



POSTGRADUATE COURSE 2003

# ETHICAL ISSUES IN RESEARCH

*- informed consent-*

**Effy Vayena**

**Department of Reproductive Health and Research  
World Health Organization  
Geneva, Switzerland**



## Ethical Issues in Research in Reproductive Health

### Objectives of this session:

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



## Ethical Issues in Research in Reproductive Health

- Importance of ethics in research:
  - Human participants
  - Risks/ benefits not always predicted
  - Harm
  - Abuses in research



## Workshop on Ethical Issues in Research in Reproductive Health



**Nazi experiments**



**Nuremberg trial- Nuremberg code 1947**



## Ethical Issues in Research in Reproductive Health

- Tuskegee syphilis experiment : 1932-1972
- Contraceptive research on poor women
- Plutonium injections

agreement about these abuses



## Ethical Issues in Research in Reproductive Health

### Fundamental Ethical Principles in Research

- Respect for persons
- Beneficence
- Distributive justice



## Workshop on Ethical Issues in Research in Reproductive Health

Nuremberg code  
1947



Declaration of Helsinki  
1964/1975



CIOMS Guidelines  
1982/2002

- Respect for persons
- Beneficence
- Justice



## Workshop on Ethical Issues in Research in Reproductive Health

Respect *for persons*



Respect for autonomy

### CIOMS Guidelines- 2002

“For all biomedical research involving human subjects, the investigator must obtain the ***informed consent*** of the prospective subject or, in the case of an individual who is not capable of giving informed consent, the permission of a legally authorized representative in accordance with applicable law. Waiver of informed consent is to be regarded as uncommon and exceptional, and must in all cases be approved by an ethical review committee. ”





## Ethical Issues in Research in Reproductive Health

- Informed decision-making key issue in research involving human subjects
- International codes, guidelines, national legislation, etc.



## Ethical Issues in Research in Reproductive Health

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



## Ethical Issues in Research in Reproductive Health

### **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)**



## Ethical Issues in Research in Reproductive Health

### 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!**



## Ethical Issues in Research in Reproductive Health

What information must be disclosed?

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



## Ethical Issues in Research in Reproductive Health

### • **Research description**

- Risks
- Benefits
- Alternatives
- Confidentiality
- Compensation
- Contacts
- Voluntary participation

- Proposed study is **research**
- Objectives of the study
- Expected responsibilities
- Procedures involved (including methodological aspects, such as randomization, predetermined assignment, etc.)
- Study duration (time commitment)
- Study sponsors

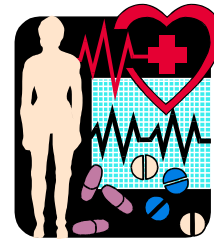


## Ethical Issues in Research in Reproductive Health

### Points to remember:

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

- Sophisticated scientific concepts



- Level of literacy



- Cultural beliefs for disease aetiology





## Ethical Issues in Research in Reproductive Health

### Points to remember:

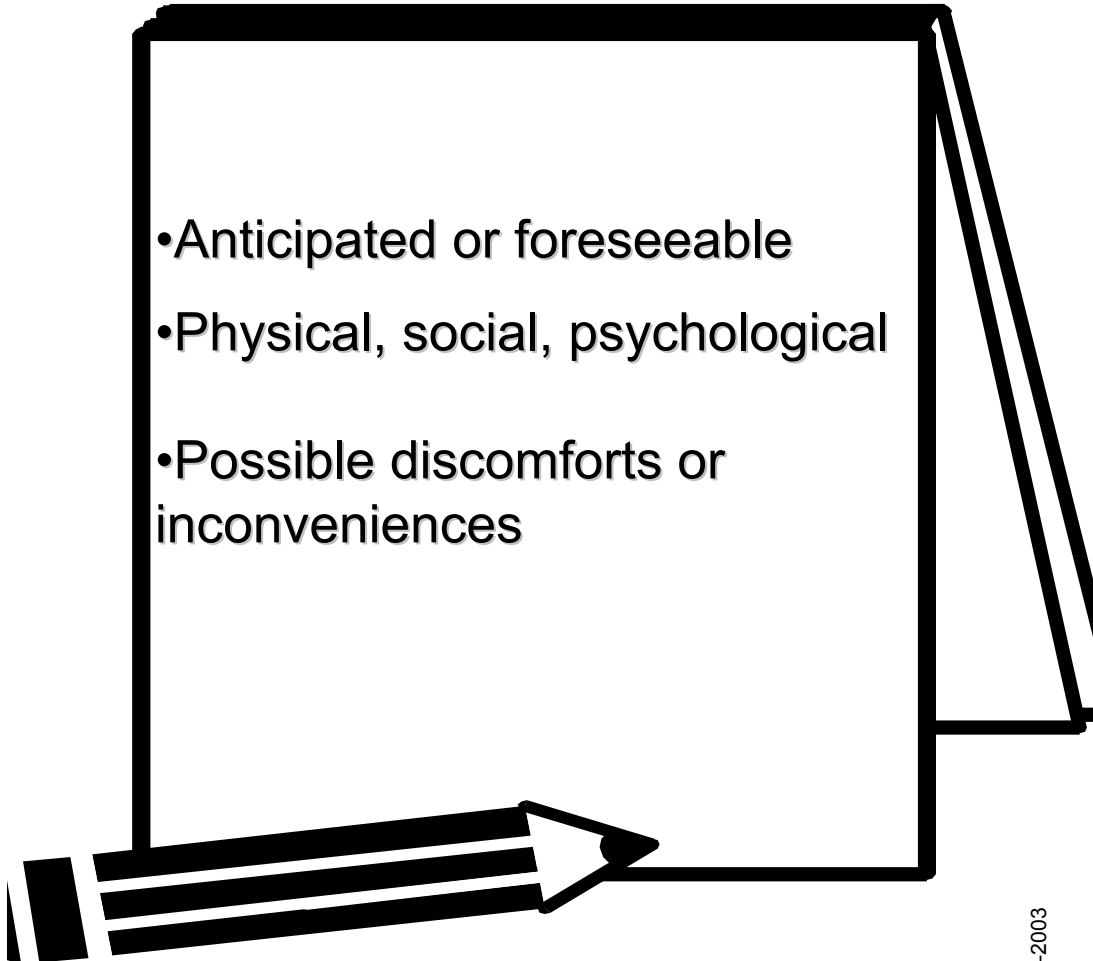
- ***describe*** fully what the subject will have to do, before, during, and following the research, including the amount of time required
- ***include*** mention of home visits when relevant





## Ethical Issues in Research in Reproductive Health

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

- 
- Anticipated or foreseeable
  - Physical, social, psychological
  - Possible discomforts or inconveniences



## Ethical Issues in Research in Reproductive Health

### Points to remember:

- ***avoid*** misleading or deceptive statements  
e.g. "There are no risks to this research"
- ***avoid*** unduly alarming statements



## Ethical Issues in Research in Reproductive Health

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



- possible benefits to subjects themselves

- reasonably expected, no exaggeration

- possible benefits to others, or just contributions to scientific knowledge



## Ethical Issues in Research in Reproductive Health

### Points to remember:

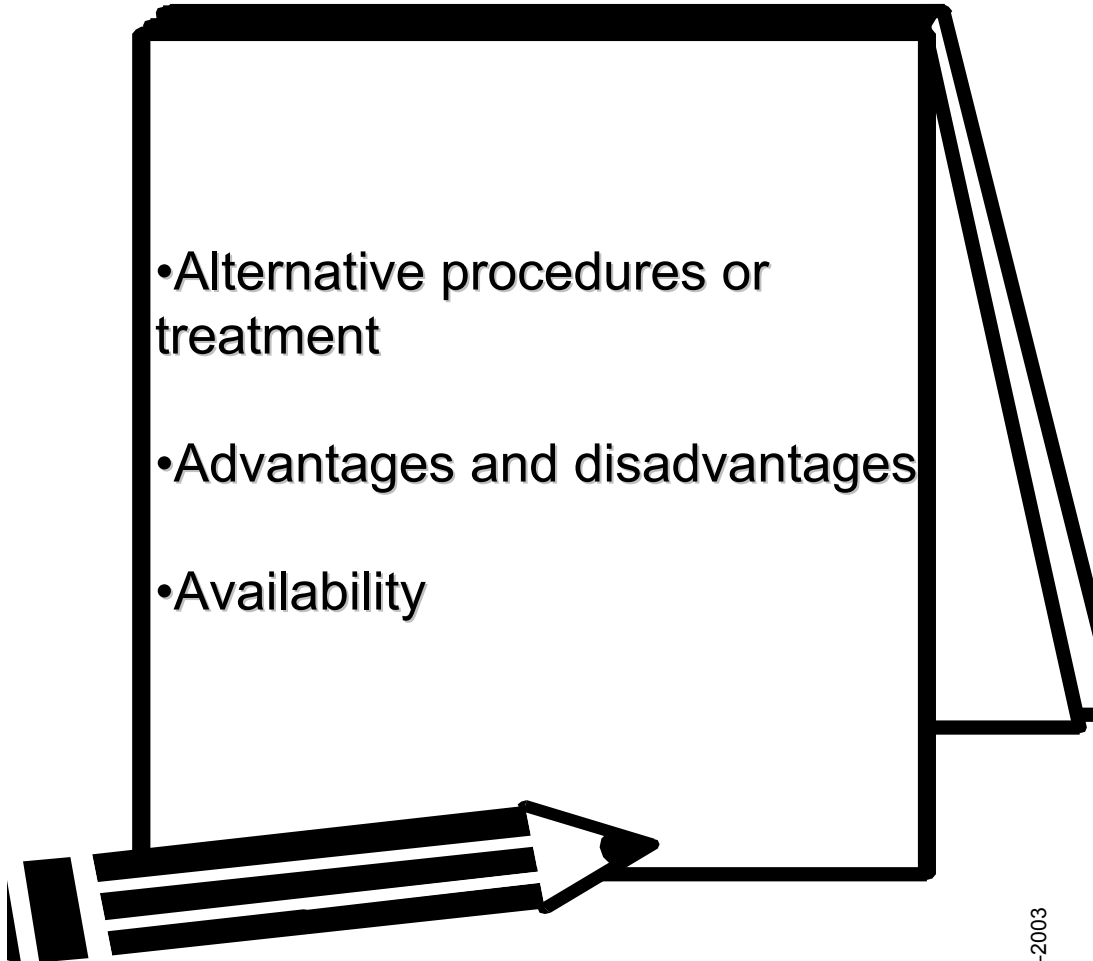
- ***do not*** overstate the benefits to subjects of the research

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



## Ethical Issues in Research in Reproductive Health

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

- 
- Alternative procedures or treatment
  - Advantages and disadvantages
  - Availability



## Ethical Issues in Research in Reproductive Health

### Points to remember:

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



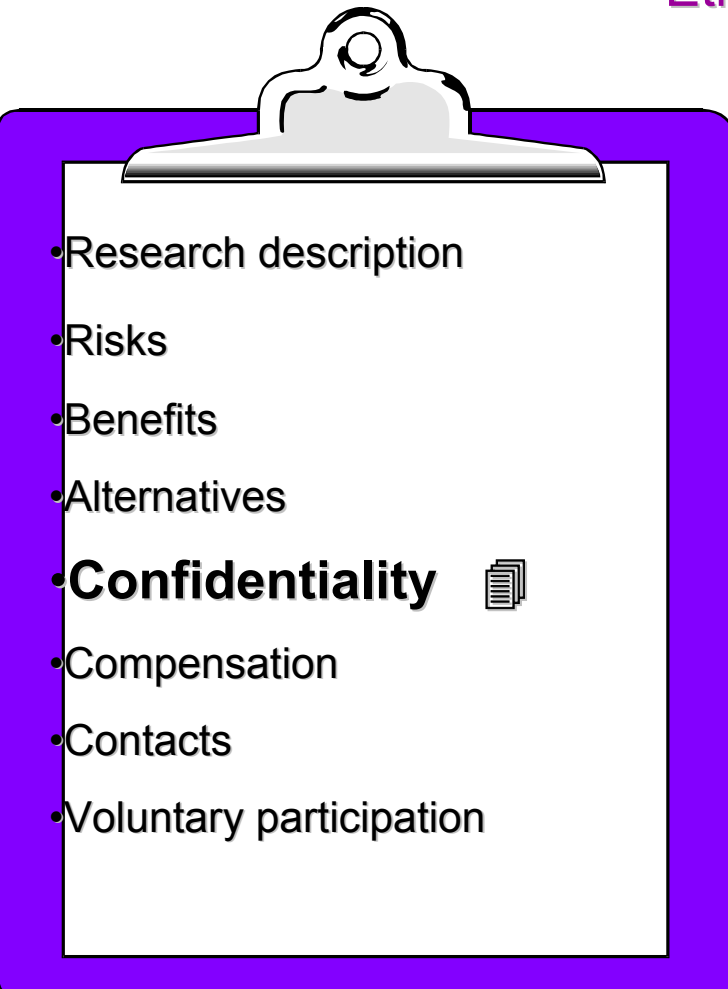

## Ethical Issues in Research in Reproductive Health

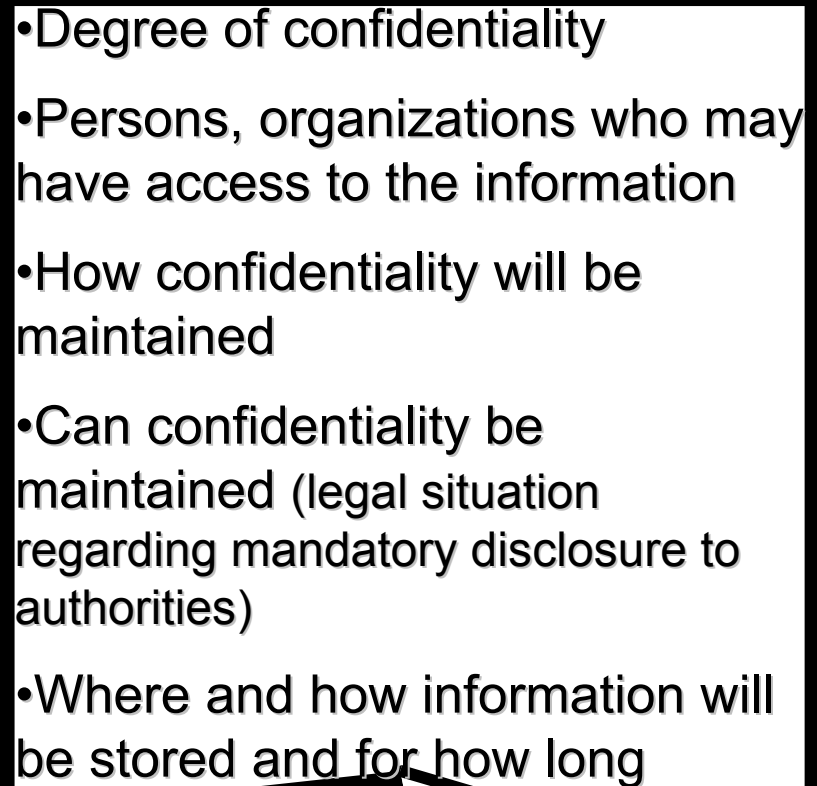
### Points to remember:

- **avoid** a *therapeutic misconception*



## Ethical Issues in Research in Reproductive Health

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

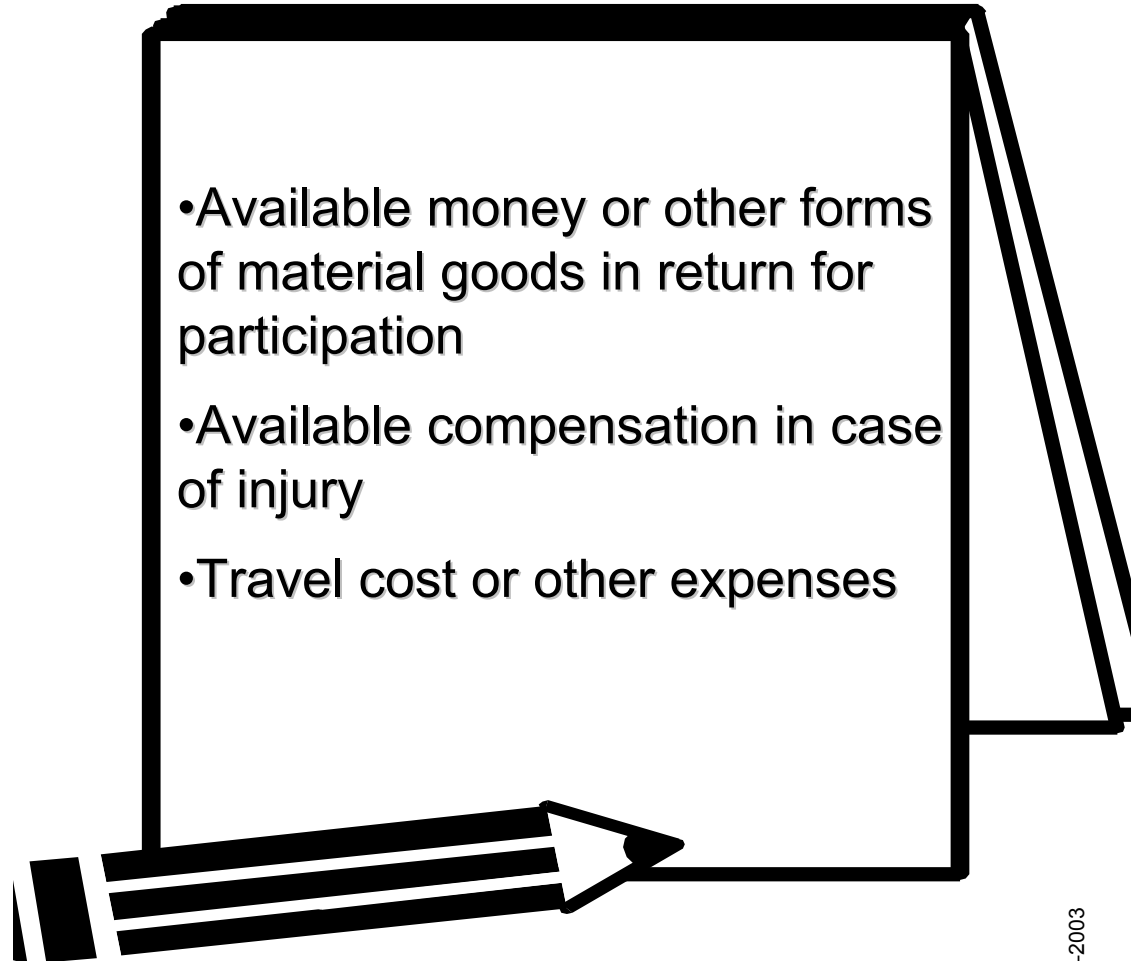
- 
- Degree of confidentiality
  - Persons, organizations who may have access to the information
  - How confidentiality will be maintained
  - Can confidentiality be maintained (legal situation regarding mandatory disclosure to authorities)
  - Where and how information will be stored and for how long





## Ethical Issues in Research in Reproductive Health

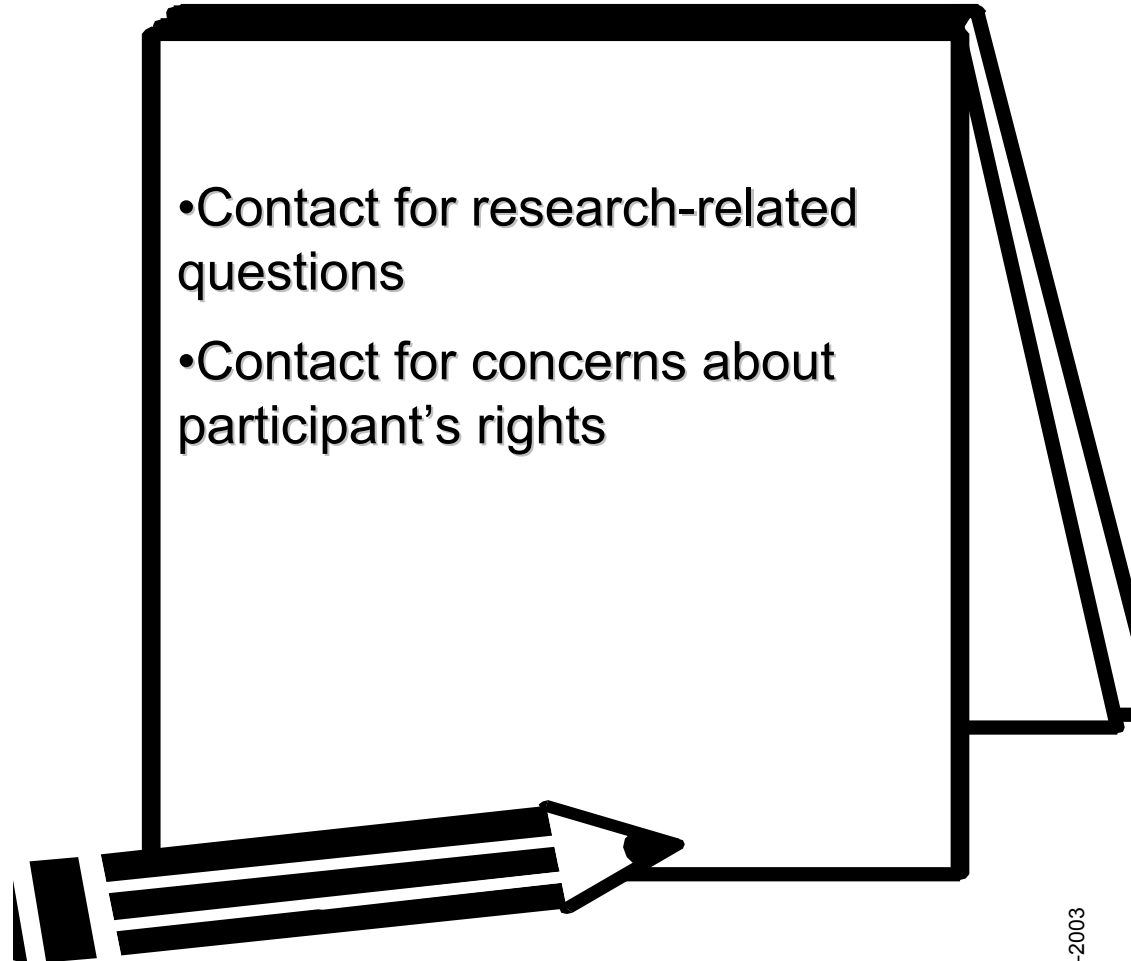
- 
- Research description
  - Risks
  - Benefits
  - Alternatives
  - Confidentiality
  - **Compensation** 
  - Contacts
  - Voluntary participation

- 
- Available money or other forms of material goods in return for participation
  - Available compensation in case of injury
  - Travel cost or other expenses



## Ethical Issues in Research in Reproductive Health

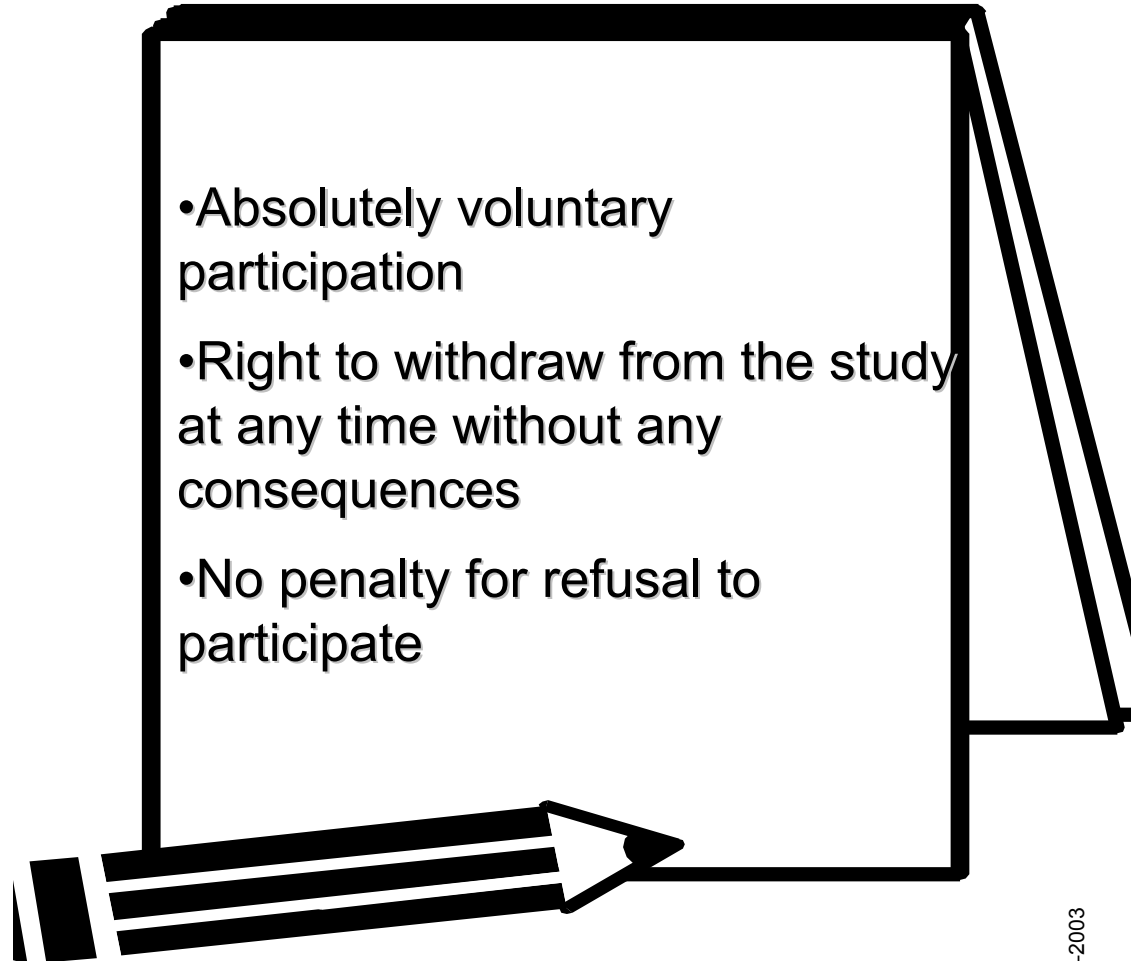
- 
- Research description
  - Risks
  - Benefits
  - Alternatives
  - Confidentiality
  - Compensation
  - **Contacts** 
  - Voluntary participation

- 
- Contact for research-related questions
  - Contact for concerns about participant's rights



## Ethical Issues in Research in Reproductive Health

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

- 
- Absolutely voluntary participation
  - Right to withdraw from the study at any time without any consequences
  - No penalty for refusal to participate



## Ethical Issues in Research in Reproductive Health

### 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



## Ethical Issues in Research in Reproductive Health

### **Who obtains consent**

**Investigator / physician**

**Third party (healthcare worker, interpreter)**



## Ethical Issues in Research in Reproductive Health

### **How to obtain cosent**

- 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



## Ethical Issues in Research in Reproductive Health

### **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**



## Ethical Issues in Research in Reproductive Health

### 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)

DEPARTMENT OF REPRODUCTIVE HEALTH AND RESEARCH



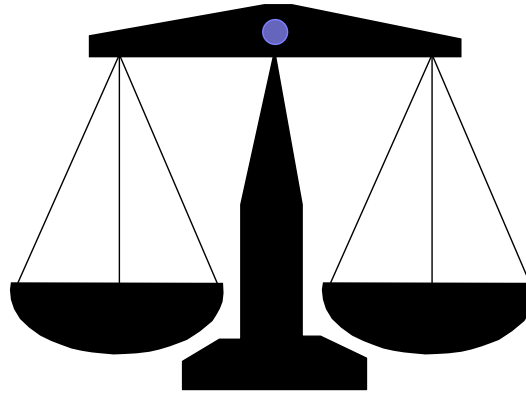
DÉPARTEMENT SANTÉ ET RECHERCHE GÉNÉSIQUES





## Ethical Issues in Research in Reproductive Health

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 in Reproductive Health

### 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 in Reproductive Health

**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**