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EDITORIAL

Ethics of research

Ethical conduct of research involving humans has gained relevance and importance over the years with the expansion of research beyond boundaries of traditional medical and clinical research into a multiplicity of disciplines with human participation. Human research is regarded as research conducted on or with or about people, or their tissues or cells or data obtained from them.

Historically, it is stated that the Greek Philosopher Aristotle (384-322 BCE) was probably the first to discuss principles of ethics 'by studying and offering criteria to assess human behaviour'. It is believed that he taught a course of ethics at the Lyceum during his mature years which was based on the many treatises he wrote on the subject. Increased attention to ethics in human research started after the Second World War following the judgment of the International Military Tribunal which also included 10 principles of permissible medical experiments which have since then been referred to as the Nuremburg Code (1949). Later discussions by the World Medical Assembly of the Code led to the adoption of the Helsinki Declaration (1964) which has been revised many times since then.

The Council for International Organizations of Medical Sciences (CIOMS) which in association with the World Health Organizations (WHO) undertook its work on ethics in biomedical research in late 1970s. It has published an updated version with a wider scope of coverage titled 'International Ethical Guidelines for Health-Related Research Involving Humans' (2016). Close cooperation with World Medical Assembly has ensured that the guidelines are closely aligned to the Helsinki Declaration.

Traditionally, ethics has received much attention both in clinical practice and in health research. Faculties of Medicine were the first to establish ethics review boards and ethics review committees in Sri Lanka to undertake review of research proposals with human participation for ethical aspects and issues and granting approval. The primary aim is to safeguard the interests and right of participants of research and prevent their exploitation. There is no doubt about the value of health research and the benefits it has brought and will continue to bring to ensure health, wellbeing, safety and quality of life of people. Most research on human participants is simple, observational, descriptive and non-invasive and the ethical issues though may be minimal, still needs explicit attention and review by an ethics review board before approval. The more complex research where human participants are subject to 'experimentation' or 'interventions' has many ethical issues that need to assessed by recognized ethics review committees with experience and capability to do so. If a new drug, a new vaccine, medicinal product, device, or equipment not already in use by people is to be tested on humans before being granted approval for use in day-to-day life by the appropriate authority, the researcher should adopt recommended procedures, regulations and registration mechanism prescribed. In Sri Lanka any interventional research requires applying and obtaining approval of ethics review committees that have been gazetted under the National Medicines Regulatory Authority (NMRA) as being approved by name to undertake ethics review. The interventional research should also be registered with the Sri Lanka Clinical Trials Registry. Both these need to be submitted to the Clinical Trials Evaluation Committee of the NMRA in order to be evaluated prior to being granted approval and registration. These approvals and registrations are also requested by peer reviewed high impact journals to consider such research manuscripts for publication.

There are certain values which provides the framework for principles guiding formulation of research proposals and ethics of research. These include and are not limited to respect, integrity, justice, beneficence and research merit. It is implicit in research that badly designed, conduced, analysed and reported research is unethical. Clinical Centre researchers at National Institute of Health of USA have enunciated seven principles to guide the conduct of ethical research. These are social and clinical value, scientific validity, fair subject selection, favourable risk benefit ratio, independent review, informed consent, respect for potential and enrolled subjects.

Given the importance of scientific merit and integrity of research, good research practice needs much attention both by researchers and research institutions. In order to meet these needs the National Health Research Council and the Education, Training and Research Unit of the Ministry of Health have taken steps to publish, 'The Code of Conduct on Health Research in Sri Lanka' (2018) (available at *http://www.health.gov.lk/moh_final/english/public/elfinder/files/publications/2018/TheCodeofConduct.pdf)*

The Code covers aspects of: formulation of research proposals; management of research data and primary materials; collaborative research; conflict of interest; supervision of research; peer review, and dissemination of research findings, publication and responsible authorship.

With the expansion of research on human participation into may other sciences such as branches of engineering, computing, bio technology, genetics, artificial intelligence, machine learning, nano technology and others, the ethical issues of human research have reached a new dimension. It has to be emphasized that whatever the branch of science or discipline, if the research requires human participants, then approval of an ethics review committee is a must. Thus, it behoves on research institutes, universities, and faculties to establish ethics review committees beyond the traditional practice of having ethics review committees in medical faculties. It is necessary that members of such a committee, functions within the set terms of references, standard operating procedures, ensure confidentiality and also have appropriate training in ethics of research, approval processes and documentation. In Sri Lanka too universities have gone one step ahead to establish ethics review committees at university level to facilitate research on humans in disciplines other than health and medical practice.

Time has come when universities and research institutions take steps to develop codes of conduct on research, conduct courses on such practices and ethics of research for all researchers in order to safeguard the interests and safety of both researchers and participants of research.

Rohini de Alwis Seneviratne