomedical Ethics*

1. DISCLOSURE

- Disclosure: How much information must be given?
  - "Full disclosure is impossible" (Freedman, p. 171)
  - How information is presented is crucial
  - An overload of information can actually hamper informed consent

1. DISCLOSURE

- Disclosure must:
  - Be specific
  - Explain alternatives
  - Explain risks and benefits
  - Involve an opportunity for questions from participants

WHAT IS ADEQUATE DISCLOSURE?

- **3 Standards**:

1. **Research Community**: What a typical researcher would disclose
2. **Subjective**: What the participant wants to know
3. **Objective**: What a reasonable person would want to know

2. COMPREHENSION

- **Comprehension**: What must you do to ensure the participant has consented?

READING LEVEL

- Informed consent documents should be written in plain language at a level appropriate to the subject population, generally at an 8th grade reading level.
- A best practice is to have a colleague or friend read the informed consent document for comprehension before submission with the IREC application.
- Always:
  - Tailor the document to the subject population
  - Avoid technical jargon or overly complex terms.
  - Use straightforward language that is understandable.

READABILITY

- Literature on the readability of informed consent for research with adult subjects reports poor readability and a gap between the provided information and average reading skills in society (Jefford & Moore, 2008; Kass et al, 2011; Malik, Kuo, Yip, & Mejia, 2014; Souza et al., 2013; Sudore et al., 2006; Terranova et al., 2012).
- This issue is even more problematic with children participants.

READABILITY

- **4th Grade** "We may learn about new things that might make you want to stop being in the study. If this happens, you will be informed. You can then decide if you want to continue to be in the study."
- **8th Grade** "We will tell you about new information that may affect your willingness to stay in the study"
- **University** "During the course of the study, you will be informed of any significant new finding (either good or bad), such as changes in the risks or benefits resulting from participation in the research of new alternatives to participation, that might cause you to change your mind about continuing in the study. If new information is provided to you, your consent to continue participating in this study will be re-obtained"

EXAMPLE OF READABILITY - ADULTS

Participation in this Study - Adults

- For this study, we are taking oral tissue biopsy samples, saliva and buccal swaps. These will be used for genetic and epigenetic analysis of potential cancer biological markers for oral squamous cell carcinoma. Participation in this study is absolutely voluntary. If you agree to participate in this study, your doctor will set up time for you to give oral biopsy, buccal swab and saliva samples. Even if you agree to take part in this study, you have the right to withdraw from the study at any point.

EXAMPLE OF READABILITY - CHILDREN

Participation in this Study - students from Grade 5

The purpose of the study is to understand how quality of education is perceived, what issues and challenges are there in achieving the perceived quality of education, and what possible solutions can be found to improve the quality of education in rural schools in Kazakhstan. Thus it is important to explore the voices and perspectives of key stakeholders (such as principals, vice principals, teachers, students, parents, and school education officials from the MOES and regions) regarding the quality of education they aspire for, the issues and challenges they face in achieving it, and the possible solutions they recommend for improving the quality of education in rural schools in Kazakhstan.

3. VOLUNTARINESS

- Consent must be free of coercion or undue influence from others
- Simple in theory although often trickier in practice
  - Pressure from instructors
  - Pressure from health care providers

4. COMPETENCE

- **No competence, no consent**
  - We often talk about parents or guardians consenting *for you*, but we need to remember this is really a very different thing.
- Competence is not all or nothing
  - Perhaps I am competent to drive a car, but not to make complicated decisions for myself

WHAT IS COMPETENCE?

- Being rational?
  - i.e., using reason to pursue your own goals?
  - What about the person who carefully figures out how to pursue his project of dismembering himself?
- Having the right goals?
  - A competent person reaches reasonable conclusions based on reasonable goals?
  - There's a danger of paternalism here

INCOMPETENCE

- What if the participant isn't competent?
  - How can we include the participant in such a case?

WHAT IF THE PARTICIPANT ISN'T COMPETENT?

- A proxy consent ought to be obtained on behalf of the incompetent participant
  - Who? Parents? Doctors? Courts?

II. BASIC INFORMATION TO PROVIDE SUBJECTS IN THE CONSENT PROCESS

1. Introduction to you and the research
2. Purpose of the research and the research activities
3. Benefits to participation in the research
4. Potential risks/harm
5. An explanation of your confidentiality procedures

BASIC INFORMATION TO PROVIDE SUBJECTS IN THE CONSENT PROCESS

6. Risks associated with research questions
7. Confidentiality procedures for research questions
8. The voluntary nature of participation
9. Compensation
10. Providing the opportunity to ask questions
11. Providing contact information

1. INTRODUCTION TO YOU AND THE RESEARCH

- Introduce yourself and invite people to be in your research study. Be sure to use the word "research."
- The following example could be used in either oral or written consent processes. Use this example to stimulate your thinking about how you want to interact with your subjects.
- *Hello, my name is (name) and I am an professor at Nazarbayev Univesity. I am conducting a survey research study to understand how university students cope with pain. If you are interested, I would like to ask you some questions.*

1. INTRODUCTION TO YOU AND THE RESEARCH

- An introduction similar to the following example may be useful when you are presenting information to people who are not familiar with the research process, including children:
- *I am (name), a professor at Nazarbayev. I am asking you to take part in a research study. The purpose of this consent form (this conversation) is to give you the information that will help you decide to be in this study or not. Please feel free to ask any questions you have as you read this form (as I explain my research to you). Feel free to ask questions about the purpose of the study, what I will ask you to do, the possible risks or benefits, or anything else you would like to ask. When I have answered all your questions, you can decide if you want to be in the study or not. This process is called informed consent.*

2. THE PURPOSE OF THE RESEARCH AND THE RESEARCH ACTIVITIES

- Explain the purpose of the study, the activities that subjects will participate in, the number of subjects, and the estimated duration of the study.
- Present activities in the order they will be experienced by the subjects.
- Remember to write in a conversational style. Provide sufficient information for a subject to make a decision, but aim for brevity.

3. BENEFITS TO PARTICIPATION IN THE RESEARCH

- Describe the benefits to the subjects, if any. If there are no direct benefits to the subjects, describe what you hope to learn.

4. POTENTIAL RISKS/HARM

- Describe the risks to the subjects, if any.
- If there are no risks, it is not necessary to say so.
- There are generally two types of risk in social and behavioral research: 1) a breach of confidentiality leading to the release of confidential, sensitive, or personal information, and 2) risks of harm associated with research questions.

5. AN EXPLANATION OF YOUR CONFIDENTIALITY PROCEDURES

- Participants may disclose personal, sensitive, or even potentially damaging information to you, presumably within a relationship of trust.
- To ensure that such information is protected, you have developed the confidentiality procedures you listed in your Protocol. Explain these procedures in everyday language to your potential subjects.

5. AN EXPLANATION OF YOUR CONFIDENTIALITY PROCEDURES

- **Example script**
- *I have a designed a way to protect the information you will share with me (to make sure no one will know what you share with me). I need to be able to connect your answers to the short questionnaire with the transcript from our interview. I will assign you a number and put the number on your questionnaire and your transcript, but not your name. On a separate piece of paper I will list your name and the number I have given you. When I have all the questionnaires and transcripts connected, I will destroy the list with your name on it.*

6. RISKS ASSOCIATED WITH RESEARCH QUESTIONS

- A potential risk associated with research question is probing for personal information that subjects might experience as an invasion of privacy, or presentation of material that subjects might consider sensitive, offensive, threatening, or degrading.
- These risks can be managed by providing several examples of the kinds of questions you plan to ask and making it clear that subjects may skip questions they don't want to answer.

6. RISKS ASSOCIATED WITH RESEARCH QUESTIONS

- The following text was part of a child assent process for children who had been abandoned by their parents.
- *You will be asked to answer some questions about your everyday thoughts and feelings and also about how you feel living apart from your parents. Some of the questions may be difficult to answer. Some of the questions may make you feel uncomfortable or sad. Of you want to skip a question just tell me and we will go on. You could say "next question' to let me know you want to skip to the next question.*

7. CONFIDENTIALITY PROCEDURES FOR RESEARCH QUESTIONS

- Either in the introduction to the confidentiality procedures or within the discussion of the procedures themselves, it is a good practice to acknowledge that the procedures were developed to protect subjects' privacy or to state your concern for their well-being.

7. CONFIDENTIALITY PROCEDURES FOR RESEARCH QUESTIONS

- Some methods to protect confidentiality are:

A. Not collecting identifiers
B. Using fictional names and misleading identifiers
C. Using unique identifiers
D. Reporting results in aggregate

7. CONFIDENTIALITY PROCEDURES FOR RESEARCH QUESTIONS, CONTINUED

- Other concerns with confidentiality are:

A. Using names

B. Audio-recording interviews

C. Multiple persons in focus groups

A. USING NAMES

- There may be situations in which subjects do not object to their names being used, or even prefer that they be identified in your report. Nevertheless, you should ask if it is permissible.
- *With your permission I would like to use your name in my report and attribute quotations to you.*

B. AUDIO-RECORDING INTERVIEWS

- If you want to record an interview with an individual you must receive permission from the person.
- If you want to record a group session, you must have permission from all members to record the session – or limit the group to those who agree to be audio taped. It may be appropriate to offer group participants the option of using pseudonyms during the session.

C. MULTIPLE PERSONS IN FOCUS GROUPS

- Focus groups are unique in that there are significant limits upon the level of confidentiality that can be offered. It may be the case that focus group participants already know each other or that the topic is harmless, and therefore confidentiality is not an issue; however, that may not always be true.

C. MULTIPLE PERSONS IN FOCUS GROUPS

- Sample language when confidentiality may be an issue
- *Every effort will be made to protect your identity as a participant in the study. You will not be identified in any report or publication of this study or its results. Even though we will emphasize to all participants in the study that comments made during the focus group sessions should be kept confidential, it is possible that participants may repeat comments outside the group at some point in the future. Therefore, we encourage you to be open as you can, but remain aware of our limits in protecting confidentiality.*

8. THE VOLUNTARY NATURE OF PARTICIPATION

- Make it clear to potential subjects that their participation is voluntary.
- Example scripts:

Your participation in this research is completely voluntary. You may choose only to answer certain questions and may end the interview at any time. or

It is perfectly OK if you don't want to try this. No one will be mad at you and we will still care for you just like we always do. (Text from an assent process for children.)

9. COMPENSATION

- In most cases, you will probably not have a budget for compensation subjects. If you do, describe any compensation or incentives you will offer. If you plan to compensate subjects, tell them what will happen if they withdraw from the study. Will they receive partial or full compensation?
- Compensation cannot be so high as to unduly influence people to participate in your study. How high is too high will depend upon the setting and the population from which you are recruiting subjects.

10. PROVIDING THE OPPORTUNITY TO ASK QUESTIONS

- Give potential participants an opportunity to ask questions before they decide to be in the research. For example:

Do you have any questions about me, my research, or our interview before we begin?

If you have any questions about this research, please ask me now. If you have questions at a later time, you can contact me at (phone, email, local address, in person - whatever is most appropriate for the setting and circumstance).

11. PROVIDING CONTACT INFORMATION

- Give potential participants contact information for the principal investigator and IREC. For example:

All research with human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject, you may contact the committee, anonymously if you wish, at (phone or email.)

- If you are using an oral consent process, consider providing subjects with cards that include the appropriate contact information.

III. FINAL ISSUES

TWO FINAL ISSUES

1. Documenting Consent
2. Parental Permission and Child Assent

1. DOCUMENTING CONSENT

- Documenting consent is the final and most likely the most important component of the consent process. That is, it must be done correctly.
- We will discuss: A) Obtaining Signatures; B) Copying Subjects; C) Oral Consent

A. OBTAINING SIGNATURES

- When using written form, create the appropriate signature section. In this part of the form, you switch from second person when addressing the potential subject to first person for the subject to provide his or her agreement to participate.

Participant's Agreement: I agree to participate in the research described above.

*Signature of Research Participant:*_____ *Date:* ___

B. COPYING SUBJECTS

- Subjects who sign consent forms must be given a copy of the form. The subjects should be told in the consent form that they will receive a copy. (Their copy does not need to be signed.)
- Insert this information before the signature section:

  You will be given a copy of this form for your records.

C. ORAL CONSENT

- When you prepare an oral consent script, you need to write as if you were speaking. This can be a challenge. One technique is to tell a friend what you imagine you would tell a subject. If you record your conversation, you can convert the recording into a script.
- The Oral Consent has two elements, the presentation of information as well as the participant's consent.

C. ORAL CONSENT – EXAMPLE SCRIPT

- *I am a(n) _____ (i.e. sociologist) from Nazarbayev University. I am conducting a study on _____, and I would like to ask you some questions about that. I would like to tape record our conversation, so that I can get your words accurately. If at any time during our talk you feel uncomfortable answering a question please let me know, and you don't have to answer it. Or, if you want to answer a question but do not want it tape recorded, please let me know and I will turn off the machine. There may be some things that I can't record for your protection; for example if you tell me about… I will have to turn off the recorder and erase what you said. If at any time you want to withdraw from this study please tell me and I will erase the tape of our conversation. I will not reveal the content of our conversation beyond myself and people helping me whom I trust to maintain your confidentiality. I will do everything I can to protect your privacy, but there is always a slight chance that someone could find out about our conversation. Now I would like to ask you if you agree to participate in this study, and to talk to me about _____. Do you agree to participate, and to allow me to tape record our conversation?*

2. PARENTAL PERMISSION AND CHILD ASSENT

- When research subjects are minors, parents provide permission for their children to become research subjects and children provide their assent to participate.
- If a parent provides permission, but a child does not want to be in the research, the child's wishes prevail.
- Assent must be tailored to the emotional and cognitive maturity of the children.

FOR MORE INFORMATION…

- NU IREC Website:

https://nu.edu.kz/about-us/institutional-research-ethics-committee

FOR MORE INFORMATION…

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QUESTIONS?