

# **REGULATIONS RELATING TO MINIMUM TRAINING RECOMMENDATIONS FOR ETHICS COMMITTEE MEMBERS & RESEARCHERS**

## **Introduction**

The Health Research Ethics Council [NHREC] is established in terms of the National Health Act, Section 72[1].

The functions of the NHREC are:

- Determine guidelines for the basic training that will enhance functioning of health research ethics committees [RECs]
- Advise sources of training available to members of these Ethics committees or refer to the relevant statutory training institutions where necessary.
- Advise the national department and provincial departments on any ethical issues concerning research
- Institute such disciplinary action as may be prescribed against any person found to be in violation of any norms and standards or guidelines set for the conducting of research in terms of this Act

In order to perform the above functions the NHREC may:

Establish ad-hoc Committees:

The Training Sub-Committee was established during a NHREC meeting:  
..... date.

## **Composition of the Training Subcommittee:**

- The committee shall comprise a minimum of 5 member's viz. the chairperson /coordinator; Deputy Chairperson, Member of the Secretariat and other additional members.
- All Members must have ethics research training or be actively involved in Research Ethics training and related fields.
- Membership shall include any other member from the NREC and co-opted members who have the relevant expertise.

## **Objectives of the Training Subcommittee:**

1. To establish basic competencies for research ethics training recommended/required of individuals who serve on Research Ethics Committees and Researchers conducting research.

## **Core competencies to be achieved**

The individual undergoing research ethics training should among others:

- Show respect for research participants, researchers and other colleagues without prejudice, and with an understanding and an appreciation of their diversities of background and opportunity, language, religion and culture. [All]

- Strive to improve ethical review of research and ethical conduct of research. [REC members]
- Use his or her professional capabilities to contribute to individual research participant and community welfare. [Both]
- Demonstrate awareness, through action or in writing, of the ethical and legal responsibilities involved in individual research, participant care and the provision of care to populations. [Both]
- Consider the impact of health research on the environment and the impact of the environment on health research [REC members/Both]
- Demonstrate knowledge, skills and attitudes consistent with professional ethical practice, human rights and law in the field of health research. [Researchers]
- Be able to refer to or consult with a variety of stakeholders, including practitioners with greater professional ethics and human rights experience, or institutional ethics committees in making tough ethical decisions. [REC members]
- Demonstrate an ability to engage in ethical reasoning and decision making.[Both]

### **Core Content**

Pertinent international and national research and professional ethics, human rights and law literature and documents including the DOH Guidelines, should guide delivery. These three components need to be integrated into but not limited to the following content:

- Guiding Principles, and pertinent Ethics and Human Rights Theories
- Basic understanding of legislation and other laws that regulate Research in South Africa [Both]
- Research Ethics Committees – Composition, Function and Processes [REC members]
- Other Pertinent Oversight Bodies – Regulatory (MCC), DSMB'S, etc [REC members and some researchers e.g. those involved in drug-related clinical trials]
- Understanding the nature and purpose and process of ethics review in research investigations [REC members]
- Latest developments nationally and internationally with regard to ethics in research and international liaisons.
- Ethical issues pertinent to collaborative multi-country research
- Informed consent in research [Both]
- Privacy and Confidentiality in Research [Both]
- Vulnerable Groups [Both]
- Emergency Care Research [Both]
- Research involving Fetuses and pregnant women [Both]
- Research involving Collectivities [Both]
- Ethics specific to epidemiological research [Both]
- Ethics and Social Sciences Research [Both]

- Ethics and Genetics Research [Both]
- Biopiracy, Benefit sharing and Tissue Research [Both]
- Research Misconduct [Both]
- Conflicts of interest [Both]
- Ethics and Stem Cell Research [Both]
- Public Health Research Ethics [Both]

### **Functions of the Training Subcommittee**

**The functions of the committee include but are not limited to the following:**

- To define the basic content of training required.
- To facilitate availability of training by approved commercial and higher education groups i.e. assist in getting other institutions to provide the training with the support from the Department of Health or fundraising to enable people to run the training.
- To liaise/interact with the NHREC working group on vulnerable groups working on new provisions to protect vulnerable research participants, to ensure that new guidelines are included in the training.
- To liaise with the Communication Subcommittee of NHREC to develop guidelines and strategies to work with various Public, Regional and Academic Ethics Committees.
- To investigate the feasibility of web-based/on-line training
- To facilitate the sharing of best practices in ethics training.