

## **Expert Advisory Panel on the Clinical Practice Guidelines and Research Methods and Ethics (GRME)**

### **Objective**

To ensure that the Guidelines Review Committee (GRC), Research Ethics Review Committee (ERC) and International Clinical Trials Registry Platform (ICTRP) of WHO receive the best possible technical guidance and support on the methodological and ethical aspects of health research.

### **Terms of Reference**

- Advise on the methodological and ethical aspects of health research.
- Advise on current scientific and technical issues and developments related to the creation and utilization of health research evidence.
- Suggest guidelines for minimum standards for the conduct and reporting of health research and practice guidelines performed by the Organization.
- Provide ad-hoc advice on specific technical and policy issues relevant to the 3 activities when requested by the Organization.
- To strengthen and promote collaboration between WHO and appropriate international and national agencies; such as the Cochrane Collaboration, the CONSORT group, etc.
- Give advice on any other matters relevant to the strategies and activities to be carried out in the context of the objective set out above.

### **Functions**

- The WHO Expert Advisory Panel on Clinical Practice Guidelines and Research Methods and Ethics will be composed of individuals with expertise in the design, conduct, analysis, reporting, synthesis, interpretation, publication, dissemination or implementation of research evidence in health.
- The Panel is being established primarily to support the activities of the WHO Guidelines Review Committee, the WHO Research Ethics Review Committee and the WHO International Clinical Trials Registry Platform.
- Advice will usually be sought and received via email correspondence and/or telephone or teleconference communication.
- Technical Advisory Groups: These will be utilized if and as required as one-off groups to address specific needs.
- Individual Panel members may also be invited to advise other WHO Units or Departments.

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### **Criteria for Selection of Experts**

Individuals invited to join the Expert Advisory Panel on Clinical Practice Guidelines and Research Methods and Ethics (GRME) will be scientists of high international standing in the fields of biostatistics, clinical trials, systematic reviews, evidence-based practice guidelines and similar.

They will have:

1. appropriate academic training and relevant experience
2. proven scientific excellence and/or technical excellence in one or more of the abovementioned fields
3. international experience and/or recognition
4. gender balance and geographical distribution
5. balance between established experts and younger promising scientists

### **Administration**

- The Secretariat will be based in the Department of Research Policy and Cooperation (RPC/IER)

### **About the Functions**

#### WHO Guideline Review Committee (GRC)

In response to concerns about the quality of WHO guidelines, and following up on recommendations by the Advisory Committee on Health Research (ACHR) and resolution EB120.R15 of the 120<sup>th</sup> Session of the Executive Board it was decided to establish the WHO Guidelines Review Committee (GRC). The GRC is responsible for developing and implementing standards and procedures for guideline development that ensure that WHO guidelines are consistent with internationally accepted best practice, including appropriate use of evidence.

#### WHO Research Ethics Review Committee (ERC)

The WHO Research Ethics Review Committee, is responsible for reviewing the ethical aspects of WHO supported research proposals involving human participants. The Committee plays an important role in ensuring that WHO supported research is conducted in an ethical manner which respects the rights of research participants and recognizes the responsibilities of researchers.

As stated in the WHO Manual, the ERC's function is "to provide ethical review of research projects involving human participants funded or otherwise supported by WHO and to approve,

reject, or modify research proposals submitted to it. The Committee shall be guided by the Declaration of Helsinki, the CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects, and supplemented by other internationally accepted statements of ethical guidance adopted by the Committee. The Committee may also consider and provide advice to the Organization on any matter of general policy relating to ethical aspects of research involving human participants."

#### The International Clinical Trials Registry Platform (ICTRP)

In November 2004, at the Ministerial Summit on Health Research, those present called for action by "*All major stakeholders, facilitated by WHO secretariat, to establish a platform linking a network of international clinical trials registers to ensure a single point of access and the unambiguous identification of trials.*" (The Mexico Statement on Health Research). This was further expanded on during the 58<sup>th</sup> World Health Assembly (WHA 58.34) held on 25<sup>th</sup> May 2005. The global scientific community, international partners, the private sector, civil society, and other relevant stakeholders were called upon to "establish a voluntary platform to link clinical trials registers in order to ensure a single point of access and the unambiguous identification of trials with a view to enhancing access to information by patients, families, patient groups and others".

ICTRP staff collaborate with stakeholders on the development and implementation of policies and procedures related to improving access to information about clinical trials. This information includes protocol information registered prospectively (before the first participant is recruited) through to reporting the findings of a trial once it has been completed. The ICTRP stakeholders include health care consumers, biomedical journal publishers, ethics review committees, funding agencies, health care policy makers, trial sponsors (including the pharmaceutical and device industries), regulatory agencies and the various trial registries that exist (or are being established) in countries or regions. That is, all those involved in the production and utilization of health research evidence.

The GRC, ERC and ICTRP are all supported administratively by the RPC department in the IER Cluster.