KwaZulu-Natal, South Africa

KwaZulu-Natal Health Act, 2009

KwaZulu-Natal Provincial Health Research and Ethics Committee Regulations, 2012

Provincial Notice 128 of 2012

Legislation as at 9 November 2012

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KwaZulu-Natal Provincial Health Research and Ethics Committee Regulations, 2012 (Provincial Notice 128 of 2012)

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South Africa

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Provincial Notice 128 of 2012

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I hereby make the Regulations contained in the Schedule hereto, under section 74(1)(b) of the KwaZulu-Natal Health Act, 2009 (Act No. 1 of 2009), in order to regulate the KwaZulu-Natal Provincial Health Research and Ethics Committee.

Dr SM Dhlomo

Member of the Executive Council of the Province of KwaZulu-Natal responsible for Health

1. Definitions

In these Regulations, "the Act" means the KwaZulu-Natal Health Act, 2009 (Act No. 1 of 2009) and any word or expression to which a meaning is assigned in the Act bears the meaning so assigned to it and, unless the context indicates otherwise -

"**Chairperson**" means Chairperson of the Committee;

"**Committee**" means the KwaZulu-Natal Provincial Health Research and Ethics Committee established in terms of section 9 of the Act; and

"**vulnerable participants**" means children, pregnant and lactating women, persons with mental illnesses or physical disabilities, indigent persons, members of communities unfamiliar with medical concepts and persons with restricted freedom, such as prisoners.

2. Duties of Committee

(1) The Committee must approve research proposals and protocols for all human subject health research projects undertaken within the Province for the purpose of ensuring the protection of the dignity, rights, safety and well-being of all human participants, especially vulnerable participants, from health-related research undertaken.

(2) The Committee must perform all its functions in accordance with the Research Ethics Guidelines issued by the National Department of Health as contemplated in section 72(6)(a) of the National Health Act, 2003 (Act No. 61 of 2003).

(3) In order to enable the Committee to perform the functions contemplated in section of the Act, the Committee may -

(a) apply any reasonable measures to ensure compliance with its directives emanating from its functions in the Act;

(b) instruct any person to modify health research protocols or to cease health research projects conducted contrary to its directives; and

(c) request any other information as it deems necessary in the execution of its functions.

(4) The Committee must keep a repository of all applications received.

(5) The Committee may engage with and advise relevant organizations, bodies or individuals involved in research on the Provincial priorities in respect of health research.

(6) The Committee may advise the responsible Member of the Executive Council on research proposals submitted to the Committee.

3. Appointment of members on Committee

(1) The Committee must comprise of members as set out in section 10 of the Act.

(2) Members are appointed by the responsible Member of the Executive Council after consultation with the heads of the respective institutions, organizations or entities referred to in section 10(1)(c) and section 10(2) of the Act.

4. Term of office of Members of Committee

A Member of the Committee holds office for a period not exceeding five years.

5. Termination of membership of Committee

A member ceases to be a Member of the Committee on any of the following grounds -

(a) inability to perform the functions of his or her office;

(b) his or her estate is sequestrated or he or she has entered into a compromise with the creditors of his or her estate;

(c) misconduct;

(d) absence from more than two consecutive meetings of the Committee without the Committee's leave;

(e) written resignation;

(f) he or she ceases to hold any qualification or office necessary for his or her appointment to the Committee;

(g) he or she ceases to be a South African citizen;

(h) he or she becomes a mental health care user as defined in section 1 of the Mental Health Care Act, 2002 (Act No. 17 of 2002);

(i) he or she is convicted of a criminal offence involving fraud, misrepresentation or any other breach of trust;

(j) he or she is convicted of an offence in respect of which he or she is sentenced to imprisonment without the option of a fine;

(k) the responsible Member of the Executive Council, in the interest of the public and for just cause, and after consultation with the member, terminates his or her appointment to the Committee; or

(l) death of the member.

6. Filling of vacancies

Whenever a vacancy occurs on the Committee under circumstances contemplated in regulation 5, the responsible Member of the Executive must, subject to the provisions of regulation 3, appoint a person to fill such vacancy for the unexpired portion of the period of office of the member in whose place such person is appointed.

7. Meetings of Committee

(1) The first meeting of the Committee must be held as soon as possible after the appointment of its members, at a time and place to be determined by the Head of Department, and all subsequent meetings must be held as determined by the Chairperson.

(2) A special meeting of the Committee -

(a) may be convened by the Chairperson at any time; or

(b) must be convened by the Chairperson at such place and time and on such date as he or she may determine and within 30 days of receipt of a written request by the Chairperson or a written request signed by at least a third of the members.

(3) A written request contemplated in subregulation (2) must state clearly the purpose for which the meeting is convened.

8. Quorum, procedure at meetings and decision-making

(1) A quorum of any meeting of the Committee is one half of the total number of members plus one.

(2) The Committee must determine the procedure to be followed at its meetings.

(3) The Committee must, at its first meeting, elect a Deputy Chairperson.

(4) At all meetings of the Committee the Chairperson or, in his or her absence, the Deputy Chairperson must preside.

(5) The decision of the majority of the members of the Committee present at any meeting thereof constitutes a decision of the Committee and, in the event of an equality of votes, the person presiding at the meeting in question must have a casting vote in addition to his or her deliberative vote.

(6) *Ex officio* members, as contemplated in section 10(1)(b) and (i) of the Act, do not have the voting rights on any matter on which the Committee is required to make a decision.

(7) The Committee may co-opt any person to attend and participate in its deliberations on any matter, but such person may not vote on any matter.

(8) A decision taken by the Committee or an act performed under the authority of the Committee is not invalid merely by reason of -

(a) an interim vacancy on the Committee; or

(b) a person who was erroneously appointed in terms of requirements contemplated in section 10 of the Act.

(9) (a) A member of the Committee who has any interest, whether direct or indirect, in any matter being considered or to be considered by the Committee must disclose the nature of his or her interest to the Committee.

(b) The disclosure contemplated in paragraph (a) must be recorded in the minutes of the meeting.

(c) The member must be recused by the Chairperson and may not be present during, or participate in, any deliberation or decision of the Committee relating to that matter.

9. Duties of Chairperson

The Chairperson of the Committee must -

(a) ensure that all research referred to the Committee is completed within the time frame specified in the proposal;

(b) ensure that every member of the Committee conducts himself or herself in a manner that befits the status of the Committee;

(c) where the Chairperson is the head of Department, liaise with or advise the responsible Member of the Executive Council on issues relating to the Committee;

(d) where the Head of Department is not the Chairperson, the nominated representative in consultation with the Head of Department must liaise with or advise the responsible Member of the Executive Council on issues relating to the Committee; and

(e) generally ensure that the Committee -

(i) performs its functions;

(ii) fulfils its objectives in terms of the Act; and

(iii) complies with the relevant provisions of the Act.

10. Manner of referral of research proposals, decision on research proposals

(1) Any person or organisation intending to conduct health-related research at any public health care establishment must submit a research proposal for approval by the Committee to -

(a) the Chairperson of the Committee at the address provided in regulation 14;

(b) the head of the relevant health care establishment where the research, if approved, is to be conducted; and

(c) the Head of Department, if he or she is not the Chairperson.

(2) Each research proposal must contain, at least, the following information -

(a) the exact nature of the research;

(b) the health care establishment or place where the research is to be conducted;

(c) the likely impact of the research on the normal operation of the relevant health care establishment or place;

(d) the likely impact of the research on the status of research participants or health care users utilizing the particular health care establishment;

(e) any negative or undesirable consequences arising from the carrying out of the research; and

(f) a project plan setting out and explaining the various stages of the research and time frames for each stage.

(3) In addition to the information contemplated in subregulation (2), a research proposal must be accompanied by a research project plan containing -

(a) the study information;

(b) the study title and principal investigators and abstract or summary of the study;

(c) the motivation for conducting the study including the aim, purpose or objectives of the study;

(d) the designated research area;

(e) methodology of study;

(f) the study design, study population, sampling and research pilot sites, where applicable;

(g) data collection methods;

(h) instruments and data analysis;

(i) ethical considerations;

(j) proposal on feedback and dissemination-of-findings mechanism;

(k) budget and human resource allocations;

(l) the various stages within which the research would be completed;

(m) references and appendices; and

(n) a letter of provisional permission from facilities, pending the Committee's approval.

(4) All research proposals must be submitted to the Committee in the manner set out in the KwaZulu-Natal Provincial Health Research and Ethics Policy issued by the KwaZulu-Natal Department of Health.

(5) The Committee must, within 30 days of receipt of any research proposal -

(a) approve the research proposal;

(b) reject the research proposal; or

(c) approve the research proposal, with conditions; and

(d) notify the researcher, in writing, of the decision and the reasons for the decision.

(6) Where the Committee has rejected the research proposal contemplated in subregulation (1), the applicant may, within the time frame contemplated in section 67(1) of the Act, lodge a notice of intention to appeal the decision of the Committee with the responsible Member of the Executive Committee.

(7) The provisions of section 67 of the Act apply, with the necessary changes, in relation to the procedure to be followed by the applicant contemplated in subregulation (6).

(8) When considering any research proposal, the Committee must have due regard for the subject matter of the research proposal, as well as any applicable national or provincial health policy and legislation which may impact on the subject matter of the research proposal.

11. Research findings

(1) A report containing the findings of a research proposal contemplated in regulation 10 must, within 30 days after the finalization thereof, be submitted to -

(a) the Chairperson of the Committee at the address provided in regulation 14;

(b) the head of the relevant health care establishment where the research, if approved, is to be conducted; and

(c) the Head of Department, if he or she is not the Chairperson, for review and final approval as contemplated in section 11(1) of the Act.

(2) The report contemplated in subregulation (1) must contain, at least, the following information -

(a) the findings;

(b) the health care establishment or place where the research was conducted;

(c) the likely impact of the research on the promotion of health and provincial priorities in respect of health research;

(d) the degree of the impact of the research on the status of research participants or health care users utilizing the particular health care establishment;

(e) any negative or undesirable consequences which arose from the conduct of the research; and

(f) any challenges encountered during the various stages of the research.

(3) The findings of the report contemplated in subregulation (2) may be used by the Department for planning and decision-making.

(4) The Head of Department must ensure that a hard copy of the report contemplated in subregulation (1) is kept in the Departmental library for future use by the Committee and the Department.

(5) An electronic copy of the report contemplated in subregulation (1) may, subject to the researcher's permission, be published on the Departmental web site for use by the Committee and the Department for planning and decision-making.

12. Clinical trials

(1) Any person or organisation intending to conduct a clinical trial must submit a clinical trial proposal for approval by the Committee to the Head of Department.

(2) Each clinical trial proposal must contain, at least, the following information -

(a) the exact nature of the clinical trial;

(b) the applicant's name, be it a pharmaceutical company or an agent;

(c) the likely impact of the clinical trial on the participants;

(d) the Medicines Control Council approval of the experimental medicine;

(e) any negative or undesirable consequences arising from conducting the clinical trial;

(f) proof of insurance to cover unforeseen events during the trial; and

(g) the completed application form to conduct a clinical trial obtainable from the Department.

(3) The proposal contemplated in subregulation (1) can be hand delivered, sent by post or courier, emailed or faxed to the Department.

(4) Upon receipt of the proposal contemplated in subregulation (1), the Department must-

(a) allocate a unique identifier number;

(b) check availability of all required documents and information;

(c) send the study protocol, if it is a clinical trial, to Pharmaceutical Systems Development for technical evaluation; and

(d) analyse the proposal and make recommendations to the Committee.

(5) The Committee must, within 60 days of the application being lodged, make a final decision and return the documents to the Department for recordkeeping.

13. Extensions to conduct research

(1) A person or organisation wishing to extend the period of research contemplated in regulation 10, must submit a request for approval by the Committee to -

(a) the Chairperson of the Committee at the address provided in regulation 14;

(b) the head of the relevant health care establishment where the extended research, if approved, is to be conducted; and

(c) the Head of Department, if he or she is not the Chairperson.

(2) The request contemplated in subregulation (1) must be in writing.

(3) Where a researcher wishes to extend a study to other sites the provisions of subregulation (1), read with subregulation (2), apply, with the necessary changes.

(4) The request to extend a study to other sites as contemplated in subregulation (3) must be accompanied by a letter of support from the management of the site.

(5) The Committee must, within 30 days of lodgment of the written request contemplated in subregulation (1), read with subregulation (2), decide whether the study can be extended.

(6) In deciding whether the study contemplated in subregulation (3) can be extended, the Committee must take into account other research being conducted at the same time.

14. Address of Committee

For the purposes of these regulations the address of the Committee is -

Health Research and Knowledge Management

10th Floor, Room 102, South Tower

330 Langalibalele Street

Natalia Building

Pietermaritzburg

3201

Tel.: (033) 395 3189/2805/3123

Facsimile: (033) 394 3782/086 695 4533

Email: hrkm@kznhealth.gov.za

15. Short title

These regulations are called the KwaZulu-Natal Provincial Health Research and Ethics Committee Regulations, 2012.