Good ethics is good research

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Good ethics is good research. Means does not justify ends.

- **What are the main principles of ensuring good ethics in a research?**
- **What are the instruments/forms?**

Reference materials

Research Ethics Training Curriculum*, Family Health International, *2004.

www.fhi.org **E-mail: ethics@fhi.org**

WHO Informed Consent Forms

Notes on Key Terms and Concepts

Reference materials (cont'd)

International Ethical Guidelines for Epidemiological Studies

Council of International Organizations of Medical Sciences (CIOMS) in collaboration with WHO

www.cioms.ch

2009 edition

Ethics in Research: Context and Evolution

Ethical guidelines for research were "born in scandal and reared in protectionism."

-- Carol Levine,1988

"Medicine's worst corruption had occurred among its best technicians."

-- Leo Alexander, 1947

Research Ethics Principles and Conventions

Fundamental Issues of Ethics in Health Research

- **Ethics in health research is grounded in moral principles – understanding of rights and responsibilities**
- **Ethics in medicine dates to Hippocrates (5th century BC): Do no harm**
- **Nuremberg Code (1947): Voluntary consent**

Declaration of Helsinki (1964)
World Medical Association

- **Distinguishes research that is "therapeutic" from research that is not of immediate benefit to subjects**
- **Highlights physician's duties, not just patient rights**
- **Helsinki (2001): well-being of human subjects take precedence over interests of science and society**

Guidelines on Protection of Human Subjects (PHSC)

- Declaration of Helsinki, World Medical Association, 1964, updated 2001
- US National Commission for Protection of Human Subjects: Belmont Report, 1979
- Council for International Organization of Medical Sciences (CIOMS), 2002
- National guidelines, Institutional Review Boards (IRB) and oversight mechanisms
- WHO: Ethics Review Committee (ERC)
- Professional organizations

Role of Institutional Review Board (IRB)

- Review ethics of research that involves human subjects
- Ensure that rights and welfare of participants are preserved
- Provide oversight of compliance with national, state and institutional regulations and procedures

Fundamentals of Ethics in Research Involving Humans

- **Respect for persons**
  - ✓ **Autonomy and self-determination**
  - ✓ **Privacy and confidentiality**
  - ✓ **Protection**
- **Beneficence and non-maleficence**
  - ✓ **Weigh benefits and risks, but do no harm**
- **Justice**
  - ✓ **Equitable distribution of burdens and benefits of research, inclusion and exclusion criteria**

Elements of Study Information or Fact Sheet

- **Description of research procedures including: who, what, why, where, when**
- **Risks described**
- **Benefits described**
- **Alternatives to participation discussed**
- **Confidentiality explained**

Information Sheet (IS) is often the only piece of document that the study participant will likely ever see. Need to make it a stand alone document. Need to ensure that elements / characteristics of what makes a good IS are included in it.

Elements of Informed Consent

- Description of research including: who, what, why, where, when
- Risks described
- Benefits described
- Alternatives to participation discussed
- Confidentiality explained

Elements of Informed Consent (cont'd)

- Compensation for injuries or health problems resulting from study discussed
- Contacts: whom to contact with questions and concerns about the research
- Explanation of voluntary participation and withdrawal
- Subjects receive copy of consent form
- Consent process explained in language the respondent understands

Informed Consent

- **Determination of whom to seek informed consent from (depends on the study design -- study population)**

- **Determination of consent for what specific activities (e.g., at admission, exit, follow up, or complications)**

Informed Consent Forms (ICFs)

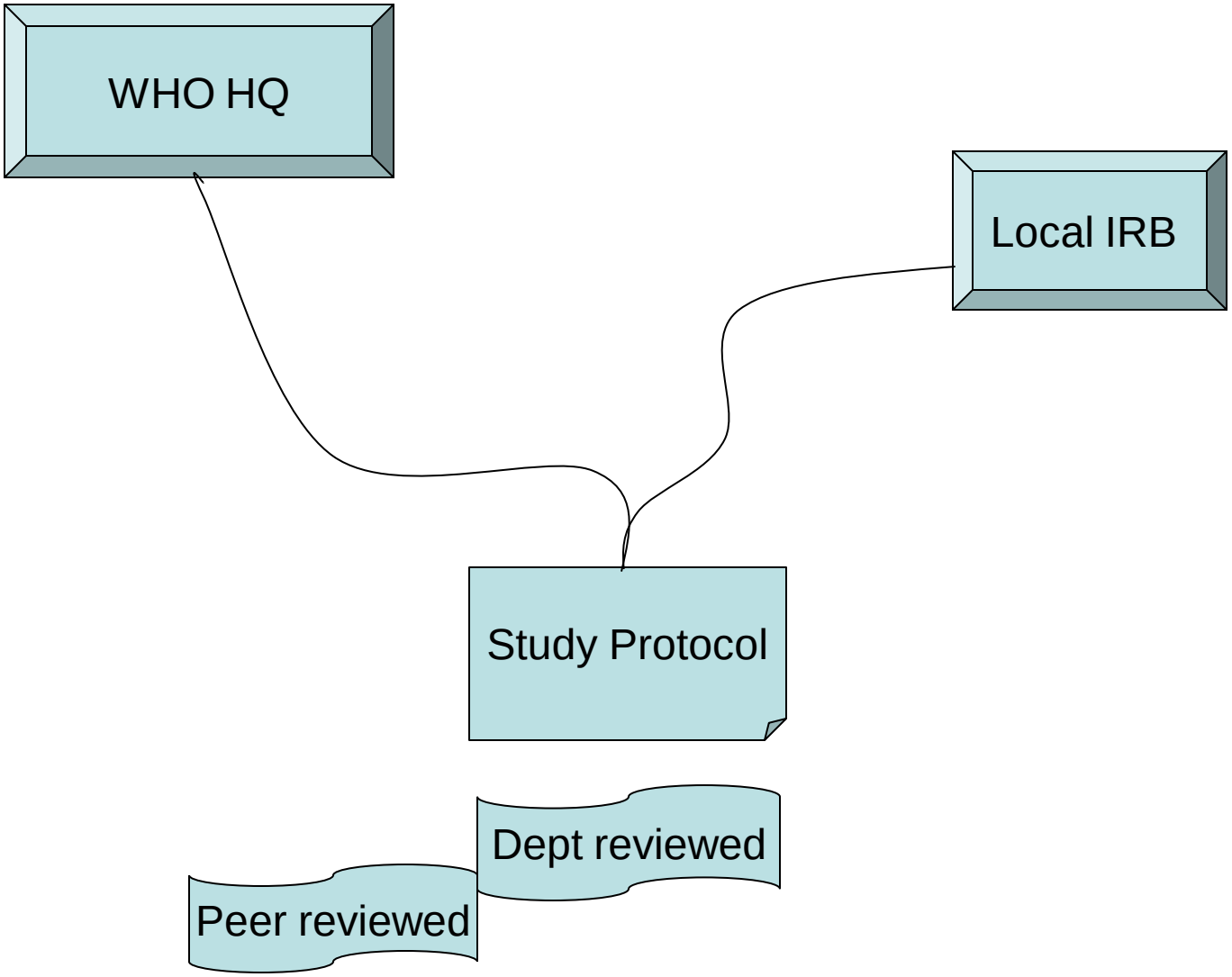
1. ICF Parental Consent for Clinical studies
2. ICF – Parental Consent for Qualitative studies
3. ICF – Sample Storage
4. Informed Assent
5. ICF for Clinical studies
6. ICF for Qualitative studies
7. Process of Securing Informed Consent

Participation of Community

- **Standard informed consent process takes as given that individuals make their own decisions, but in some cultures, decision-making is collective. This is especially important for youth, women, and other vulnerable populations.**
- **Emerging practice to establish a community advisory board that consults with researchers about the informed consent process and the experiment itself**
- **Permission of community leaders enhances informed consent**
- **Role of community advisory group – early advice and later debriefing**
- **Contribution of local advocates, service providers, youth**
- **Participation in benefits – eventual access to effective intervention**

Source: Woodsong & Karim, "A Model Designed to Enhance Informed Consent: Experiences from the HIV Prevention Trials Network," *American Journal of Public Health* 95, No. 3 (2005)

Protocol Submission to IRB



ERC Submission Review Outcome

1. **Exemption from ERC review** *(within 1 wk)*

2. **Expedited Review** *(within 2 weeks)*

3. **Committee Review** *(within 3 months)*

WHO ERC, Draft, May 2010

Exemption from review

The relevant activity is limited to public health surveillance or evaluation of health programmes carried out pursuant to statutory or regulatory authority.

WHO ERC, Draft, May 2010

Outcome of Review and Reporting the Outcome of Review

1. Approved as submitted

2. Requires amendments and/or clarifications
   - A. To be reviewed by the Chair
   - B. To be reviewed by the primary reviewers
   - C. To be reviewed by the Committee

3. Disapproved

Takeaways

- **Protecting the rights and safety of human subjects is of utmost concern to researchers**
- **A host of international and national laws govern research, but many important decisions fall to the local IRB**
- **Issues concerning minors: Informed consent of adolescent minors for treatment and research involves a calculation of risks and benefits to adolescents and an assessment of their maturity**
- **Role of local IRBs – adapt and institutionalize good practices (e.g. determining research and non-research)**

Assignment

- ✓ **Review *Research Ethics Training Curriculum* and try to take online course on research ethics and get a certificate**

  Family Health International, *Research Ethics Training Curriculum*.

- ✓ **Make yourself familiar with the WHO Informed Consent Forms**

- ✓ **Find out local IRB and make yourself familiar with their broad policies and procedures**

If any questions/comments, please email me.

Thank you!