ETHICAL ISSUES IN RESEARCH

- informed consent -

Effy Vayena
Department of Reproductive Health and Research
World Health Organization
Geneva, Switzerland
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
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
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!
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
Points to remember:

- Use simple, nontechnical language that subjects can understand

- Sophisticated scientific concepts

- Level of literacy

- Cultural beliefs for disease aetiology
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
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**
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
Points to remember:

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

- Investigator / physician
- Third party (healthcare worker, interpreter)
**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
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)
...in some cultural contexts it may be appropriate to obtain agreement from the community or assent 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
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
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**