Ethical issues in sexual and reproductive health research

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Learning objectives

- Definitions
- Principles of research ethics
- The development of contemporary research ethics
- The informed consent process
- Protection of research participants
- Special issues

Acknowledgement

This presentation was adapted mainly from the Research Ethics Training Curriculum (RETC) developed by Family Health International (FHI 360) https://www.fhi360.org/resource/research-ethics-training-curriculum-retc-second-edition

The lotus flower represents **purity and perfection** in many culture. FHI 360 used this image to "symbolize the fundamental ethical elements" and "challenges the research community to aspire to a pure and perfect research design – the foundation on which ethical research is developed and implemented".

FHI 360, 2009.

Definitions

Research

"A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge."

OHRP, 2021
Image: https://pixabay.com/photos/school-a-book-knowledge-study-1661731/

Definitions cont'd.

Human subject

"A **living individual about whom** an investigator (whether professional or student) conducting research:

(i) Obtains information or biospecimens through **intervention or interaction** with the individual, and, uses studies, or analyzes the information or biospecimens; or

(ii) Obtains, uses, studies, analyzes, or generates **identifiable private information or identifiable biospecimens**."

Definitions cont'd.

Intervention

Physical procedures by which investigators collect information or biospecimens and manipulations of the subjects or the subjects' environment for the purpose of the research.

Interaction

Communication and interpersonal contact between investigators and research participants (verbally, in writing, or electronically), to obtain information about them for the research.

Definitions cont'd.

Private information

- Information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place
- Information that has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public

Human research

- Data from living individuals
- Biological material from living individuals
- Interaction or intervention with a living individual
- Use of a non-FDA approved, drug, device or biological

Fundamental principles of human research ethics

Human research ethics rest on three fundamental principles that are considered the foundation of all regulations or guidelines governing research ethics:

- **Respect for persons**
- **Beneficence**
- **Justice**

- These principles are considered universal, transcending geographic, cultural, economic, legal, and political boundaries.

- Although these principles are universal, the availability of the resources needed to maintain them is not universal.

Respect for persons (and community)

Respect for persons recognizes the right and capacity of all individuals to make their own choices and decisions. It refers to respect for the:

- **Autonomy and self-determination**
- **Freedom, and capacity to decide, make choices**
- **Dignity of the people and the individual**
- **Respect for the community and local culture**

Beneficence

The principle of beneficence refers to "No harm" or "non-maleficence"

- **Holds the researcher responsible for the participant's physical, mental, and social well-being** throughout participation in the study
- Risks reduced to a minimum
- Benefits to the participant must be weighed against potential risks of participating
- Benefits for the communities where the research is conducted

Justice

The principle of justice forbids placing one group of people at risk solely for the benefit of another.

The researchers and sponsors have the obligation to:

- **Distribute the risk and benefits in an equitable manner for both potential participants and communities**
- **Equitable recruitment of research participants**
- **Special protection for vulnerable groups**
- **Protection of underprivileged communities**

Vulnerable research participants

Vulnerability is "**substantial incapacity to protect one's own interests** owing to such impediments as lack of capability to give informed consent, lack of alternative means of obtaining medical care or other expensive necessities, or being a junior or subordinate member of a hierarchical group." (The Council for International Organizations of Medical Sciences (CIOMS))

- **Vulnerable groups include** pregnant women or fetuses, neonates, children, prisoners and participants who may be vulnerable due to their cultural, social, or economic characteristics.

Principles of research ethics: summary

- All codes and regulations advocate three fundamental principles:
  - Respect for persons
  - Beneficence
  - Justice
- These principles apply not only to the person, but also to the community at large
- Vulnerable research participants require special protections

The development of contemporary research ethics

- **Guidelines, codes, and regulations created to guide the conduct of research involving human participants**

- Development driven by historical events, in response to the increasing globalization of research and in an attempt to provide answers to new problems and challenges created by a dynamic research environment

- Each reflects the principles of respect for persons, beneficence, and justice

Guidelines, codes, and regulations

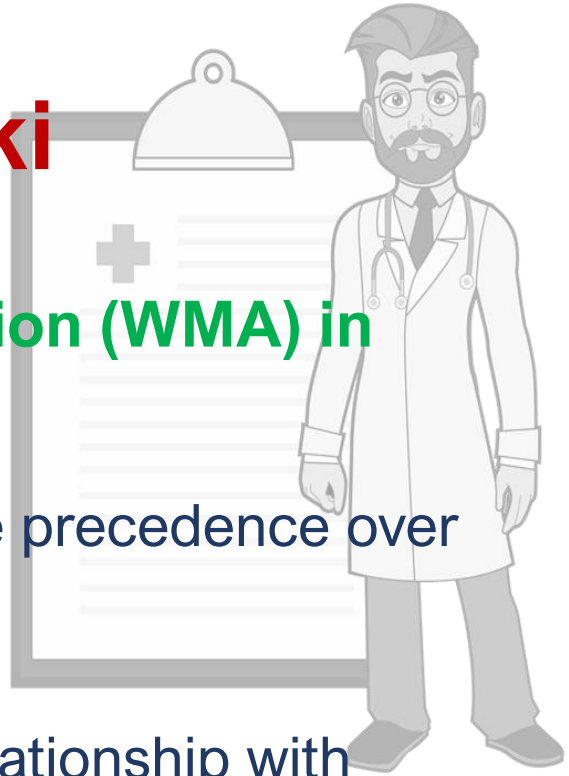
- The Nuremberg Code
- The Declaration of Helsinki
- The Belmont Report
- The Common Rule
- Council for International Organizations of Medical Science (CIOMS) Guidelines
- International Conference on Harmonization (ICH)

The Nuremberg Code

A 10-point statement guiding physicians in the conduct of research on human participants which came into existence at the end of World War II

- It requires that **"the voluntary informed consent of the human subject is absolutely essential"**:
  - **Capacity to consent**
  - **Freedom from coercion**
  - **Comprehension of the risks and benefits involved**
- The minimization of risk and harm
- A favorable risk/benefit ratio
- Qualified researchers using appropriate research designs
- Freedom for the participant to withdraw at any time

The Declaration of Helsinki



Created by the World Medical Association (WMA) in 1964.

- The well-being of the participant should take precedence over the interests of science and society
- Consent should be in writing
- Use caution if participant is in dependent relationship with researcher
- Limited use of placebo (use only “where no current proven intervention exists or where, for compelling and scientifically sound methodological reasons, the use of placebo is necessary, and participants will not be subject to any serious risk”)
- Greater access to benefit

The Belmont Report

The national commission for the protection of human subjects of biomedical and behavioral research was established in 1974 in response to the Tuskegee study, which took place in the southern united states from 1932 to 1972.

In 1978, the commission submitted its report: *The Belmont report: ethical principles and guidelines for the protection of human subjects of research.*

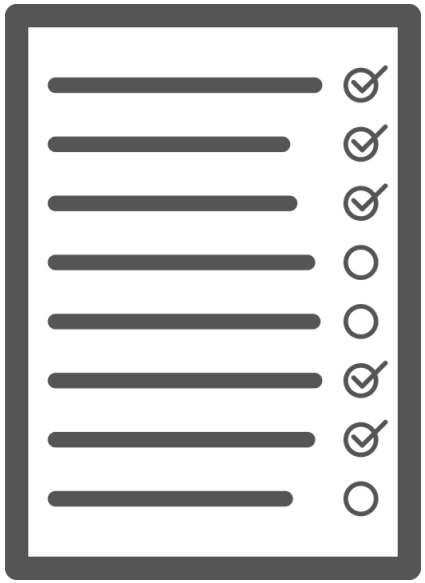
The report sets forth the fundamental ethical principles underlying the acceptable conduct of research involving human participants: **Respect for persons, beneficence, and justice**

The U.S. Code of Federal Regulations (also called the Common Rule)

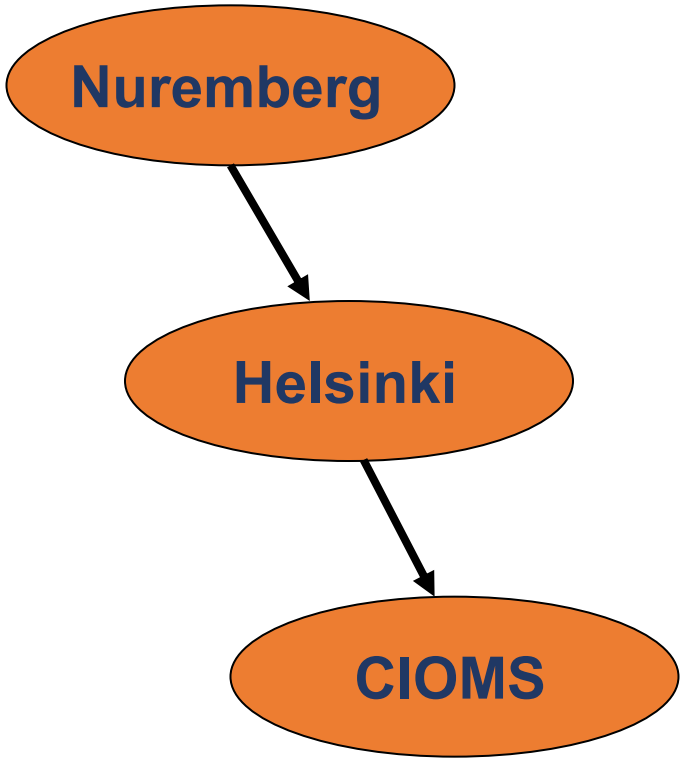
In 1991, the federal policy (referred to as the Common Rule) was adopted by 16 federal agencies that conduct, support, or otherwise regulate human participant research in the United States. Institutions conducting research that is funded by the U.S. government nationally or internationally must agree to abide by the Common Rule.

The Common Rule requires:

- Prior ethics committee approval
- Written informed consent and documentation
- Equitable recruitment of research participants
- Special protection for vulnerable groups
- Continuing review of approved research



Council for International Organizations of Medical Science (CIOMS) Guidelines



The CIOMS Guidelines are designed to be used in developing national policies on the ethics of biomedical research.

In 1982, CIOMS issued the Proposed International Ethical Guidelines for Biomedical Research Involving Human Subjects. The guidelines were revised in 1993 and 2002.

The current guidelines are 21 and are based on the three principles of research ethics. Topics include:

- Informed consent
- Research in developing countries
- Protection of vulnerable populations
- Role of ethics committees
- Community participation
- Obligations of the sponsor, the researcher, and the host country

International Conference on Harmonization (ICH)

- **In 1990, representatives of the regulatory agencies and industry associations of the United States, Japan, and Europe met and formed ICH.**

- In 1996, the ICH finalized **the Guidelines for Good Clinical Practice (GCP).** The GCP Guidelines provide standards for ethical and scientific quality for developing, conducting, and recording clinical trials in the pharmaceutical industry:
  - Standardize drug development and approval process
  - Protocol development standards
  - Review by ethics committee
  - Researcher responsibilities
  - Sponsor responsibilities
  - Informed consent of the participants

Other reports and guidelines

- National Bioethics Advisory Committee (NBAC) in 2001 (now disbanded) – Ethical and Policy issues in international Research: Clinical Trials in Developing Countries.

- Nuffield Council on Bioethics – UK based: Reported on ethical issues in international research in its 2002 publication, *The Ethics of Research Related to Healthcare in Developing Countries.*

- HIV Prevention Trials Network (HPTN): Ethics Guidance for Research developed in 2003 for HIV prevention researchers – Emphasizes mutual accountability among peers and the thoughtful translation of ethical considerations into action.

National regulations and guidelines

- Many countries have national regulations on the conduct of human research.
- Yet, many countries still lack or are developing formal regulations.
- Existing international recommendations, such as the Declaration of Helsinki or the CIOMS International Ethical Guidelines, are important references, but they are not a substitute for national or local regulations.

Does your country have established guidelines for the conduct of research? Does your local institution?

From fundamental ethical principles to local guidelines

- The three fundamental principles of human research ethics – respect for persons, beneficence, and justice – are commonly embodied in national regulations or international guidelines.
- **These regulations and guidelines need to be adapted or transformed into institutional standard operating procedures** (SOPs) to be used at the local level to guide the planning, review, approval, and conduct of human research.
- The process allows the application of fundamental principles within the context of local laws and cultural and economic circumstances.

The informed consent process

- **Designed to empower the potential participant to make a voluntary informed decision, free of coercion, on whether to participate or not in a research study.**

- Research Ethics Committees (RECs) have the responsibility to assure that the informed consent process is appropriate for vulnerable individuals or groups.

What is informed consent?

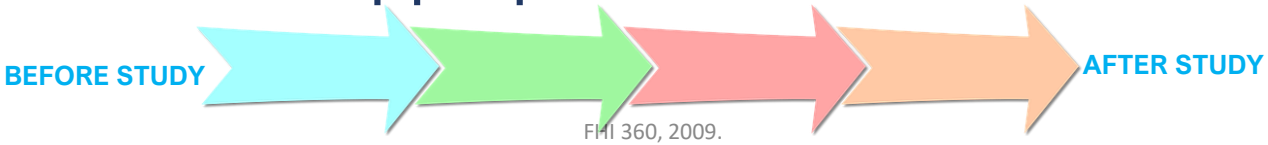
The CIOMS International Ethical Guidelines define informed consent as consent given by a competent individual who:

- **Has received the necessary information**
- **Has adequately understood the information**
- **After considering the information, has arrived at a decision without having been subjected to coercion, undue influence or inducement, or intimidation**

- Informed consent is a process that requires the participation of numerous people, including researchers, RECs, and community representatives.
- It is an obligation to obtain appropriate informed consent from participants in a research study before participation is initiated.

Informed consent as a process

- Informed consent is **a communication process between the research team and the participant**
- It starts before the research is initiated and continues throughout the study
- The potential participant must understand the information provided and be empowered by it to make a voluntary decision about whether or not to participate in the study.
- The type, extent, and method of the proposed informed consent process require the review and approval of an appropriate REC.



FHI 360, 2009.

Informed consent – before study initiation

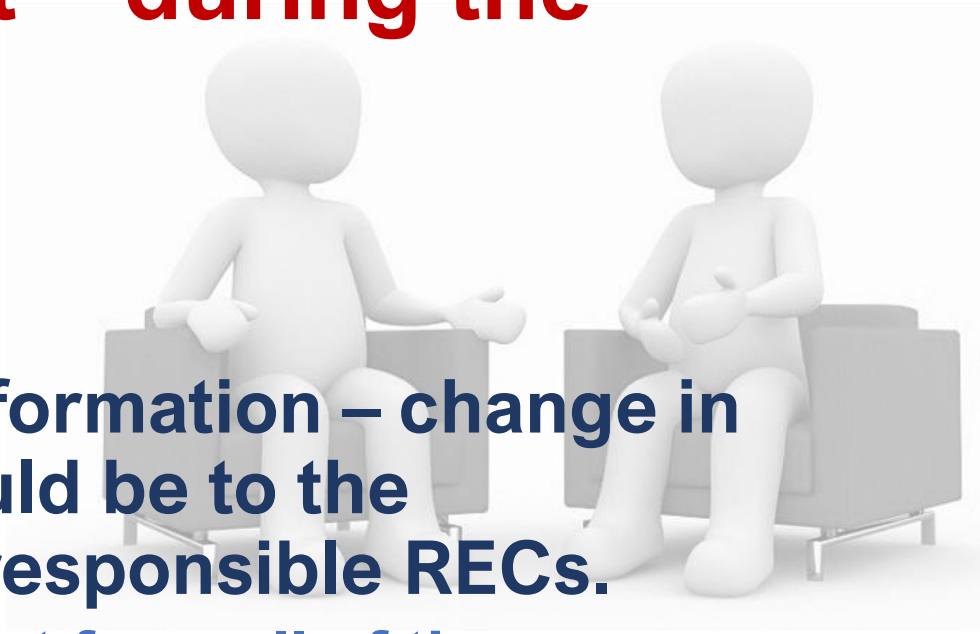
- Knowledge of the local culture and resources available – conditions of local health services, languages, social norms, and conditions special to the type of participants
- Community participation
- Identification of risks and benefits, before and after the study
- Pilot testing
- Knowledge of the local REC requirements

Informed consent – study initiation

At this stage of the process:

- Information is presented
- Participants decides
- It is important who presents the information:
  - should be by individuals with communication or counselling skills
  - the researcher may not be the best option
  - some guidelines may require the presence of a witness
- Support materials are helpful – illustrations, videos
- Understanding is assessed – correct any problem with understanding

Informed consent – during the study



- Reinforce key points
- Communicate new information – change in risk/benefit ratio should be to the participants and the responsible RECs.
  - May require re-consent from all of the participants
- Address rumours – may cause undue concern to the participants if they arise

Information in informed consent

- Necessary versus excessive information –

"Adequate information" defined as **"the amount of information necessary to the individual to make a reasoned decision about whether to participate in the research"**

- Long forms versus short forms
- Common Rule and CIOMS Guidelines are valuable resources - *Common Rule categorizes necessary information into eight basic elements and CIOMS Guidelines propose 26 elements, most of which provide additional guidance on the Common Rule elements.*
- Not only what, but how, when, and by whom
- Participants understanding assessment necessary

Development of informed consent materials

- Use local language
- Write for appropriate reading level
- Illustrate with appropriate concepts and images
- Perform a translation and back-translation
- Pilot test for appropriateness - *involves a person who knows the materials and uses them with someone who is very similar to the individuals to be recruited for the study. Based on results from this test, the materials may need to be revised to make them more understandable.*

Informed consent is an educational and communication process. The research team may find individuals with experience in these fields very helpful.

Community representation and the informed consent process

- To provide culturally appropriate guidance
- Community and participants' perspectives – in selecting the type and sufficiency of information that the potential participant may actually need or expect and how it may best be presented
- Possible vigilance of the process – to assure that informed consent is conducted in accordance with the approved process

Essential elements of informed consent

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

Essential elements of informed consent: Research description

- **Description of the research and participant's participation, including identification of experimental procedures**
  - Research study
  - The purpose or objectives of the research
  - Anticipated duration of study, number of participants and study sites
  - Expected responsibilities of participants
  - Procedures involved
  - Explanation of placebo and randomization
  - Names of the research sponsors and members of the REC that reviewed and approved the research

Essential elements of informed consent: Risks

- **Description of reasonably foreseeable risks**
  - Anticipated or foreseeable risk
  - Physical, social (stigma, discrimination, loss of respect, or public ridicule), & psychological
  - Culturally appropriate – what is considered a risk or side effect, and whether it is severe, differs from culture to culture
  - Decision on the amount of information on possible risks, and how it is presented to be made by the researchers and the REC
  - If any new risks are identified during the research, the informed consent must be revised and all of the participating individuals must be notified promptly

Essential elements of informed consent: Benefits

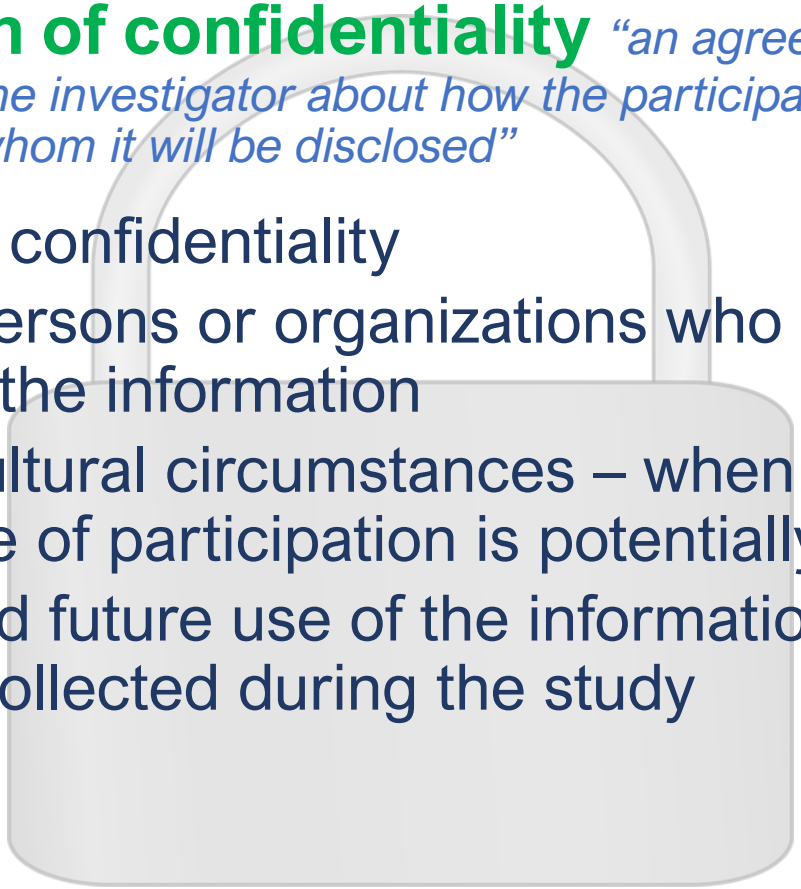
- **Description of expected benefits**
  - Reasonably expected
  - No exaggeration – should not be coercive
  - Benefits available once research is ended
  - Anticipated benefits to the community participating in the research - *CIOMS Guidelines say to include "the expected benefits of the research to the community or to society at large, or contributions to scientific knowledge"*

Essential elements of informed consent: Alternatives

- **Potentially advantageous alternatives to participation**
  - Alternative procedures or treatment
  - Advantage and disadvantages
  - Availability
  - **The informed consent form must describe treatment alternatives that are available or may be made available—including other options to participating in the research**
  - For some studies, the only alternative may be not to participate

Essential elements of informed consent: Confidentiality

- **Explanation of confidentiality** *"an agreement between the participant and the investigator about how the participant's data will be handled and to whom it will be disclosed"*
  - Degree of confidentiality
  - Indicate persons or organizations who may have access to the information
  - Special cultural circumstances – when public knowledge of participation is potentially damaging
  - Anticipated future use of the information or tissue samples collected during the study



Essential elements of informed consent: Compensation

- **Explanation of compensation for injuries**
  - Available compensation in case of injury
  - Treatment available and cost
  - Fair payment for time, travel or inconvenience – should be reasonable, based on local costs, and commensurate with the extent of participation
  - Not coercive

- **Compensation should not be so high as to unduly influence a potential participant's decision to participate in the study.**

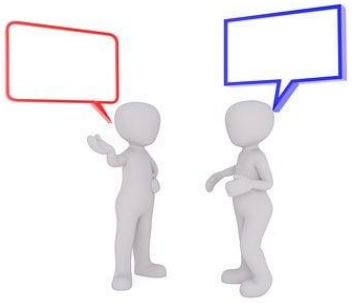
Essential elements of informed consent: Contacts

- **Whom to contact about the research and participants' rights**
  - **Contact for research** - related questions or side effects, injuries, or complications: Usually a member of the research team
  - **Contact for concerns about rights as a participant**: A member of the REC would be appropriate

- Contact information should be realistic and economically viable and culturally appropriate
- As much as possible, contact persons should be available at all times

Essential elements of informed consent: Voluntary participation

- **Explanation that participation is voluntary**
  - **Absolutely voluntary**
  - **Right to discontinue at any time**
  - **No penalty for refusal**



- **In the informed consent form, it is necessary to state that participation is absolutely voluntary.** This element of the informed consent should explicitly indicate that refusal to participate in the research or the desire to withdraw from the study at any time will not result in any penalties or loss of benefits to which the participant is otherwise entitled, including health care.

Documentation of informed consent

- **Part of informed consent process**
- **Usually in writing** *An important step in the process of informed consent is the signing, or other type of evidence, that documents the consent. All guidelines encourage written documentation as much as possible.*
- **May not always be necessary**
- **Ethics Committee review and approval** *The need for documentation will vary according to the specifics and the setting of the research. Low-risk survey research may not require the participant's signature, and in some locations, participants may be uncomfortable signing forms. The REC responsible for the study determines and approves the method of documenting, or not documenting, informed consent.*

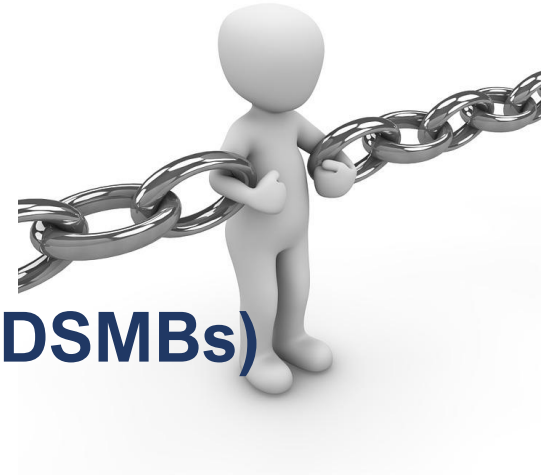
Waiver of informed consent

- **Minimal risk** – Research should involve no more than minimal risk to the participant
- **Rights and welfare of participants protected** – waiver will not adversely affect the rights and welfare of the participants
- **Research not possible without a waiver**
- **Appropriate information provided** – the participants will receive additional pertinent information after their participation ends

All requests should be submitted to the REC when the protocol is submitted for review.

Protection of research participants

Research may be monitored by:



- Research Ethics Committee
- Data and Safety Monitoring Boards (DSMBs)
- Other stakeholders
  - Sponsor or monitor
  - Regulatory agencies
  - Institutional regulatory and compliance offices
  - Public interest groups

Research Ethics Committees (RECs)

- Names of committees vary by location – *The World Health Organization uses the terminologies Ethics Committees (ECs) or Research Ethics Committees (RECs)*
- REC is required by ethical and regulatory guidelines

To work effectively and consistently, the REC must develop standard operating procedures (SOPs) that defines its functions and to guide its reviews. SOPs should include the:

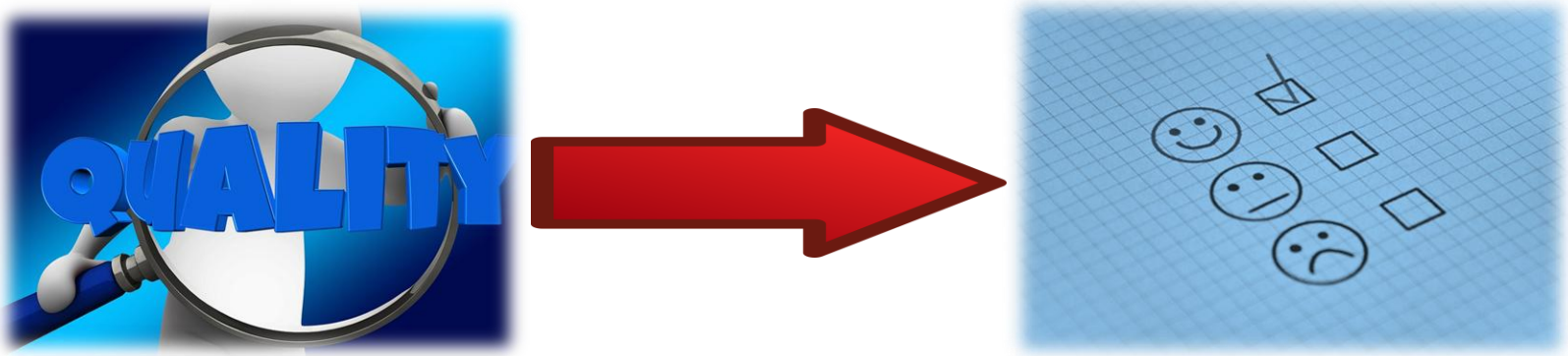
- **Authority under which the committee is established**
- **Criteria for selecting members**
- **Processes followed by the REC**

- REC must work effectively with research staff
- REC requires adequate resources

Role of the Research Ethics Committees

- **Review and approval of research study:**

Primary responsibility of EC is to **review research to ensure the protection of human participants through the application of the three principles of research ethics.**



Role of the Research Ethics Committees

Beyond the initial review and approval of a research study:

- Conduct regular review of ongoing research
- Review all modifications and amendments to approved research – protocol and informed consent documents, recruitment materials, data collection instruments, and clinical investigator brochures
- Monitor active research studies for compliance
- Investigate problems that could impact the safety of participants
- Investigate allegations of research misconduct and possible violations of the rights of research participants
- When problems are discovered, report them as required by local SOPs and regulations

Research Ethics Committees: Criteria for review and approval

At a minimum, the REC should address six core issues:

1. **Scientific design and conduct of the study**
   - Appropriateness of research design?
   - Qualified researchers?
2. **Recruitment of research participants**
   - Appropriate recruitment methods?
   - Safeguards for vulnerable populations?
3. **Community considerations**
   - Benefits to community?
   - Consultation with community?

Research Ethics Committees: Criteria for review and approval (cont'd)

4. Care and protection of research participants

- During and after the research?
- Monitoring the research?

5. Informed consent

- Complete information?
- Written documentation?

6. Confidentiality issues

- Adequate protection?
- Risk of breach?

The REC should grant approval only when all of these questions have been answered.

Data and Safety Monitoring Boards (DSMB)

A DSMB is a committee that is created to review the data from randomized clinical trials to determine whether it is safe for the study to continue.

- Must be independent **with no potential conflicts of interest**
- Chosen for their technical experts
- Review safety data and compare study arms
- Authority to “break the blind”
- Rules for stopping the research
- Complementary to the mission of the REC

Protecting research participants: Other stakeholders

In addition to the oversight of RECs and DSMBs, ongoing research may be subject to monitoring from several different groups who want to ensure that the research is being conducted correctly. They are:

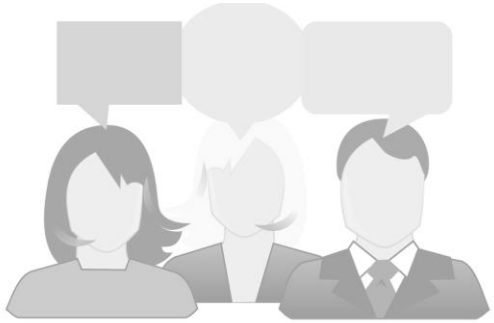
- **Sponsor or monitor**
- **Regulatory agencies**
- **Institutional regulatory and compliance offices**
- **Public interest groups**

Unofficial oversight: High-profile research studies may attract the attention of the media and public interest groups that are organized on behalf of selected communities (e.g., people living with HIV/AIDS, women at increased risk for breast cancer, etc.)

Responsibilities of sponsors and researchers

- **Sponsors and researchers share many responsibilities throughout the research process, primarily:**
  - Protect the safety and well-being of research participants
  - Design ethical research that addresses a local research need
  - Ensure proper ethical review and approval of the research
  - Conduct the research according to the highest ethical standards
  - Apply and share the knowledge gained by the research

Sponsor's responsibilities



- Select only qualified researchers
- Provide necessary support to implement the research properly - methodologically sound protocols, operational procedures, training
- Require the review and approval of a properly established REC
- Promote research integrity - monitor study sites, manage potential conflicts of interest, training
- Ensure the appropriate management of serious adverse events (SAEs) – in some settings
- In international research,
    - Comply with all local ethical, regulatory and legal requirements
    - Ensure the local relevance of the research
    - Ensure the availability and access to health care services necessary for the safe conduct of the research
    - Assist in capacity building
    - Post-trial responsibilities – make the products of the research available to the participants and the host community

Researcher's responsibilities

Protection of research participants:

- Develop scientifically and technically appropriate research protocols
- Ensure appropriate informed consent
- Protect the confidentiality of the participants as stipulated in the informed consent
- Conduct research according to protocol
- Conduct the research with integrity
- Comply with REC requirements
  - Report adverse experiences, protocol violations, participant complaints
- Post-study
  - Protect the long-term interests of participants- e.g., facilitate access to the study product

Researcher's responsibilities cont'd.

In addition to clinical and scientific skills, researchers should possess the following human qualities:

- **Integrity**
- **Respect**
- **Compassion**
- **Professionalism**
- **Courtesy**
- **Sensitivity**

FHI 360, 2009.

Researcher's responsibilities: Summary

- Research with human participants is a privilege, not a right, and is given to the researcher by the society.
- The protection of the well-being of the research participant is the primary responsibility of the researcher.
- Protecting the participant is more important than the pursuit of new knowledge, the benefit to science that may result from the research, and personal or professional research interests.

Special issues

- Conflict of interest
- Pregnant and breastfeeding women as research participants
- Adolescents as research participants

Special issues: Conflict of interest

"When there is a substantial risk that secondary interests of one or more stakeholders in research unduly influence their judgment and thereby compromise or undermine the primary goal of research."

- Competitive environment for academic researchers
- Increasing commercialization of research
- Conflicts of interest can influence the choice of research questions and methods, recruitment and retention of participants, interpretation and publication of data, and the ethical review of research
- Managing conflicts of interests safeguards the scientific integrity of research and protects the rights and interests of study participants

Special issues: Conflict of interest
cont'd.

Types of conflict of interest:

- **Researchers** – academic, financial,
- **Research institutions** (universities, research centres, or pharmaceutical companies) – reputational, financial
- **Research ethics committees** – dual role (research and REC member), financial

- **General rule:**

  "A potential serious conflict of interest exists when there is a significant possibility that the actions of an investigator resulting from professional, academic, or financial interests will result in biased study results or cause harm or wrong to participants".

Management of conflict of interest

To identify, mitigate, eliminate, or otherwise manage conflicts of interest is a shared responsibility by all stakeholders with the research institutions playing a critical role.

- Education of researchers and research ethics committees.
- Disclosure of interests to research ethics committees
- Disclosure of interests to participants
- Mitigation of conflicts
- Policies and measures for managing conflicts of interest must be transparent and actively communicated to those affected.

Special issues: Pregnant and breastfeeding women as research participants

- Distinctive physiologies and health needs
- In pregnant women, initiate research only after careful consideration of the best available relevant data
- Permission of another person **MUST** not replace the requirement of individual informed consent by the pregnant or breastfeeding woman

Special issues: Pregnant and breastfeeding women as research participants cont'd.

- For research interventions or procedures **that have the potential to benefit** either pregnant or breastfeeding women or their fetus or infant:
  - risks must be minimized and outweighed by the prospect of potential individual benefit
- For research interventions or procedures **that have no potential individual benefits** for pregnant and breastfeeding women:
  - the risks must be minimized and no more than minimal
  - the purpose of the research must be to obtain knowledge relevant to the particular health needs of pregnant or breastfeeding women or their fetuses or infants

Special issues: Pregnant and breastfeeding women as research participants cont'd.

- REC may permit a minor increase above minimal risk in compelling situations when research cannot be conducted in non-pregnant or nonbreastfeeding women

- Short-term and long-term follow-up of the fetus and the child – depending upon the study intervention and its potential risks

- **General rule**:

  "Health-related research involving pregnant women that has the potential for harm to the fetus should be conducted only in settings where women can be guaranteed access to a safe, timely and legal abortion in the event that participation in the research makes the pregnancy unwanted."

Special issues: Adolescents as research participants

- **Before undertaking research involving children and adolescents, the researcher and the research ethics committee must ensure that:**
  - A parent or a legally authorized representative of the child or adolescent has given permission.
  - The agreement **(assent)** of the child or adolescent has been obtained in keeping with the child's or adolescent's capacity, after having been provided with adequate information about the research tailored to the child's or adolescent's level of maturity.
  - If children reach the legal age of maturity during the research, their consent to continued participation should be obtained.
  - In general, the refusal of a child or adolescent to participate or continue in the research must be respected, unless, in exceptional circumstances, research participation is considered the best medical option for a child or adolescent.

CIOMS, 2016; WHO, 2018

Special issues: Adolescents as research participants cont'd.

Researcher and REC must ensure that:

- Potential individual benefits and risks have been assessed
- For research interventions or procedures **that have the potential to benefit children or adolescents:**
  - the risks must be minimized and outweighed by the prospect of potential individual benefit

CIOMS, 2016; WHO, 2018

Special issues: Adolescents as research participants cont'd.

Researcher and REC must ensure that:

- For research interventions or procedures **that have no potential individual benefits for participants**:
  - the interventions and procedures should be studied in adults first, when these interventions and procedures target conditions that affect adults as well as children and adolescents, unless the necessary data cannot be obtained without participation of children or adolescents
  - the risks must be minimized and no more than minimal

- When the social value of the studies with such research interventions and procedures is compelling, and these studies cannot be conducted in adults, REC may permit a minor increase above minimal risk.

CIOMS, 2016; WHO, 2018

Special issues: Adolescents as research participants cont'd.

- **Assent**
  - Children and adolescents who are legally minors cannot give legally valid informed consent, but can give assent
  - To give assent means that the child or adolescent is meaningfully engaged in the research discussion in accordance with his or her capacities
  - Assent is a **process** and not merely the absence of dissent
  - The researcher must involve the child or adolescent in the actual decision-making process and use age-appropriate information

Special issues: Adolescents as research participants cont'd.

- **Deliberate objection**
  - An expression of disapproval or refusal of a proposed procedure
  - Children and adolescents who are too immature to give assent

- **Permission of a parent or legally authorized representative**
  - The researcher must obtain the permission of at least one parent or guardian in writing, consistent with applicable laws and regulations

Special issues: Adolescents as research participants cont'd.

- **Waiver of parental permission**
  - In certain circumstances, research ethics committees may waive parental permission – permission of a parent is not feasible or is undesirable, "emancipated" or "mature" minors
  - Special protections must be in place to ensure that the best interests of the children or adolescents are being served – involvement of independent child advocates, a relative, trusted friend, or family physician (chosen by the child) who is not involved in the research project to represent the child

- **Observation of the study by a parent or guardian**
  - To a reasonable extent and without violating the privacy of other study participants

Resource for case studies

- **Casebook on ethical issues in international health research. WHO; 2009. Available from: https://apps.who.int/iris/handle/10665/44118 (in English, Arabic, Chinese and Russia)**

  The casebook contains 63 case studies, each raising an important and difficult ethical issue connected with planning, reviewing, or conducting health-related research. The purpose of the book is to encourage thoughtful analysis of these issues by researchers and members of research ethics committees, particularly those involved with studies that are conducted or sponsored internationally.

Other online training resources in research ethics

- Globethics.net (a global network of teachers and institutions with the vision to embed ethics in higher education) https://www.globethics.net/
- Government of Canada: Panel on Research Ethics https://ethics.gc.ca/eng/education.html (available in English and French)
- The Fogarty International Center https://www.fic.nih.gov/ResearchTopics/Bioethics/Pages/teachers-students.aspx
- Training and Resources in Research Ethics Evaluation (TRREE) - on-line training programme on the ethics and regulation of health research involving human participants https://elearning.trree.org/ (available in several languages)

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Thank you!