MEDICAL RESEARCH ETHICS COMMITTEES (MRECS)

Information about MRECs activities in developing countries is limited. Research ethics committees (RECs) in these countries were reported to have limited expertise while ethics principles are still in their early stages. Members of these committees meet infrequently, have no formal training in ethics and many lack important financial and administration resources. Against this, there is an exponential increase in clinical drug trials funded with multi-national pharmaceutical companies. Countries of the developing world offer many advantages, mainly lower overhead costs for conducting drug trials when compared to industrial nations. Supervision and monitoring mechanisms are either weak, absent or amenable to manipulation. Offering unproven therapy and exploiting desperate patients are other problems. Egypt with a population of 85 millions, very low per capita income and very limited annual health care expenditure has witnessed a recent intensity of research activities, and similar to other developing countries, there is a growing concern with the potential for exploitation in the area of international research. Therefore, the establishment of MRE committees is critical in order to ensure that risks to subjects are minimized and reasonable in relation to anticipated benefits. Respect for the dignity of research subjects, to make appropriate compensation for any injury which may occur during research and to protect confidentiality.

MRECS IN EGYPT

The present regulations in Egypt are governed by the Egypt Constitution (1971, part 3, article 43: "Any medical or scientific experiment may not be undergone on any persons without his free consent". Also by the Profession Ethics Regulations issued by the Minister of Health and Population No. 238/2003, article 52-61. In Egypt, the total number of RECs is 15, most being affiliated to universities with medical schools and research institutions. In addition, a recently developed REC has been started in the Ministry of Health and a single private independent REC developed by a group of medical professionals.
CAIRO UNIVERSITY MEDICAL RESEARCH ETHICS COMMITTEE

Established in 2003 after approval of the medical school dean and board of directors. The new committee members and chairman were selected and approved by the board of directors in 2008. In 2011 a new set of regulations was approved by the committee members which addressed the required documents to be reported to the committee, details of the consent form, rules governing research protocols evaluation, committee decisions and recommendations. Research protocols reviewing procedures follow international guidelines (Declaration of Helsinki, International Ethical Guidelines for Biomedical Research Involving Human Subjects and the Council of International Organization of Medical Societies-(CIOMS). Committee members meet regularly at monthly intervals.

During the period 2008 to June 2011, a total of 150 protocols were reviewed by committee members, 39% of protocols were multi-center projects and 7% national collaboration projects.

**Decisions Regarding Submitted Protocols:** 67% approval, 27% conditional approval, 16% deferral and 1% disapproval.

**Types of Research:** Experimental studies phase III constitute the majority of research protocols (32%), 19% were observational descriptive studies, 17% experimental studies phase II, 14% observational analytic studies, 6% experimental studies phase IV, 6% diagnostic test evaluation studies, other categories in 12%. 53% of studies were randomized trials and 34% have placebo groups, 11% involved genetic testing and 6% stem cell research.

**Consent:** A written consent was available in 80% of studies.

**Sources of Funding:** 44% were self-funded by the investigators, 40% were funded by international pharmaceutical companies, 10% by international agencies, 3% by Egyptian government and 3% local national, pharmaceutical companies.

**Other Activities of the REC:** Organization of annual workshop, establishment of REC filing system and database, generation of a number of documents covering standard operating procedures, standardized application form, standardized review form, confidentiality agreement form, and REC annual report.

**Future Activities:** Establishment of REC complete management information systems, release of research protocol online system and a research ethics training modules for researchers- "Video Conference Unit."

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