

Geneva Workshop 2015

# Research Ethics

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World Health  
Organization



# Structure

- Why bother with ethics?
- Defining ethics and research
- Principles of human research ethics
- Research ethics systems
- International research ethics
- From theory to practice

# Why bother with Ethics?

- Funding and publishing requirement?
  - Human beings are treated with Fairness and justice
  - Values that you uphold
  - Accountability and transparency
  - Public trust in science.

# Defining **Ethics** and Research

- What does "**ethics**" mean?

Ethics is concerned with what is good, right, fair, and just, and with establishing moral duties, obligations, and rights

- Who decides what is "**ethical**" ?

– There will be **many different answers** to this question!

- Different ways to establish ethical codes include:

- Accepted mores of the times
- International codes and regulations
- History
- Community consultation
- Professional group consultation

# Defining Ethics and Research

- According to the WHO Manual, “**research**” is defined as:  

“any social science, biomedical, behavioural, or epidemiological activity that entails systematic collection or analysis of data, with the intent to develop or contribute to generalizable knowledge”
- What constitutes “**research with human participants**”?
- Engage with or modify environment, directly or indirectly
  - Surveys/questionnaires
  - Psychological or physiological testing or treatment
  - Behavioural/observational studies
  - Collecting and analyzing data from medical or other personal records
  - Collection of body tissues and fluids

# Principles of research ethics

- Many bioethicists follow a common approach to research ethics based on four broad principles:
  - Respect for persons
  - Non-maleficence
  - Beneficence
  - Justice
- However, there are many ways these principles can be expressed and often the goals of one value may conflict with the goals of another

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How does one balance these 4 principles?

Through an Ethical analysis .....

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What is meant by respect for persons and how can we demonstrate it?





# Principle: **Respect for persons**



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What is **autonomy**?

What is **consent**?

How are they related?

# Consent

Consent process  $\neq$  Consent document!

In order to make an informed decision, participants should be:

- Provided with **comprehensive** and **comprehensible** information about the research
- Competent
- Free to make a decision (NOT coerced, unduly influenced)

# Consent – what is important?

- A. Who obtains consent
- B. Who provides consent
- C. How is consent obtained (e.g., illiterate)
- D. How is consent recorded
- E. Content of informed consent

**What information should be disclosed?**

# Consent ..... WHO?

- Who obtains consent
  - Investigator/Physician/Nurse
- Who provides consent
  - Individual vs Community
    - The permission of a community leader CANNOT substitute individual IC**
  - Minors
    - Assent by minor and consent by parent/guardian
    - Mother-in-law, husbands, heads of colleges as proxies for parental consent?

# Consent – HOW?

- How to obtain consent
  - Seek consent after full comprehension
  - Refrain from coercion
  - Renew consent of each participant if changes/new evidence/long-term studies
- How to record consent
  - Signed form as evidence
  - Verbal/witness consent in exceptional cases:
    - Signed form may inadvertently identify individuals and expose them to risk
    - **Need clear justification and ethics approval**

# Consent – Content....

- Content of Informed Consent

Research description and contacts

## Risks

- Describe anticipated risks + discomforts
- Avoid misleading statements
- Avoid unduly alarming statements

## Benefits

- Avoid deceptive statements
- Describe possible benefits to participants and to the scientific community

# Consent

## Alternatives

- Distinguish between research procedures and those that subjects would undergo if not enrolled

## Voluntary participation

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

## Confidentiality

- Can it be maintained? (e.g., mandatory disclosure to authorities, FGDs...)
- How will it be maintained? (e.g., who will have access to data)

## Compensation



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# Privacy & Confidentiality:

Why is privacy important?

How is privacy different from confidentiality?

Harms vs. wrongs

# Privacy

- Conduct of the research (e.g., home visits, recruitment from clinics, interviews in public places)
- Management of data collected
  - Anonymize at point of collection? (if feasible)
  - Anonymize post-collection
    - Un-linking data
    - De-linking data
- Sensitive and personal questions.
- Particularly important in research into diseases that carry a social stigma

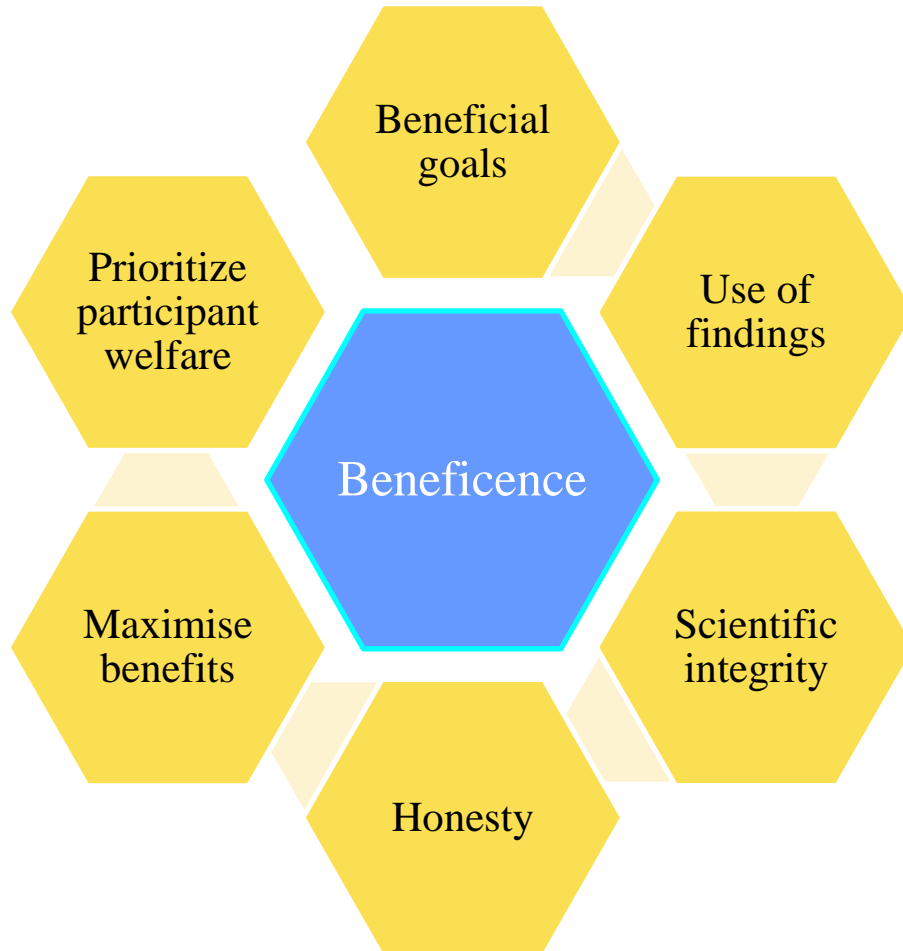
# Confidentiality

- Trust
- Protection
- Non- maleficence.
  
- Examples of breaking confidentiality.....

# Principle: Non-maleficence



# Principle: **Beneficence**



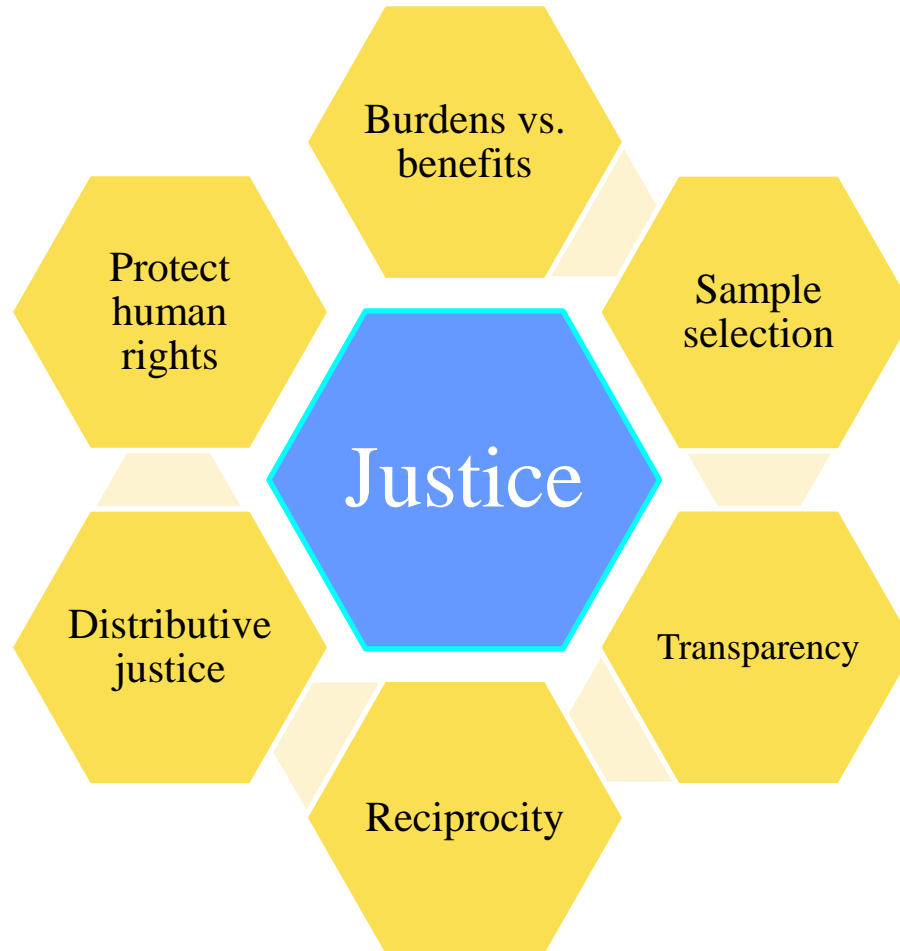
- Social Value of Research
- Scientifically robust
- Honesty and integrity
- Disseminate results
- Act on the results

# Design issues

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- Justification for Study Design
- Control group in randomized controlled trials
- Use of Placebo
- Deception in research?

# Principle: Justice



# What do we mean by **distributive justice**?

Fair allocation of resources

Also of risks and benefits.

- Comes into play in participant recruitment.



# Vulnerability

- Vulnerable research participants are persons who are at greater risk of **exploitation** often as a result of disempowerment and disadvantage
- Vulnerable persons should **not** be *automatically* excluded from research but deserve **special protections**.
- A question of justice .....

# Vulnerability.....

- Vulnerability is
  - Dynamic
  - Layered (sex, education, age, income, legal framework)
  - Contextual

Examples of vulnerability?

# Vulnerability.

- People in unequal relationships
  - Researchers/doctors and patients/participants
  - Governments and refugees or asylum seekers
- People with diminished autonomy – minors, women( ? ), prisoners,
- People with cognitive impairment or mental illness
  - intellectual disabilities
  - Temporary or permanent cognitive impairment – including through the use of substances
- People who may have engaged in illegal activity
  - Particular concern for confidentiality as ramifications of revealing criminal activity can be harmful to the participant

# Vulnerability.... (2)

- **Indigenous people groups and ethnic minorities**
  - These groups tend to be marginalized so special care should be taken to ensure research does not further disadvantage these groups
  - Expectation that research conducted in such communities directly benefits these communities
- **Rural and remote populations**
  - Due to limited health care resources in such regions, special care needs to be taken to ensure the provision of health care services for research participants does not serve as undue inducement to volunteer for the study
  - The demands of justice also indicate that the burdens and benefits of research be fairly distributed between rural and urban populations

# Sexual & Reproductive Health

- Sensitive and personal questions
- Role of husband/ partner?
- Pregnancy testing – what obligations arise?
- Research interventions as contraindications to pregnancy/  
Pregnancy as an exclusion criteria – obligations?
- Pregnancy as an inclusion criteria ....
- STI – partner testing, partner notification
- Legal procedures.

# Sexual & Reproductive Health

- Contraceptive use
- Research on pregnancy issues – fetal consequences
  - risk benefit analysis.....
  - role of husband, partner
- Minors in sexual health research
- Involvement of parents of minors
- Adolescent sexual health
- Counseling and education.

# Issues in international health research

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## Responsiveness

Who sets the agenda?

Cultural and Social differences

Power relationships between sponsor and researcher/ between researchers.

Whose regulations to follow?

Dissemination of research results, and benefits to participants and communities.

# Whose responsibility?

- Researchers
- Research staff
- Ethics committees
- Institutions that support research
- Funders and sponsors of research.



# Research ethics systems

- Research ethics systems refer to the many and varied **people, institutions, and procedures** that exist at different levels to protect research participants:
  - Legal authorities
  - Research institutions
  - Research ethics review committees
  - Individual researchers
  - Guidelines and Regulations
  - Participants



# Research ethics committees

- Part of the broader participant protection programme, research ethics committees (RECs) are responsible for reviewing and monitoring the ethical conduct of research
- RECs exist at many levels ranging from individual institutions to international governing bodies



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# Why are Ethics Committees Needed?

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# What are my responsibilities as a researcher?

# Guidelines and Regulations

- **Declaration of Helsinki:** Ethical Principles for Medical Research Involving Human Subjects. World Medical Association; 2013  
<http://www.wma.net/en/30publications/10policies/b3/index.html>
- **International ethical guidelines for biomedical research involving human subjects.** Prepared by the Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the WHO. Geneva: CIOMS; 2002 [http://www.cioms.ch/publications/layout\\_guide2002.pdf](http://www.cioms.ch/publications/layout_guide2002.pdf)
- **Standards and Operational Guidance for Ethics Review of Health-related Research with Human Participants,** World Health Organization, Geneva, 2011.
- ...

# Consequences of breaching protocols

- Ethics approval must be obtained **BEFORE** research commences
- However, if approved protocols are breached ethics approval can be revoked
- This may also lead to:
  - Investigations regarding potential research misconduct
  - Loss of funding
  - Publication bans
  - In extreme cases criminal proceedings

# From theory to practice

**Apply the principles discussed today to your own protocols!**



# Further reading

- “Casebook on Ethical Issues in International Health Research”, World Health Organization, Geneva, 2009.
- “Research Ethics Committees: Basic Concepts for Capacity-building”, World Health Organization, Geneva, 2009.
- Emanuel E et al. “What Makes Clinical Research in Developing Countries Ethics? The Benchmarks of Ethical Research”, in *Journal of Infectious Diseases*, 2004
- Darvall, Leanna. “Regulation of Human Subject Research”, in *Medicine, Law and Social Change*, Aldershot, Dartmouth, 1993, pp. 85-114.
- El Setouhy, Maged, et al. “Moral Standards for Research in Developing Countries from ‘Reasonable Availability’ to ‘Fair Benefits’”. *Hastings Center Report*, Vol. 34, no. 3, 2004, pp. 17-27.
- London, Alex John. “The Ambiguity and the Exigency: Clarifying ‘Standard of Care’ Arguments in International Research”, *Journal of Medicine and Philosophy*, Vol. 25, no. 4, 2000, pp. 379-397.
- Reich, W.T. “Appendix - Nuremberg Code 1947”, in *Encyclopedia of Bioethics*, New York, Simon and Schuster Macmillan, 1995, pp. 2763-2767.



# Thank you!

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