

Institutionalizing Ethics: Mission, Function and Responsibilities of Research Ethics Committees

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Overview

1. Historical context
2. New challenges
3. Research Ethics Committees (REC):
mission, function and responsibilities in the
context of biomedical research



1/ Historical context:

from reactive to proactive ethics



■ 19th Century:

- development of experimentation involving human participants
- concerns about the "use" of vulnerable persons (e.g. orphans, persons with mental diseases)

■ 20th Century:

- 1931 Ethical principles are raised and norms established / Weimar Republic
- 1947 Nuremberg:
 - Concept of "*voluntary consent*" (free power of choice)
 - Risk must be justified (risk / benefit)
- 1964 Helsinki / WMA
- 1979 Belmont report (US)



BUT...

Despite the establishment of ethical principles, unjustifiable research projects are designed and carried out:

- injection of live cancers cells into demented patients at the Jewish Chronic Disease Hospital in Brooklyn in 1960
- Tuskegee syphilis study in 1972
- a healthy 24 years old woman, volunteering for a study, dies in John Hopkins hospital in 2001
- ...



2/ New challenges:

- *Inflation of norms (normative framework)*
- *Institutionalization of research ethics (Research Ethics Committees)*
- *Collaborative research*



Normative framework

- Legally binding texts: national laws, regional directives (e.g. EU)
- Guidelines and declarations (e.g. Helsinki 2000, CIOMS 2002)
- WHO guidelines (e.g. HIV preventive vaccine research, TDR operational guidelines, etc.)



Need for **harmonization** at national and international levels.



Need for **institutions** responsible for the implementation of ethical guidance



Research Ethics Committees (REC)

- **Mission**
 - play a proactive role in protecting research participants and their community
 - contribute to improve normative framework adequately with research on going (casuistry)
- **Functions**
 - Evaluation and follow up of research protocols
 - In some cases -national bodies-: elaboration of local guidance documents
- **Modalities**
 - institutional (IRBs), regional, national



■ Characteristics

Research Ethics Committees should be:

- formally established (mission, functions, procedures)
- competent (multidisciplinary, training)
- independent (pluralism)
- active in international debates (networking)



Collaborative research

- Different cultural contexts and economical settings

- ➡ Different priorities of research

- ➡ Different impact of new knowledge

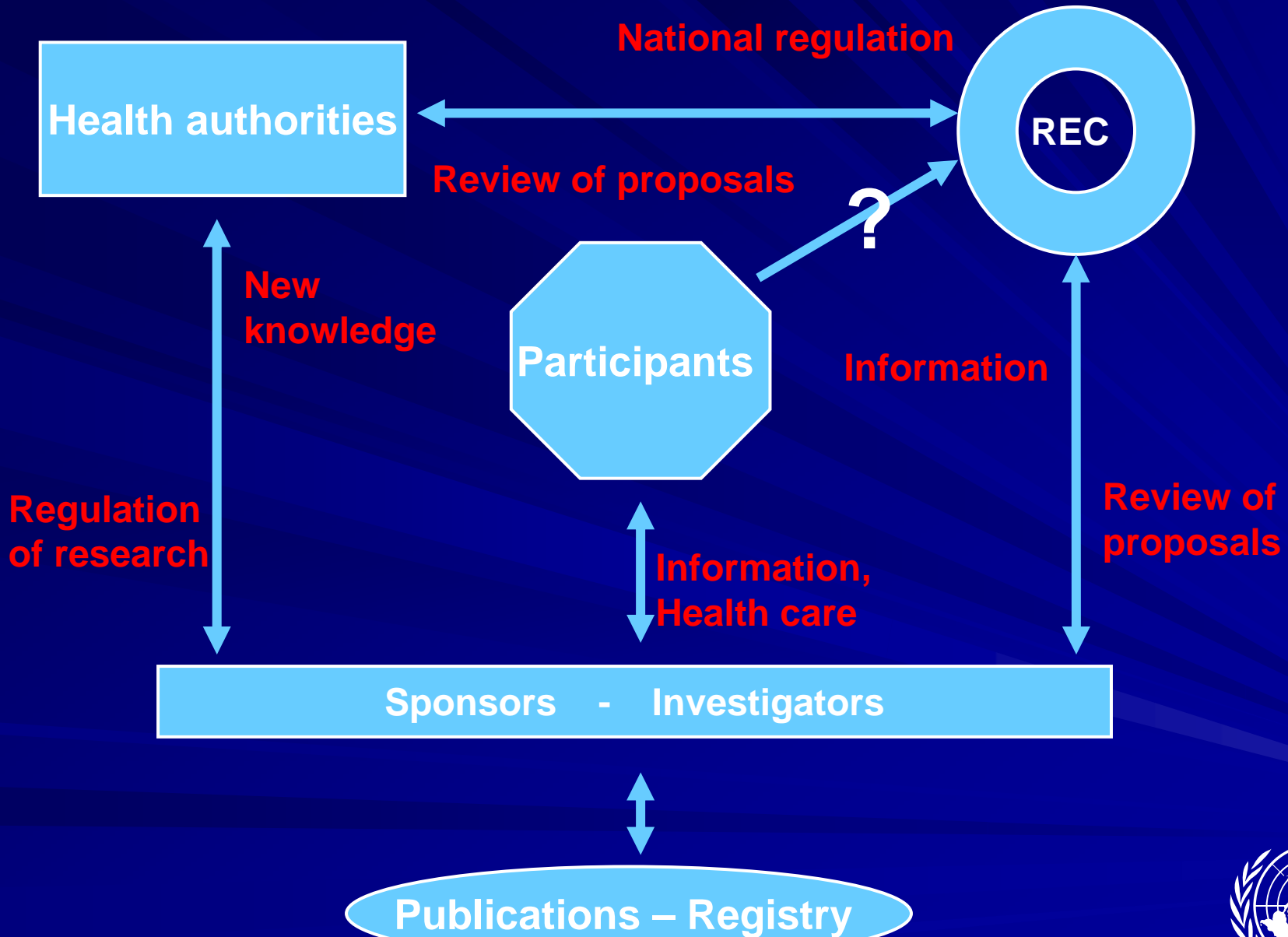


3/ RECs responsibilities

- Ethical review of research protocols
- Normative issues



Global context:



Ethical review of research protocols addresses:

- Scientific value of the research
- Risk / benefit for the potential participants
- Valid informed consent process of participants
- Respect for privacy of participants
- Risk / benefit for the community

REC must also consider:

- National priorities for health research (*10/90 gap*)
- Possibility to implement results of the research in the country (*know/do gap*)



WHO's role:

In 2002 answering the request of member states, WHO-HQ established a group to work on "Ethics and health" (now within the department of Ethics, Trade, Human Rights and Health Law). One of the areas of work is research ethics. In collaboration with other WHO's departments, regional offices, countries and international organizations, ETH

- Provides technical assistance to foster ethical review process in the countries
- Contributes to strengthen RECs' capacities
- Contributes to international debate



Synthesis

- The responsible conduct of basic and clinical research is not only researchers' professional responsibility, it requires commitment from the State and the civil society, from the governments and the citizens.
- National policies concerning research ethics should include normative aspects, capacity strengthening and strong institutions (RECs) to ensure highest ethical standards of health research
- Networking is needed to share experiences from RECs
- International debate has to be promoted



Many questions still open for the discussion:

Organisational matters:

- How to manage conflicts of interests ?
- How to do the follow up of protocols?
- How to ensure funding?
- What is the legal responsibility of REC / participants, community and local authorities?
- What information about RECs should be disseminated to the community?

Fundamental issues

- What standards of care should be adopted?
- What happens when the research is over?
- How to share the benefit of the research?



Dziękuję !