Standards & Operational Guidance for Ethics Review of Health-Related Research with Human Participants

DRAFT document for feedback

3rd National Bioethics Conference, India
17th - 20th November 2010
WHO and Research Ethics

- WHO supports, promotes, conducts research in many countries
- Provides a parallel review to all research that it supports
- Member States have requested WHO to strengthen existing mechanisms for good research practice, including ethical and peer review structures and procedures
Ethical guidance for research exists in many international documents.

- All key international ethics documents include:
  - **Principles** to guide what is defined as ethical research
  - **Specific actions to follow** in conducting ethical research

- REC review is one such specific action
  - Such an independent, third party review ensures that proposed research is consistent with principles and actions outlined
  - However no comprehensive set of standards for the functioning of RECs exist in any single document.
Challenges

- Some research is still not reviewed

- Many RECs have insufficient training, experience, or resources to provide a thorough or quality review
  - Some committees are very new
  - Some committees have few resources
  - Some committees have no members with any training in ethics, so reviews tend to focus on budget or science
  - Some committees tend to be highly bureaucratic or regulatory with less attention to ethics
Recommendations from Informal Consultation

Meeting participants recommended:

- The development of standards for RECs globally
  - Would address "non-negotiable" aspects of REC operations, functioning, and governance
  - Would be accompanied by guidelines for RECs, revised from 2000 guidelines, related to each standard

- That WHO coordinate the development of standards, in collaboration with other international agencies, especially other UN Organizations that also have a special focus on research ethics.
What is a standard?

- Standards are requirements for action in a given topic area
  - Standards are benchmarks that must be met
  - Generally developed from consensus of experts in relevant field

- Guidelines often accompany standards
  - Guidelines are possible strategies for meeting required standards
  - Guidelines should generally be followed, but they are more flexible, since target audiences may know better ways to meet standards in their environment
Are standards really needed for RECs?

- Many ethical guidelines and documents already outline key required features of RECs (e.g., multidisciplinary, independent, review according to ethics)
  - Yet no complete set of standards in one international document
  - And no set of standards accompanied by concrete, operational guidance on how to meet them

- Of course, standards only one piece of complex puzzle to improve REC functioning globally, but it is the first piece, that we hope will provide a benchmark
The role of WHO in publishing standards

Setting norms and standards is one of six core functions of WHO

THE WHO ADVANTAGE

– Its convening power (to bring together experts from around the world)
– Its leadership status (Countries often adopt WHO standards as their own standards or use them as the basis for national laws and rules)

WHO Core Functions

Building on WHO’s mandate and its comparative advantage, six core functions have been defined for the Organization.

1. Providing leadership on matters critical to health and engaging in partnerships where joint action is needed;
2. Shaping the research agenda and stimulating the generation, translation and dissemination of valuable knowledge;
3. Setting norms and standards, and promoting and monitoring their implementation;
4. Articulating ethical and evidence-based policy options;
5. Providing technical support, catalysing change, and building sustainable institutional capacity;
6. Monitoring the health situation and assessing health trends.
The Process - 1

- Members of the November Meeting were invited to provide comments on the “Silver Book” and suggest modifications to it in light of the recent developments in the area or research ethics and role of RECs.

- Based on their comments, the “Ethics Group” at WHO from 4 different departments (TDR; HRP; ETH and RPC) worked together to produce the first draft of the document.

- Presented to the International Bioethics Congress (Singapore) and 8th Global Forum for National Bioethics Bodies

- Second draft of document submitted for review.
The Process -2

- Took cognizance that the document “Operational Guidelines… popularly called the “Silver Book” is recognized as a handy, easy to use, comprehensive invaluable resource in setting up Ethics Committees in more than 100 countries and that the second version of this document should stick as far as possible to the same style when updating it.

- Brainstormed on which functions of RECs could rightfully be ‘elevated’ to the level of Standards, and then grouped them based on who had responsibility for adhering to that standard.

- The guidance from the “Silver Book” was re-organized to fit under different Standards, such that each Standard was accompanied by guidance on how to ‘operationalise’ the Standard.
Important Differences

- Standards and Guidelines
- Focus on all types of RECs, and not only RECs that review biomedical research or clinical trials.
- Recognizes that many players involved in running an REC – need different standards for each
- Provides justification for each ethics consideration that should be reviewed by the REC
- Includes a new section on respect of human dignity and human rights.
- Includes guidance on community consideration
Many players involved in running an REC – need different standards for each

- National authorities (1 Standard)
- Entity establishing REC (5 Standards)
- The REC (2 Standards)
- Staff or Secretariat to REC (1 Standard)
- Researchers (1 Standard)
Standards for national authorities

- Legislative/regulatory framework
- Adequate RECs exist (national, subnational, or institutional level)
- System exists to monitor quality and effectiveness of RECs
Standards for entity establishing ERC

- Composition
- Resources
- Independence
- Training
- Transparency, accountability, and quality assurance
Standards for REC

- Decisions based on clear and consistent application of ethical principles articulated in international guidance documents and human rights instruments, as well as any national laws or policies consistent with those principles

- Committee deliberations are thorough and inclusive

- Possibility of expedited review for certain low-risk studies
Standards for REC Staff or Secretariat

- Written Standard Operating Procedures
- Maintenance of files and records in ways that are retrievable, accountable and confidential
Standards for Researchers

- Qualified to conduct the study
- Familiar with ethical standards
- Adhere to ethics review requirements
Comments

WHO would like to have a structured feedback from you on the draft document on

*Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants*

*What is Missing?*

*What is redundant?*

*Will it help national authorities, ethics committees in raising the standards?*