Training Course in Reproductive Health/
Sexual Health Research
Geneva 2006

ETHICAL ISSUES IN RESEARCH

- informed consent-

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Objectives of this session

- review need for research ethics
- highlight key issues in research ethics
- focus on and analyse the issue of informed consent

Importance of ethics in research

Funding & publishing requirements?

Importance of ethics in research

- Human participants
- Risks/ benefits not always predicted
- Harm
- Abuses in research

Ethical Issues in Research

Nazi experiments

Nuremberg trial- Nuremberg code 1947

Ethical Issues in Research

- Tuskegee syphilis experiment : 1932-1972
- Jewish chronic disease hospital cancer experiments 1963-1966
- WIllowbrook state school hepatitis experiments 1955-1970

agreement about these abuses

Ethical Issues in Research

Nuremberg code
1947

↓

Declaration of Helsinki
1964/1975/2000

↓

CIOMS Guidelines
1982/2002

- Respect for persons
- Beneficence
- Justice

Fundamental Ethical Principles in Research

- Respect for persons
- Beneficence
- Distributive justice

Respect *for persons*

Respect *for persons*

↓

Respect for autonomy

i) Requirement that those who are capable of deliberating personal choices should be treated with respect for their capacity of self-determination;

ii) Persons with diminished or impaired autonomy or those in dependent or vulnerable positions should be protected against harm or abuse.

Ethical Issues in Research

- **informed consent, and**
- **informed decision-making**

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Informed decision-making

Informed decision-making requires:

- information from the investigator to be:
  - comprehensive (complete)
  - comprehensible (simple language)

- the decision by the subject to be:
  - based on competence (ability to understand)
  - voluntary (free of coercion, undue influence or inducement, or intimidation)

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Ethical Issues in Research

- **Content** of informed consent
- **Who** obtains consent
- **How** is consent obtained
- How is consent **recorded**

Barriers

- Confusion
- Culture
- Coercion
- Time

Consent Form

THE CONSENT FORM

- **documents the consent process**
- **it cannot substitute for the consent information and discussion**
- **it is not to provide legal protection for researchers!**

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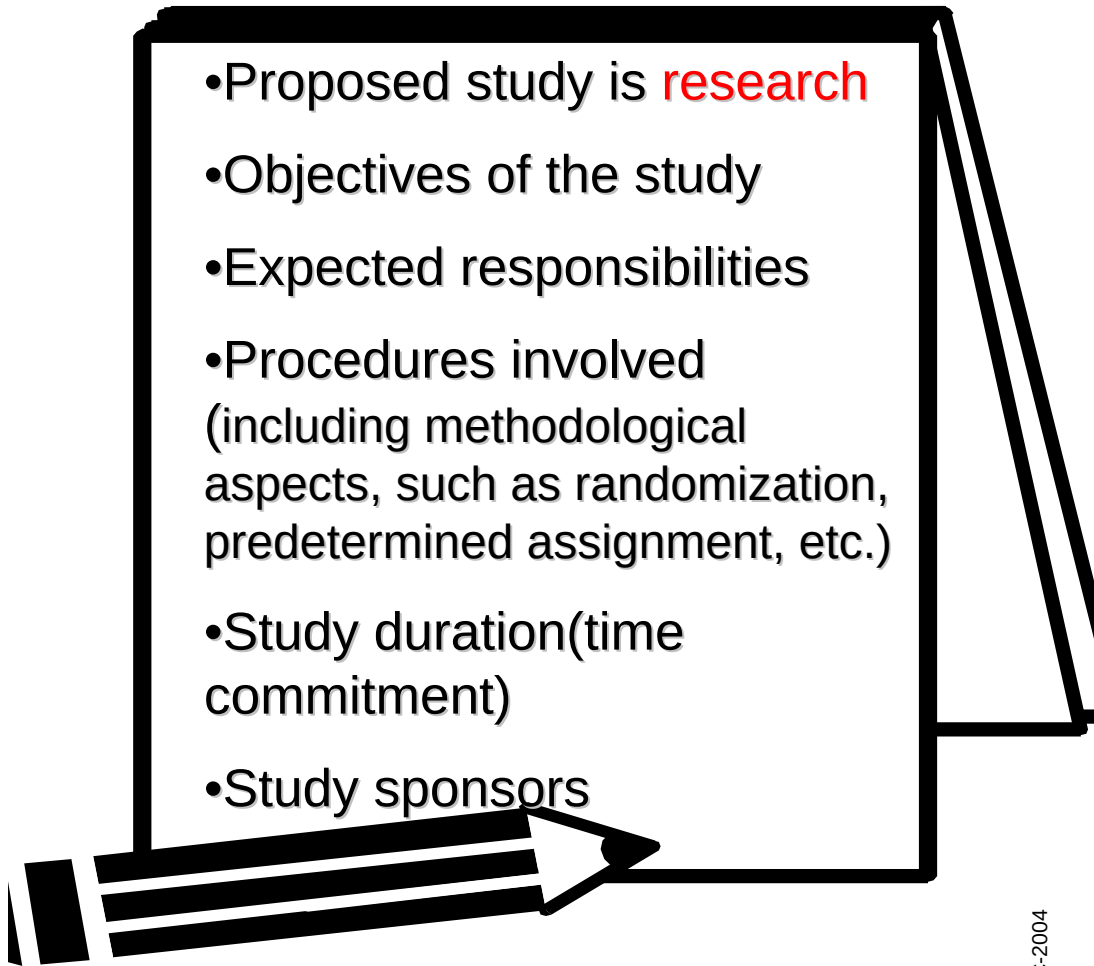
Ethical Issues in Research

What information must be disclosed?

Ethical Issues in Research

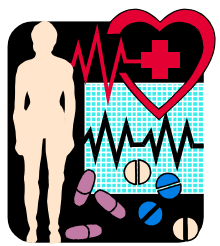


Points to remember

Points to remember:

- ***use*** **simple, nontechnical language that subjects can understand**

- **Sophisticated scientific concepts**



- **Level of literacy**

- **Cultural beliefs for disease aetiology**

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Language

Language:

Examples from US study
Waggoner , W. And Mayo D. "Who understands? A Survey of 25 Words of Phrases Commonly Used in Proposed Clinical Research Consent Forms," IRB: A Review of Human Subjects Research, vol. 17, No 1 (1995), 6-9

Ethical Issues in Research

1. If you were to use the *barrier method* for birth control, what would this involve?

Greater than 12th grade:

a)25% **b)79%** **c)90%**

12th grade or less:

a)70% **b)35%** **c)58%**

Ethical Issues in Research

1. If you were to use the *barrier method* for birth control, what would this involve?

Greater than 12th grade:

a)25% **b)79%** **c)90%**

12th grade or less:

a)70% **b)35%** **c)58%**

Ethical Issues in Research

2. What does the term *efficacy* mean?

Greater than 12th grade:

a)39% **b)82%** **c)59%**

12th grade or less:

a)29% **b)13%** **c)49%**

2. What does the term *efficacy* mean?

Greater than 12th grade:

a)39% **b)82%** **c)59%**

12th grade or less:

a)29% **b)13%** **c)49%**

3. If the drug you were to take was chosen *randomly*, what does this mean?

Greater than 12th grade:

a)39% **b)64%** **c)49%**

12th grade or less:

a)38% **b)13%** **c)4%**

Ethical Issues in Research

3. If the drug you were to take was chosen *randomly*, what does this mean?

Greater than 12th grade:

a)28% **b)64%** **c)49%**

12th grade or less:

a)38% **b)13%** **c)4%**

Double-blind

4. What does *double-blind* mean?

Grader than 12th day:

a)65% **b)37%** **c)21%**

12th grade or less:

a)29% **b)3%** **c)17%**

Double-blind

4. What does *double-blind* mean?

Grader than 12th day:

a)65% **b)37%** **c)21%**

12th grade or less:

a)29% **b)3%** **c)17%**

Ethical Issues in Research

Points to remember:

- ***describe*** **fully what the subject will have to do, before, during, and following the research, including the amount of time required**
- ***include*** **mention of home visits when relevant**

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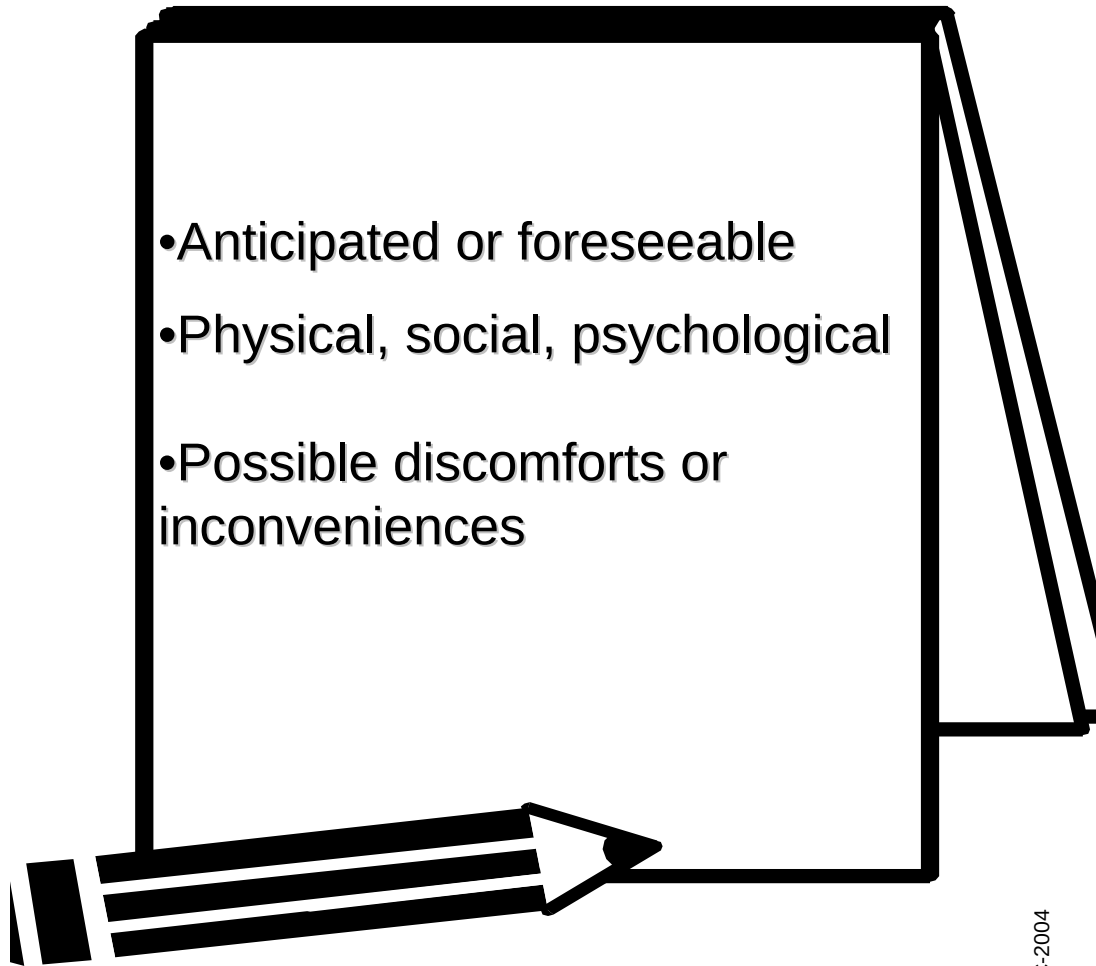
Ethical Issues in Research



Ethical Issues in Research

Points to remember:

- ***avoid*** **misleading or deceptive statements**

  e.g. "There are no risks to this research"

- ***avoid*** **unduly alarming statements**

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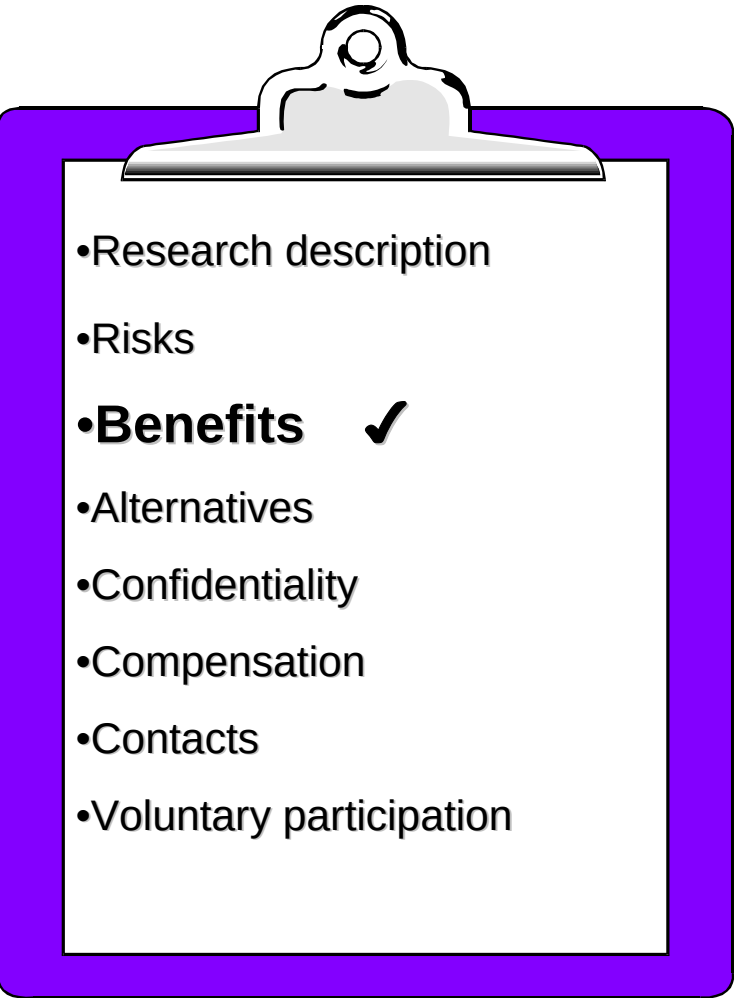
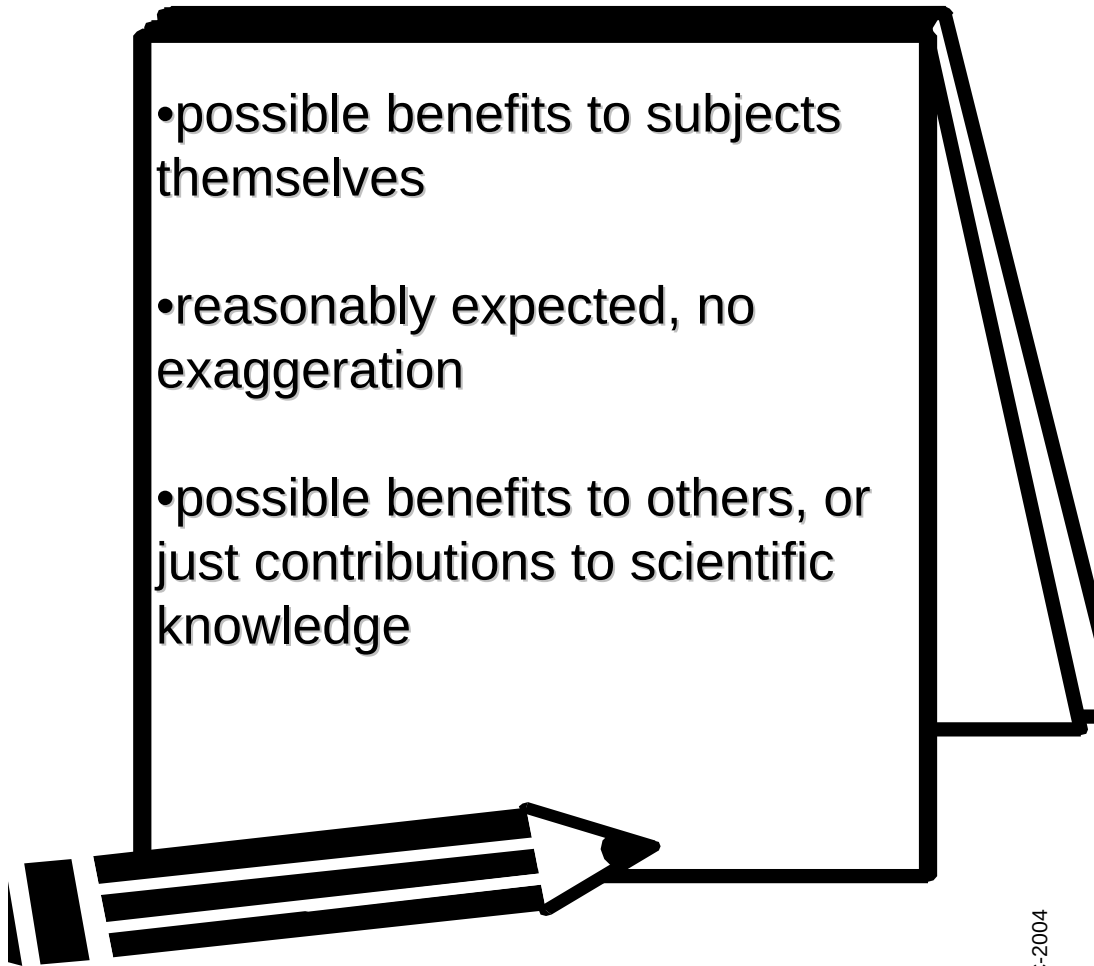
Ethical Issues in Research





Ethical Issues in Research

Points to remember:

- ***do not*** **overstate the benefits to subjects of the research**

e.g. "This new treatment will improve your condition"

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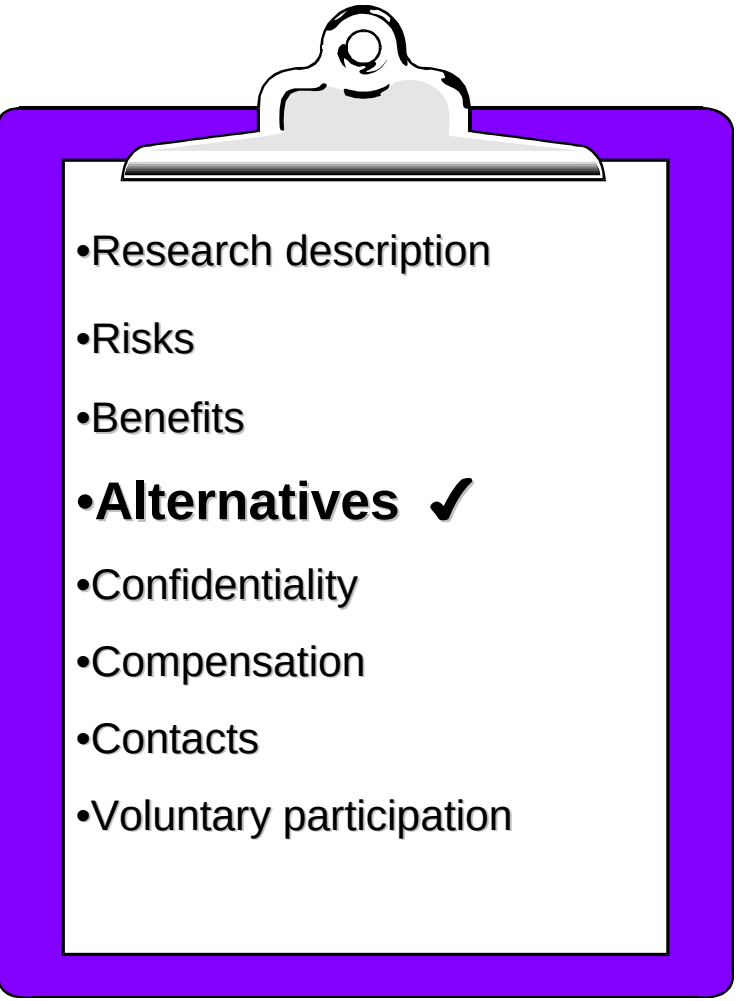
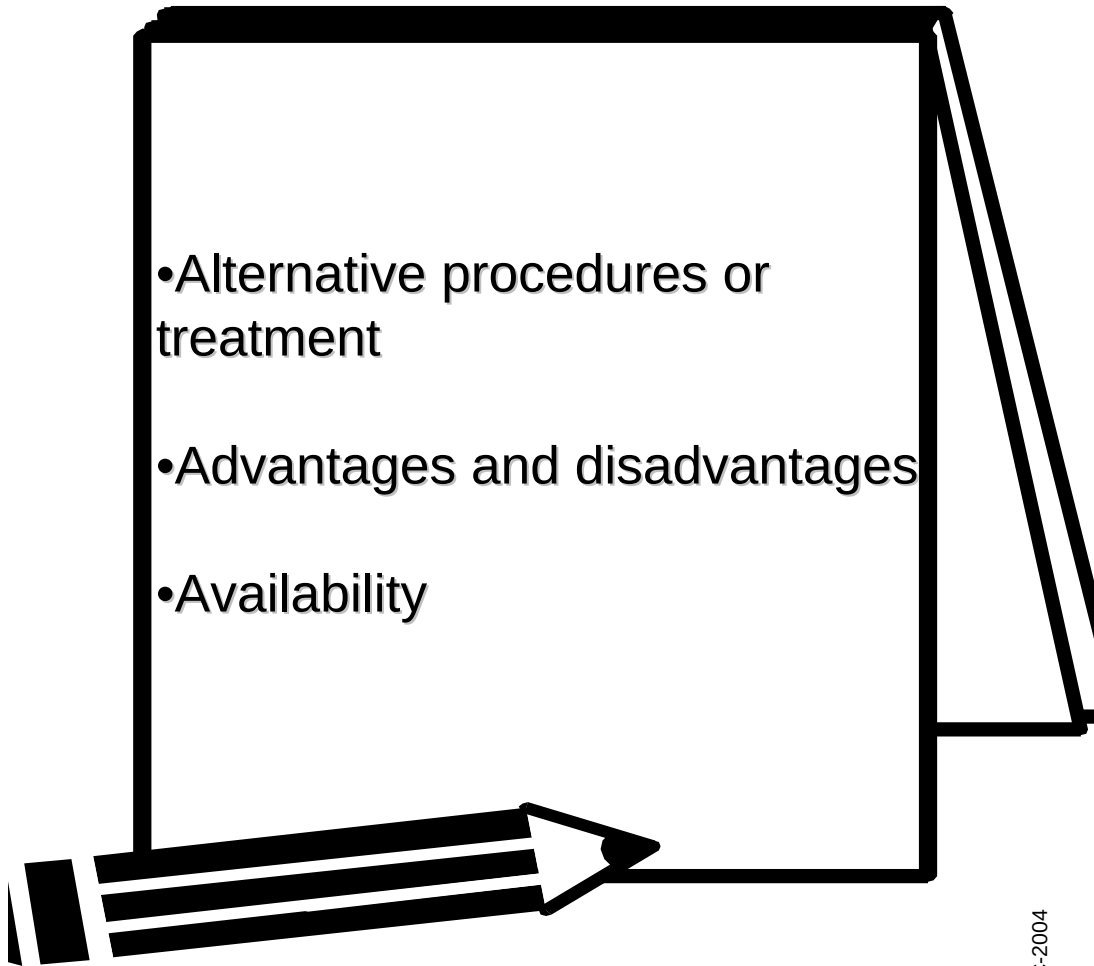
Ethical Issues in Research



- Research description
- Risks
- Benefits
- **Alternatives** ✓
- Confidentiality
- Compensation
- Contacts
- Voluntary participation



- Alternative procedures or treatment
- Advantages and disadvantages
- Availability

Ethical Issues in Research

Points to remember:

- ***distinguish clearly*** **between the research manoeuvers and any therapeutic or diagnostic procedures subjects would undergo if not enrolled in the research**

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Ethical Issues in Research

Points to remember:

- **avoid** a ***therapeutic misconception***

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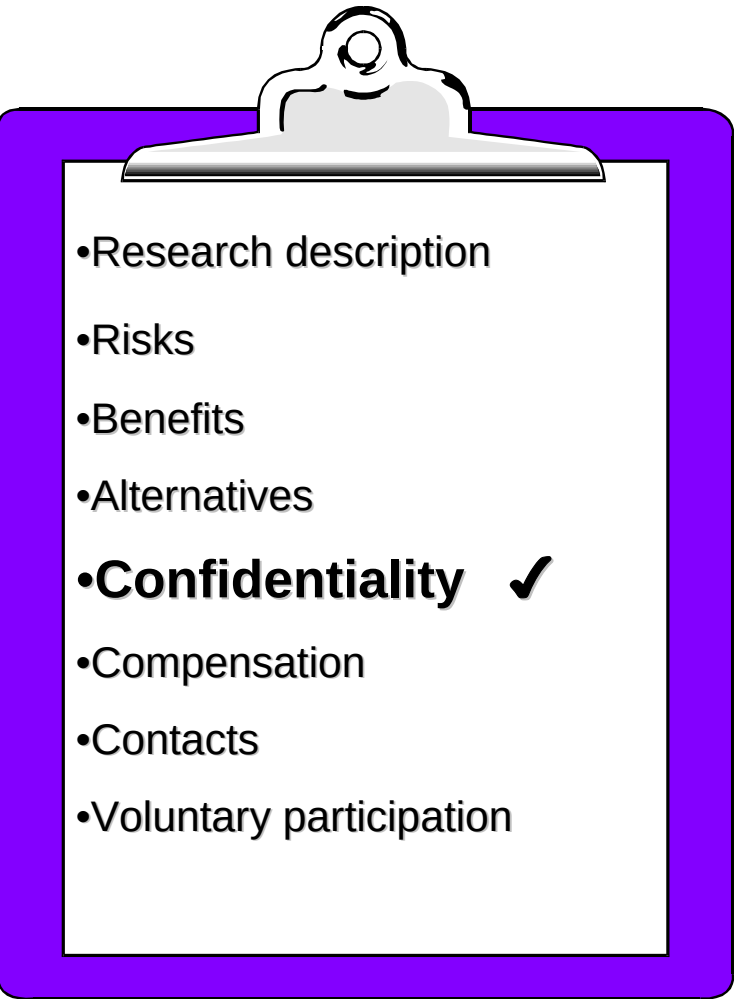
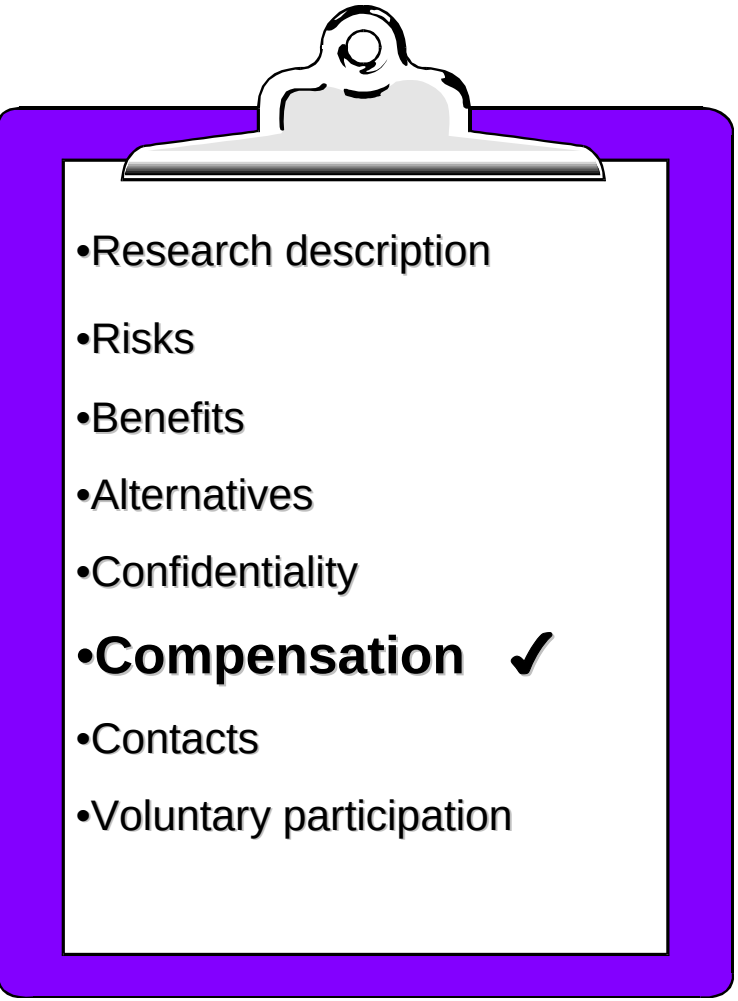
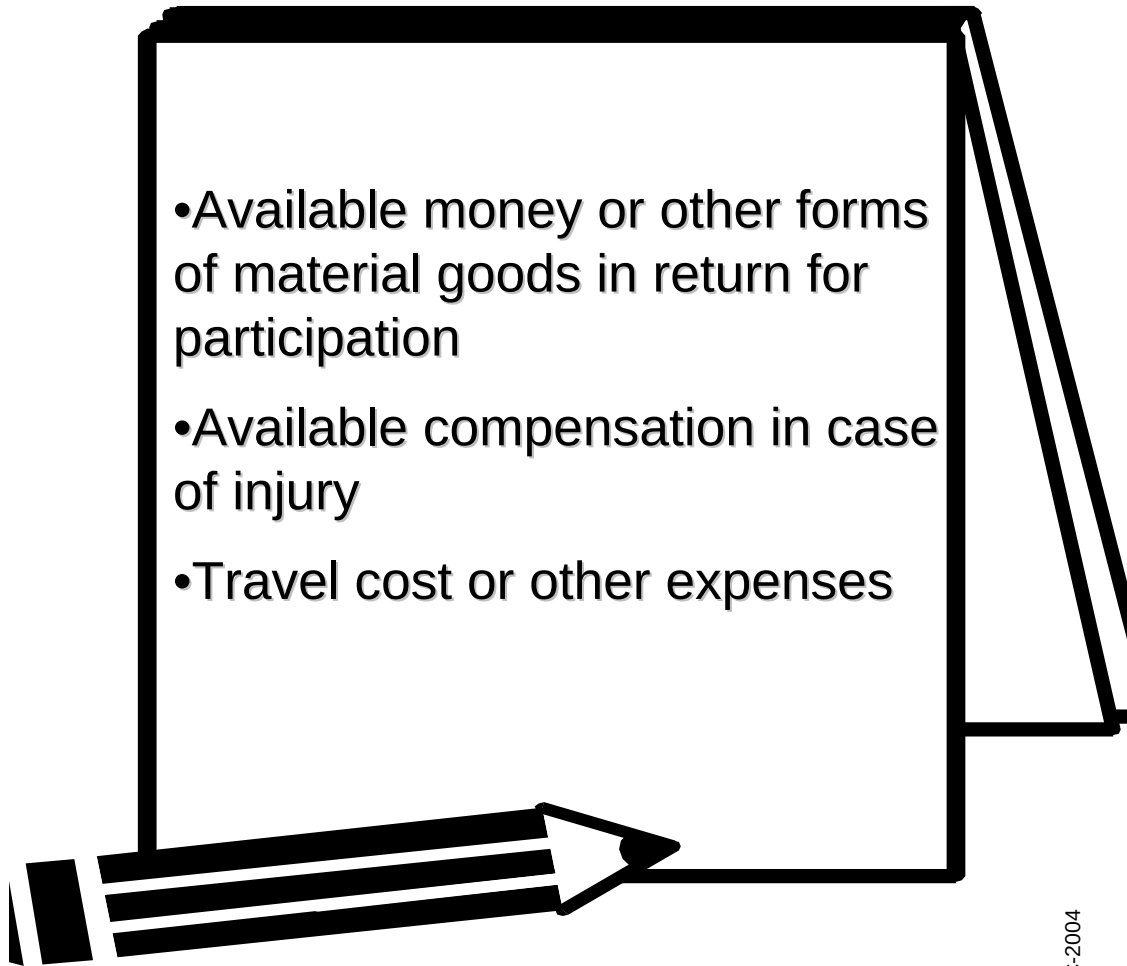
Ethical Issues in Research



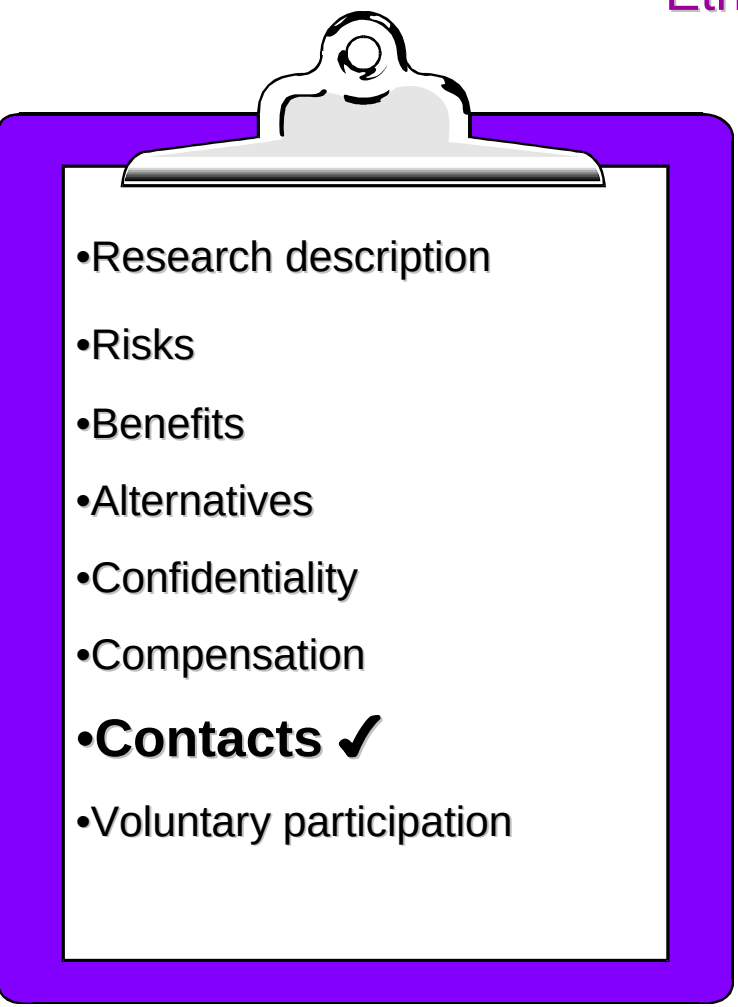
- Degree of confidentiality
- Persons, organizations who may have access to the information
- How confidentiality will be maintained
- Can confidentiality be maintained (legal situation regarding mandatory disclosure to authorities)
- Where and how information will be stored and for how long

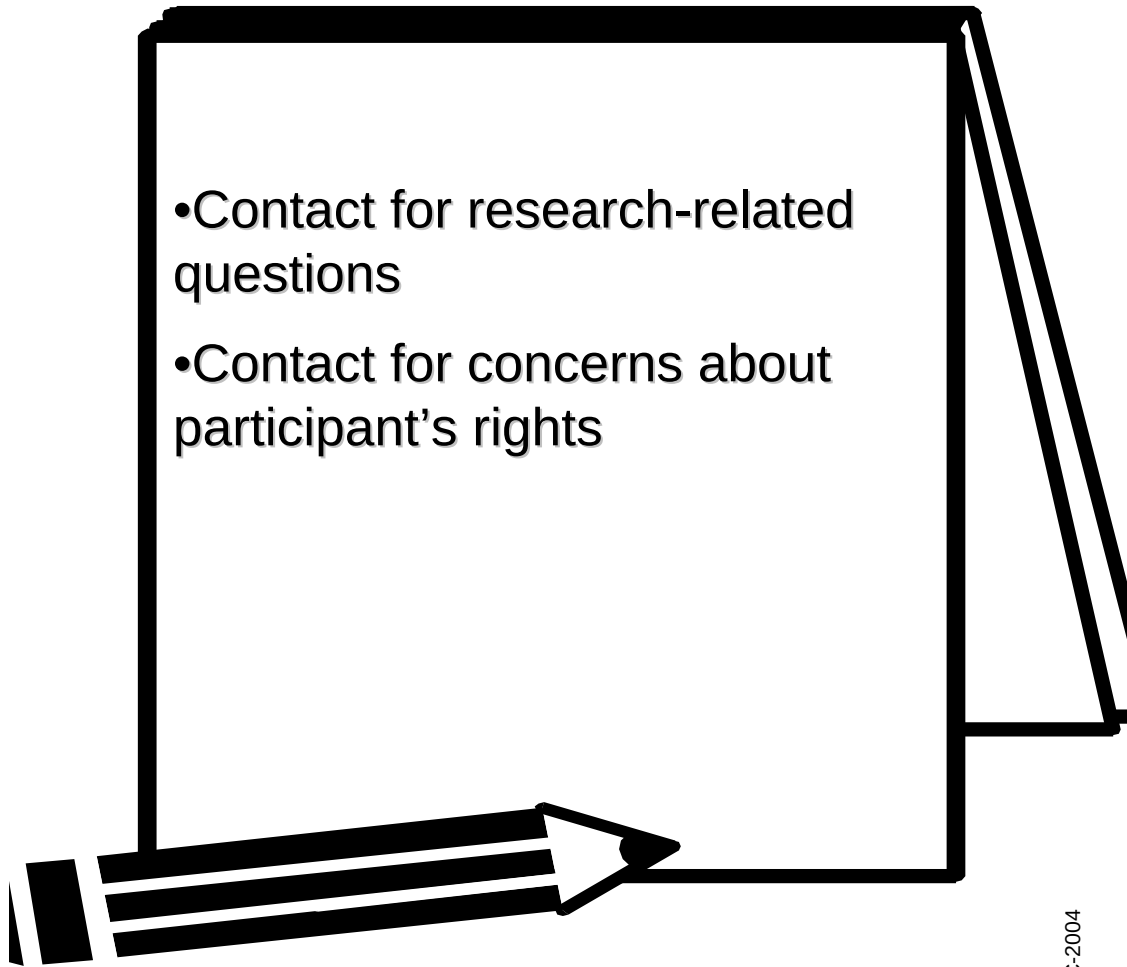
Ethical Issues in Research



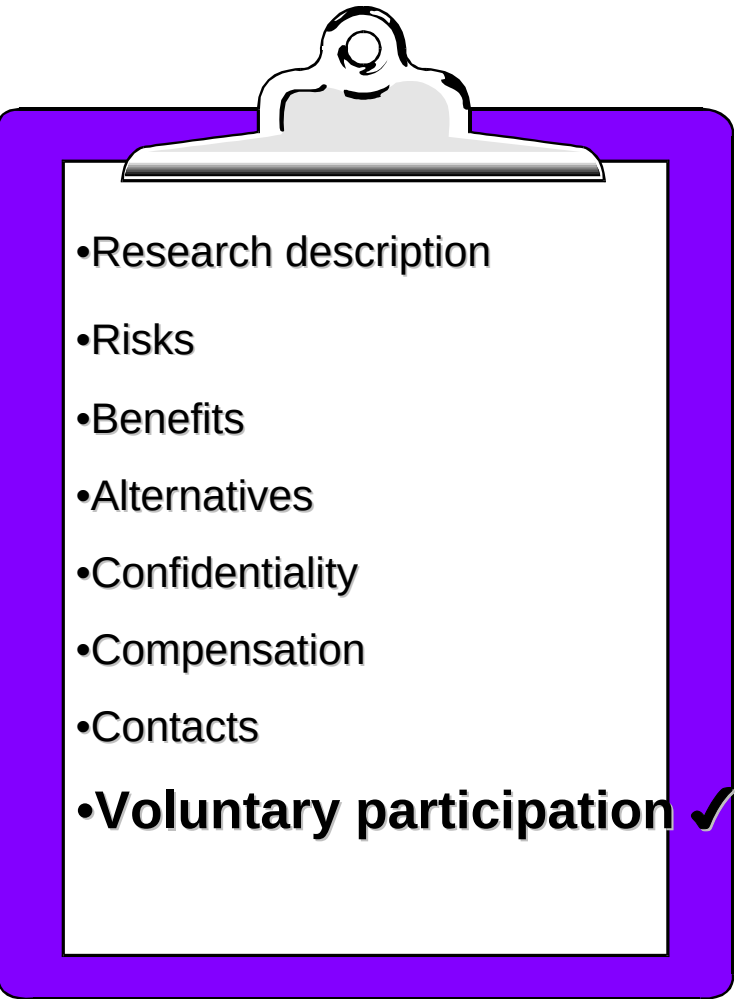


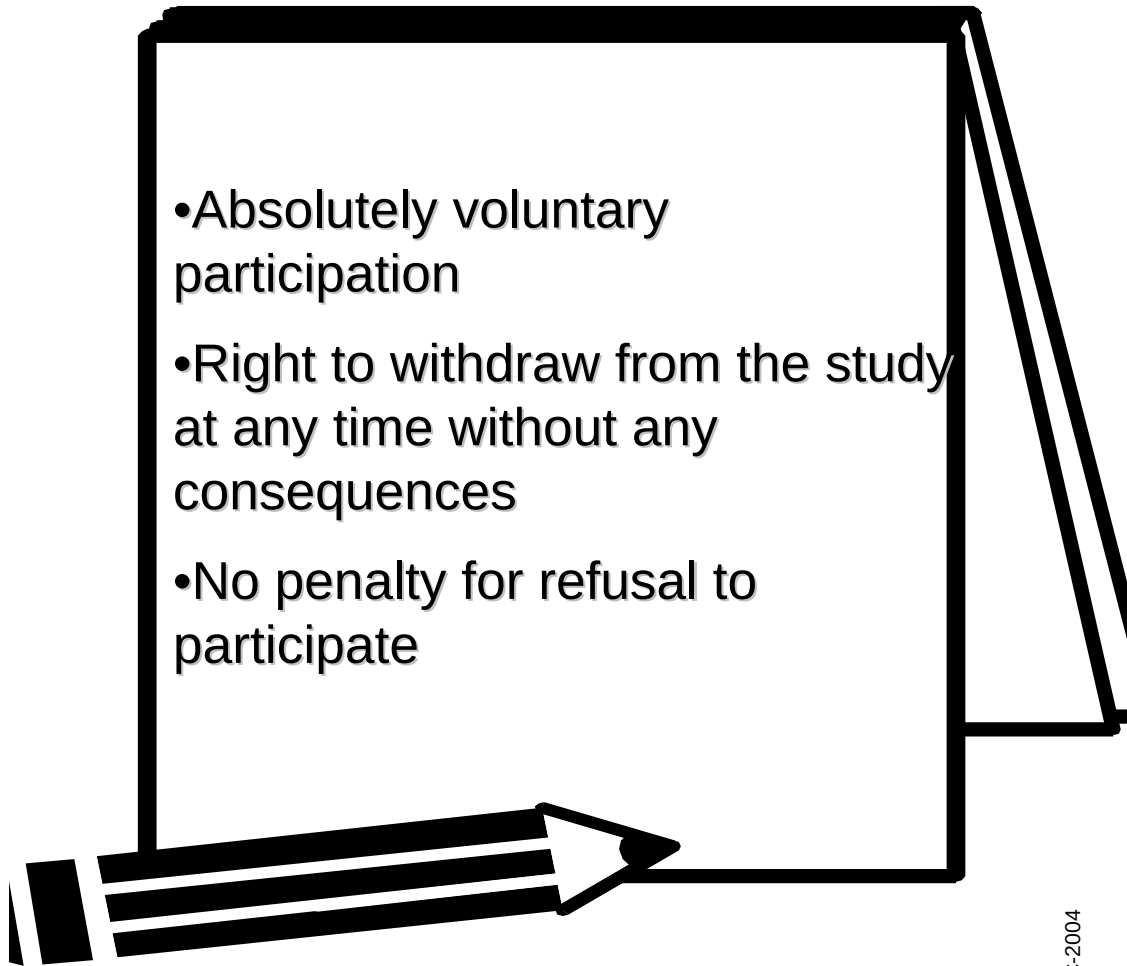
Ethical Issues in Research in Reproductive Health





Ethical Issues in Research





Points to remember:

- ***avoid*** **subtly coercive statements**

  e.g. "We trust that you will agree to participate and

  remain in this study in order to help us find a cure for your disease"

- ***do not*** **include a line for the spouse´s signature, except under certain specific and clearly defined circumstances**

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Who obtains consent

Who obtains consent

Investigator / physician

Third party (healthcare worker, interpreter)

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How to obtain consent

How to obtain consent

- **refrain from unjustified deception, undue influence**

"How useful is the issue of informed consent in the Philippines and other developing countries, since it is always the poor in trials who cannot afford the drugs on the market? It is their only realistic form of treatment and they are not truly free to decide not to participate."

Quoted in Nuffield Council of Bioethics Report, 2002, p. 79

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How to obtain consent

How to obtain consent

- refrain from unjustified deception, undue influence
- seek consent after comprehension
- in general obtain signed consent (how to record)
- renew the consent of each subject if changes in conditions or procedures
- renew the consent in long term-studies at pre-determined intervals

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How to record consent

How to record consent

signed form as evidence -investigators to justify any exceptions to this general rule and obtain approval from the ethical review committee.

- **minimal risk**
- **subjects unwilling to sign because of fear, mistrust or suspicion**
- **signed consent forms may identify subjects in sensitive research (HIV/AIDS, CSWs, etc.)**

verbal consent/ witnessing consent

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Other issues/concerns

Other issues/concerns

- respect of autonomy ⟹ informed decision making

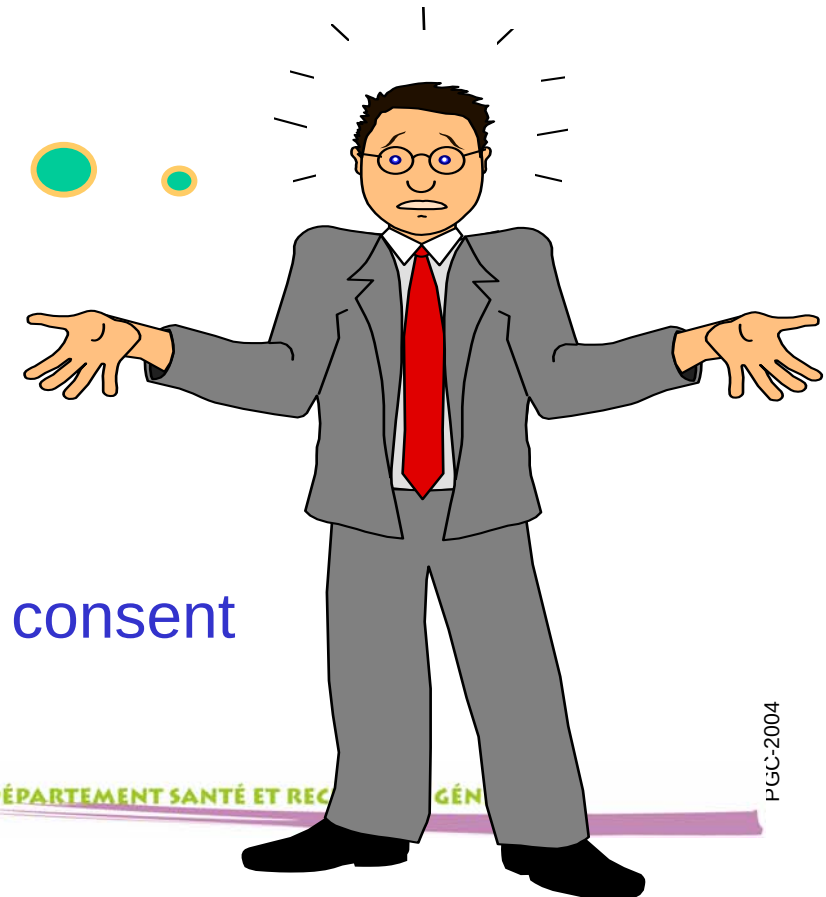
- individual versus community
  - » **community leader**
  - » **council of elders**
  - » **another designated authority**

In no case, may the permission of a community leader or other authority substitute for individual informed consent

(CIOMS)

•autonomy and locus of decision-making authority

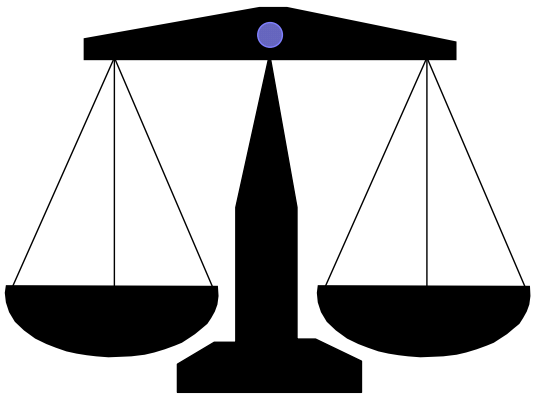
Who is making the decision?



•notion of personhood
•person versus community
•individual consent versus community consent
•women

Ethical Issues in Research

Sensitivity to cultural requirements, customs traditions



Requirement for respect for persons

...in some cultural contexts it may be appropriate to obtain agreement from the community or assent from from a senior family member before a prospective participant is approached. If a prospective participant does not wish to take part in research this must be respected. Researchers must not enrol such individuals and have a duty to facilitate their non-participation.

Nuffield Council of Bioethics Report, 2002

Ethical Issues in Research

Other issues/concerns

- respect of autonomy ⟹ informed decision making
- impaired capacity to give adequately informed consent
  - low risk standard
  - responsible family member or legally authorised representative (case of mental or behavioural disorder)
  - ethical review committee to approve

Ethical Issues in Research

Remember - the primary ethical objective is:

- **to protect the research subject from harm**
  - **physical**
  - **psychological**
  - **social (stigmatization, community exclusion)**
  - **legal (fines)**
- **not to protect the investigator from claims**

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Ethical Issues in Research

- In research on man, the interest of science and society should never take precedence over considerations related to the wellbeing of the subject.

  » Declaration of Helsinki