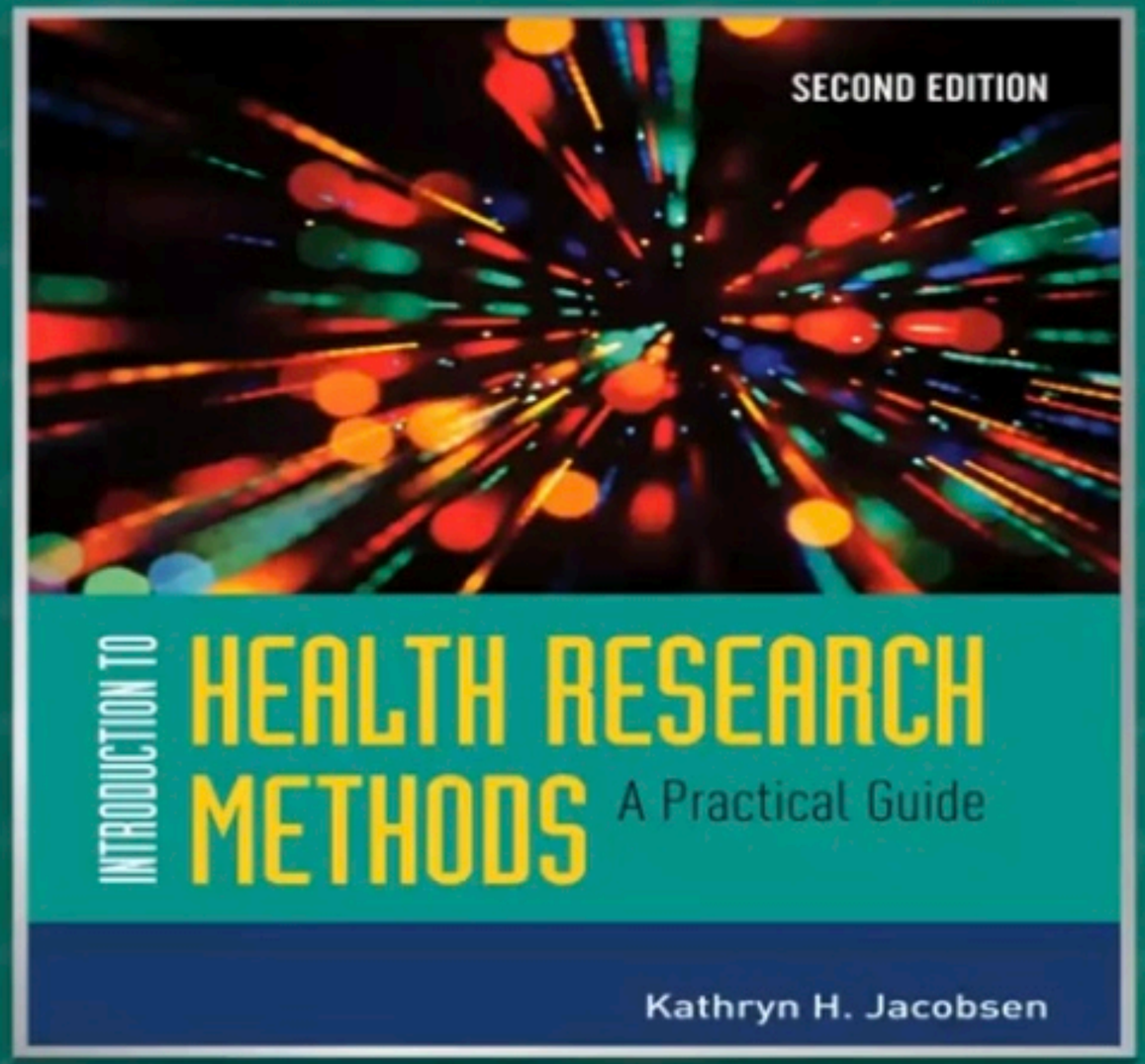
SCIENTIFIC MEDICAL RESEARCH

Week 10

Ethical Considerations

Chapter 23



23.1 Foundations of Research Ethics

- ***Nuremburg Code* (1947):** mandated voluntary consent for experimental studies of humans
- ***Declaration of Helsinki* (1964):** written by the World Medical Association to provide guidelines for physicians conducting clinical trials
- ***Belmont Report* (1979):** published by the U.S. National Commission for the Protection of Human Subjects of Biomedical & Behavioral Research to define key research principles and is a foundational document for the current U.S. federal policy for protecting human research participants (the *Common Rule*)

23.2 Respect, Beneficence, & Justice

- ***Respect for persons*** is a broad concept that emphasizes voluntariness & *autonomy.*
- ***Beneficence*** means that the study should do good;
- ***Nonmaleficence*** means that the study should do no harm.
- ***Distributive justice*** seeks to ensure that the benefits & burdens of research are equitable.

FIGURE 23-1 Eight Central Considerations ("8 Cs") in Research Ethics

Category	Examples of Questions to Ask
Contribution	• Why is the proposed project important? • How will individuals and/or communities benefit from this study?
Compensation	• Will individuals or communities that participate in the study be offered any form of inducement, reimbursement, or compensation? If so, what will be offered, and is it appropriate? Is the offer so high that it could be seen as coercive or so low that the study could be seen as exploitative? • Are the risks of participation minimal? • How will study-related injuries be handled? • Are the risks and benefits balanced?
Consent	• How will potential participants be informed about the study? • How will consent to participate be documented? • Will a test of comprehension of the informed consent statement be required? • If applicable, how will consent (and possibly assent) be acquired for children and other members of potentially vulnerable populations? • If applicable, will community meetings be held prior to beginning the study?
Confidentiality	• How will the privacy and confidentiality of participants and their personal information be maintained?
Community	• Why is research in the selected population important? • Is the source population appropriate for the goals of the research study? • Will the selection process be fair? • Will the sample size be adequate? • Are potentially vulnerable participants adequately protected? • Has the protocol been adapted to address the cultural expectations of the source population? • If applicable, has the community agreed to participate in this project?
Conflicts of interest	• Who is contributing to the project's finances and/or logistics? • Might potential conflicts of interest inhibit the ability of a rese… research?

FIGURE 23-1 (continued)

Category	Examples of Questions to Ask
Collaborators	• Are all members of the research team adequately trained to conduct ethical research? • What steps will be taken during data collection and analysis to ensure that the protocol and all ethical standards are adhered to by all members of the research team?
Committees	• Which research ethics committee(s) needs to review the project? • If applicable, what community organizations have been consulted about the proposed project?

23.3 Incentives & Coercion

- The desire to thank participants must be balanced with the need for participation in any research project to be voluntary.
- Researchers have to be very transparent about what participants will gain from participation in a research study & what they will not gain.

23.4 Informed Consent Statements

- ***Informed consent statements*** provide essential information about research projects to potential research participants so that they can make a thoughtful decision about whether to enroll in a study.
- The statement must use clear & simple language that the reader understands.

FIGURE 23-3 Content for the Informed Consent Statement

Content Area	Description
Research	A definition of "research" and a statement that the study involves research
Purpose	An explanation of the purpose and aims of the research process (except in the rare situations in which that interferes with the research goals)
Participants	A description of how and why certain individuals or communities were invited to participate in the research project and an estimate of the total number of individuals who will be recruited
Procedures	A description of the study procedures (including any physical exams, collection of biological specimens, randomization or blinding processes, interventions, or other procedures that are part of the study protocol) and the expected duration of the individual participant's involvement in the study
Benefits	A description of benefits to participants and/or to society, including a clear explanation of the compensation to be offered or a clear statement that the participant will receive no direct benefits
Risks	A description of the possible risks, discomforts, and costs associated with participation, a statement that involvement in the project may involve unforeseeable risks, and a description of how study-related injuries will be handled
Confidentiality	A description of the steps that will be taken to maintain confidentiality
Voluntariness	A statement that participation is voluntary and that the participant may withdraw from the study at any time with no penalty, along with a description for the process of withdrawing from the study
Contact information	Contact information for the researchers
Signature	Space for the participant's signature

Informed Consent Form

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2
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I understand that I am being asked to participate in a research study at Saint Francis Hospital and Medical Center. This research study will evaluate: What it is like being a mother of multiples during the first year of the infants' lives. If I agree to participate in the study, I will be interviewed for approximately 30 to 60 minutes about my experience as a mother of multiple infants. The interview will be tape-recorded and take place in a private office at Saint Francis Hospital. No identifying information will be included when the interview is transcribed. I understand I will receive $25.00 for participating in the study. There are no known risks associated with this study.

7

I realize that I may not participate in the study if I am younger than 18 years of age or I cannot speak English.

10

I realize that the knowledge gained from this study may help either me or other mothers of multiple infants in the future.

13
14

I realize that my participation in this study is entirely voluntary, and I may withdraw from the study at any time I wish. If I decide to discontinue my participation in this study, I will continue to be treated in the usual and customary fashion.

12

I understand that all study data will be kept confidential. However, this information may be used in nursing publications or presentations.

8

I understand that if I sustain injuries from my participation in this research project, I will not be automatically compensated by Saint Francis Hospital and Medical Center.

15

If I need to, I can contact Dr. Cheryl Beck, University of Connecticut, School of Nursing, any time during the study.

1,2

The study has been explained to me. I have read and understand this consent form, all of my questions have been answered, and I agree to participate. I understand that I will be given a copy of this signed consent form.

_____ _____

Signature of Participant Date

_____ _____

Signature of Witness Date

_____ _____

Signature of In Date

23.5 Informed Consent Process

- Informed consent is intended to be a process, not merely a piece of paper.
- The lines of communication between researchers & participants must remain open during & even after the data collection process.

23.6 Informed Consent Documentation

- For most research studies, the expectation is that each study participant will sign a printed copy of the informed consent statement.
- In a limited number of observational studies, the full process of acquiring & documenting individual informed consent may not be required (Implied Consent).

23.7 Confidentiality & Privacy

- ***Privacy*** is the assurance that individuals get to choose what information they reveal about themselves.
- ***Confidentiality*** is the protection of personal information provided to researchers.

23.8 Sensitive Issues

- Researchers asking questions about sensitive issues must decide ahead of time how to handle disclosures (e.g., disclosures of participation in illegal activities).
- The research team can apply for a ***certificate of confidentiality*** that protects the identity of participants from being subject to court orders & other legal demands for information.

23.9 Cultural Considerations

- A research protocol must be appropriate to the culture or cultures of the expected study participants.
- It may be helpful to have a local advisory board to facilitate communication between the community & the research team.

23.10 Vulnerable Populations

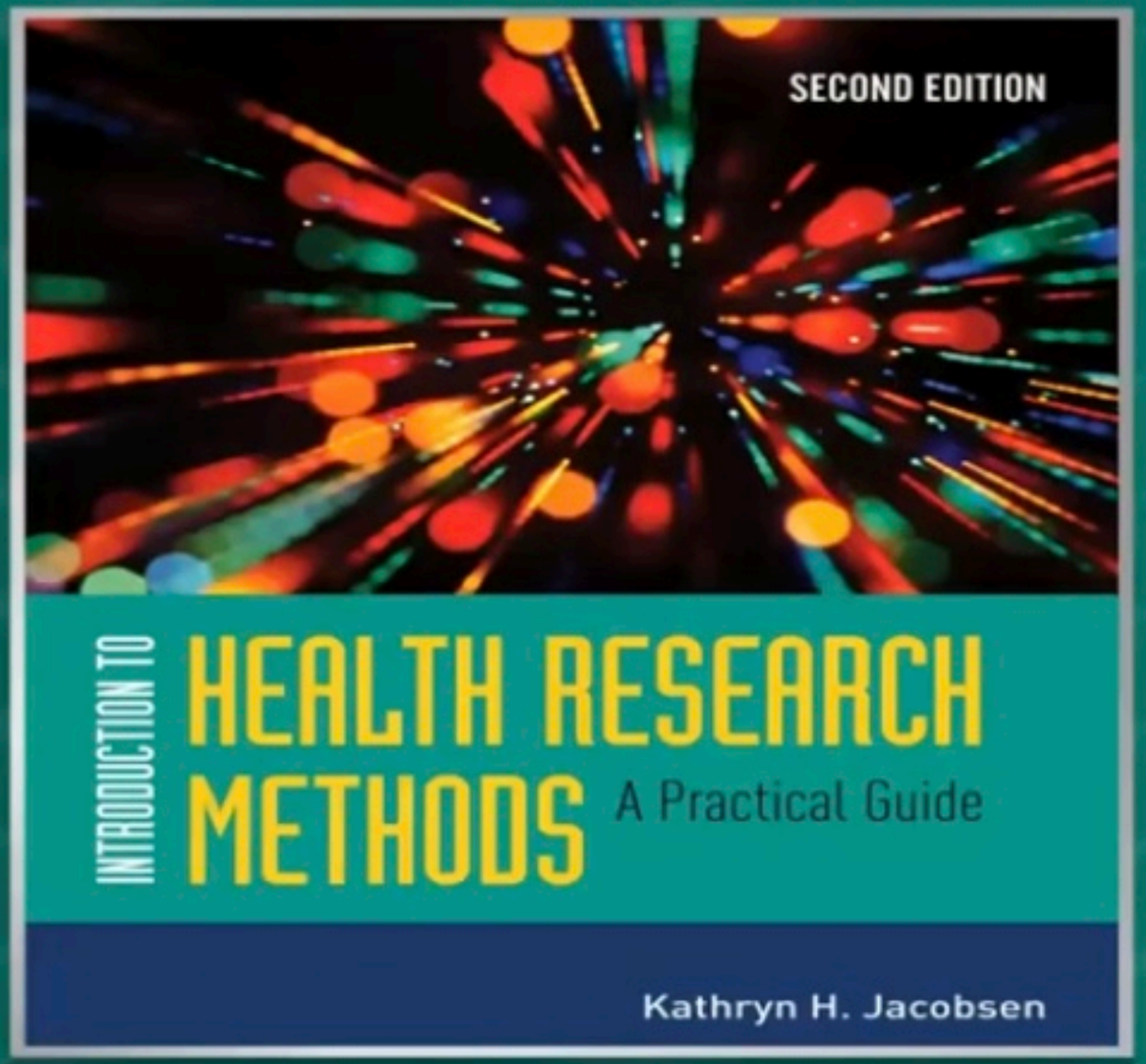
- Children & some adults with cognitive impairments may not be considered competent to make an informed decision.
- Whenever possible, in addition to having the legal representative's consent, potential participants should *assent* to their own participation.
- Other categories include: emotionally disabled, Aged subjects, Institutionalized people, Poor people, Pregnant women, & Unconscious or dying people.

23.11 Ethics Training & Certification

- Research ethics committees usually require everyone who will be in direct contact with research participants and/or their personal data to complete formal research ethics training.
- *Responsible conduct of research (RCR)* training programs may also spell out expectations & procedures for disclosing conflicts of interest, avoiding research misconduct, & exhibiting professionalism as researchers.

Ethical Review & Approval

Chapter 24



24.1 Ethics Committee Responsibilities (1 of 2)

The three primary goals of research ethics committees (RECs), often called *Institutional Review Boards (IRBs)*, are to:

1. protect the "human subjects" who will participate in research
2. protect researchers by preventing them from engaging in activities that could cause harm
3. legally protect the researcher's institution from the liability that could occur as a result of research activities.

24.1 Ethics Committee Responsibilities (2 of 2)

The major functions of ethics review boards are to:

- review new & revised research protocols;
- approve or disapprove of those protocols;
- ensure that informed consent is documented (if required); and
- conduct continuing review of long-term research projects.

24.2 Ethics Committee Composition

- Research ethics committees are usually composed of at least five members, preferably from diverse backgrounds, including both scientists & nonscientists.

24.3 Application Materials

- Some research ethics committees ask applicants to provide a narrative research statement that addresses a list of possible ethical concerns;
- Others require the completion of dozens of pages of forms.

FIGURE 24-1 Examples of Information Requested and Examined by Ethics Review Committees

Category	Considerations
Participants	• What is the anticipated composition and size of the study population? • How will participants be recruited? Does the recruitment method raise any concerns about coercion? • What are the inclusion and exclusion criteria? Are they reasonable? • Is the source population appropriate for the study question? • Are potentially vulnerable subjects protected, if applicable?
Risks and benefits	• Why is the study important and necessary? How will the proposed study benefit participants and/or their communities? • How will data be collected? Will existing data, documents, records, or specimens be used? Will individuals or groups be examined using surveys, interviews, focus groups, oral histories, program evaluations, or other methods? Will interviews be audio or video recorded? Will noninvasive clinical measures be taken? Will participants be asked to engage in exercise or tests of endurance, strength, or flexibility? What machines will be used to collect data, and will collection involve radiation exposure? Will blood, hair, nail clippings, sweat, saliva, sputum, skin cells, or other biological specimens be collected noninvasively? Will drugs or devices be tested? • What are the potential physical, psychological, financial, or other risks to participants? • Are the risks minimal (or at least minimized)? • Are the risks reasonable compared to the

FIGURE 24-1 Examples of Information Requested and Examined by Ethics Review Committees (continued)

Category	Considerations
Informed consent	• Does the informed consent statement adhere to institutional guidelines? • How will informed consent be sought? • How will informed consent be documented? • Is any modification to the usual methods of documenting informed consent being requested? Is the request reasonable? (For example, are parents being asked to provide consent for their children, and are the children being asked to assent to participation? Or is a waiver of a signed consent form being requested because the source population has a low literacy rate? Or is a request being made to have no documentation of consent because the existence of a form linking an individual to the study could harm the participant?)
Privacy and confidentiality	• How will privacy and confidentiality be maintained? • What are the plans for the protection of computerized and noncomputerized data?
Safety monitoring	• Does the informed consent statement clearly state how research participants can contact the research team and/or the ethics review board if they have concerns? • What constitutes an adverse event? How will such events be handled?
Conflicts of interest	• How is the project being funded? • Do any financial or personal conflicts of interest need to be disclosed and/or addressed?
Researcher training	• Are the investigators prepared to conduct ethical

FIGURE 24-1 (continued)

Category	Considerations
Documentation	• Are copies of all recruitment materials (if any) attached? • Are copies of the questionnaire and/or other assessment tools attached? • Is a copy of the informed consent statement attached? • Are copies of letters of approval from study sites and/or other ethics review committees attached, if applicable? • Is a copy of the grant proposal attached, if applicable? • Are copies of research ethics training certificates for all members of the research team attached?

24.4 Review Process

Once all application materials have been submitted to a research ethics committee, there are three possible next steps:

1. Exemption
2. Expedited review
3. Full review

Levels of IRB Review

Full Board

- More than "minimal risk" to subjects
- Not covered under other review categories
- Example: interventions involving physical or emotional discomfort or sensitive data

Expedited

- Not greater than minimal risk
- Fits one of the 9 Expedited Review Categories*
- Examples: Collection of biospecimens by noninvasive means, Research with existing documents/record collected for non-research purposes in which subjects are identifiable

Exempt

- Less than "minimal risk"
- Fits one of the 6 Exempt Categories*
- Example: Research with de-identified records, anonymous surveys

*Defined by federal regulation (45 CFR 46)

24.5 Review by Multiple Committees

At least three issues must be resolved prior to submission of a research proposal to multiple committees:

- The application documents that will be required
- The wording of the informed consent statement
- The order of review

24.6 Ongoing Review

- All ongoing research protocols must be re-reviewed annually (or more often, at the discretion of the ethics review committee).

24.7 Conflicts of Interest

- When a financial or other relationship (personal relationships, board membership, or others) could bias the design, conduct, or reporting of the study, the potential conflict of interest (COI) must be disclosed.
- The disclosure of a potential COI is not an admission of bias, but it is an important assurance of transparency.

24.8 Is Ethics Review Required?

- The decision to exempt a project from review can be made only by the relevant ethics committees.
- Research protocols cannot be retroactively approved, so researchers must take the time to undergo a formal review prior to collecting any data or analyzing any data files.

The End
Good Luck