POLICY : RESEARCH AND CLINICAL TRIALS

ITEM H 14-2003
CM 27.02.2003

POLICY ON RESEARCH AND CLINICAL TRIALS (ITEM H 1-2003[MC] - MC 20.2.2003)

RESOLVED:

1. **That** the contents of the report pertaining to the Policy on Research and Clinical Trials **BE NOTED.**

2. **That** the Policy on Research and Clinical Trials attached as **Annexure "A"** to the report **BE APPROVED** and **ADOPTED** by the Metro.

3. **That** Council **APPROVE** the establishment of an Ethics and Research Task Team for the Health & Social Development Department of which the terms of reference will be to oversee the implementation of the Policy referred to in (2) above.

4. **That** the researchers of the trials **BE REQUESTED** to keep on providing the trial participants with life-long supplies of any life saving drugs that should prove efficient for their condition.

ANNEXURE 'A'

POLICY ON RESEARCH AND CLINICAL TRIALS

1. POLICY PHILOSOPHY

Very often personnel who are engaged in studies, post graduate/Primary Health Care (PHC) are expected to submit Research papers as part of the requirements for examination purposes or for their degrees. Other personnel are also keen to do research on issues that will give the Directorate more substantive data for decision-making or problem solving.

As a result of the past exploitation and oppression of disadvantaged South African communities, they are vulnerable to ethical abuses by unscrupulous researchers. Extreme care and sensitivity must, therefore, be taken to prevent such exploitation.

The value of clinical trials as the optimum methodology for testing and evaluating new treatment and medicines is well accepted both within South Africa and Internatially.

Although some clinical trials are well designed, the potential to violating the rights of trial subjects or participants, particularly in vulnerable communities (eg. very poor, disabled, HIV infected children, illiterate etc.) necessitates the need to articulate Ethics Guidelines for clinical trials and research. These include the following:

- Respect for persons
- Beneficence and justice and
- Confidentiality

Other important principles include relevant and appropriate study rationale, optimal study design, investigator competence, a balance of risks and benefits for participants, transparency, patient privacy, ethical review and impartial oversight of consent procedures.

At present, when research is carried out in Gauteng Provincial Health Facilities and Hospitals, all research proposals are reviewed and approved by Institutional Review Boards or Ethics Committees before implementation. Some Universities will only allow research that has been approved by such committees. The lack of a policy in Ekurhuleni will make the Municipality to rely on the opinion of the bodies which may overlook or may not be aware of some of the of the important peculiarities within Ekurhuleni, thereby allowing unethical research to be conducted within its area of jurisdiction.

2. PURPOSE

The purpose of the Policy is to ensure that all research involving human subjects and clinical trials conducted in Ekurhuleni Metropolitan Municipality are designed and conducted according to Sound scientific and ethical standards within the framework of good clinical practice.

Compliance with these standards provides the Municipality with the assurance that the rights, safety and well being of research subjects are protected and that the data so produced are credible.

3. APPLICATION GUIDELINES

This Policy shall apply to all facilities where research involving human subjects and clinical trials are conducted.

4. LEGAL/LEGISLATIVE FRAMEWORK

- Constitution of South Africa
- Batho Pele Principles
- Patients Rights Charter
- Guidelines for Clinical Trials of Department of Health - 2000
- Declaration of Helsinki - October 2000
- International Community on Harmonization (ICH) Guidelines for Good Clinical Practice — 1997
- Association for British Pharmaceutical Industry Clinical Trial Compensation Guidelines — 1994
- World Health Organisation Technical Report Series 856 on Guidelines on Good Clinical Practice

APPLICATION PROCEDURE

1. All research on human subjects and clinical trials conducted in Ekurhuleni Metro shall be conducted in compliance with this Policy.

2. A committee must be set up to review all such research proposals.

3. The committee should consist of Councillors and persons representing medical nursing, environmental and social development and Community Health Committees (CHC Committees).

4. Such a committee must be free to co-opt. officials from other sections such as legal, laboratory, etc. where appropriate.

5. The terms of reference of this committee tote set out before its establishment.

6. With regard to clinical trials:

6.1 No clinical trials may be conducted in Ekurhuleni Metro without proof of approval by the Medicine Control Council, Ethics Committee as well as the Municipalities' Ethics Committee. Where appropriate, additional documentation such as an insurance certificate for trial participants and investigators should also be submitted before commencement of such research.

6.2 All such requests shall be submitted in writing to and approved by the Municipality prior to commencement of the trial.

6.3 Research should be appropriate for the community in which it is done.

6.4 Consent should only be given for the conduct of Phase III trials i.e. trials for which there is evidence of safety and efficacy.

6.5 The team leader (principal investigator) must be competent, qualified to do such research and have adequate experience, comply with Good Clinical Practice (GCP) and the applicable regulatory requirements.

6.6 The research team must provide and demonstrate that they have adequate resources to conduct and complete the trial within the agreed period.

6.7 The Municipality shall be indemnified of any complications or injuries that may occur as a result of untoward effect of the trial drugs.

6.8 No resources of the Municipality e.g. personnel, drugs, etc. except office space should be used for such research without prior agreement the financial aspects of the trial should be documented in an agreement with the Municipality.

6.9 The Municipality should nominate someone to ensure that participants are treated in a humane manner.

6.10 Students who conduct research must ensure that it is ethical.

7. REPORTING AND RELEASE OF TRIAL RESULTS

7.1 The results of the trial must be communicated to the municipality. All research findings must be communicated irrespective of methods they used, good, poor, indifferent.

7.2 Results of the study must be communicated as soon as possible after the completion of the trial.

7.3 Where the results are published in the journals, the Municipality and participants must be acknowledged.

7.4 Premature termination of the trial must also be reported to the Municipality and Ethics Committee with reasons for such stoppage.

8. TRIAL INCENTIVES

All participants must be adequately reimbursed for all reasonable costs incurred by their participation in the trial. The incentive must be such that it does not lead to Coercion of the participant.

9. CONFLICT OF INTEREST

Investigators and employees of the Municipality and Ethics Committee members must clearly express/disclose conflict of interest (affiliation) financial involvement or direct interest in the subject matter or material used in research, or sponsorships hips support for attendance of conferences etc. which may affect their decision making.

10. ROLES AND RESPONSIBILITIES

10.1 Medicines Control Council (MCC)

Review and approval of all clinical trials in South Africa

10.2 Ethics Committee

Ethical approval of all clinical trials conducted in the facilities under their jurisdiction by ensuring the protection and respect of the Rights, Safety and Well-being of subjects involved in the trial.

Review, approve on comment on clinical trial protocols/research protocols, suitability of researchers, and facilities and especially methods and procedures of obtaining informed consent.

10.3 Principal Investigator

He is the team leader. He must be competent in terms of qualifications, expertise and experience. Knowledgeable and responsible for all trials related activities. The contact person between the sponsor, MCC and Ethics Committee. He should have sufficient time to properly conduct and complete the trial and ensure that all personnel assisting in the trial are adequately trained.

10.4 Community

Report any unethical behavior or abuse of subjects by Researchers.

10.5 Director Cooperate Services (Legal Advisors)

Advise the Municipality and assist in the drawing of agreements and indemnity documents with the researches.

10.6 Executive Director

Ensure that all clinical research that is conducted within the Municipality has been approved by the Medicine Control Council and Ethics Committees.