National Health Research Ethics Council

Guideline for the Management of Complaints

Complaints and Advisory Disciplinary Committee (CADC)

FEBRUARY 2015

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1. DEFINITIONS

Complainant means a person or entity that submits a complaint to the NHREC

Respondent means an individual, organisation or research ethics committee against whom a complaint is made

Complaints and Advisory Disciplinary Committee (CADC) means a Standing Committee of the NHREC.

Complaints Administration Officer means the person designated in terms of paragraph 3.1 to receive complaints and to manage the process of responding to them.

Ad Hoc Appeals Committee means the Committee appointed in terms of paragraph 5 to hear appeals.

National Health Research Ethics Council(NHREC) means the Council established in terms of s 72 of the National Health Act 61 of 2003.

2. INTRODUCTION

This document provides a framework for management of complaints and allegations of ethics-related health research misconduct in compliance with section 72 of the National Health Act 61 of 2003 (NHA) and the terms of reference of the NHREC.

2.1 Terms of Reference of NHREC

Section 72 of the NHA requires the NHREC to

a) Adjudicate complaints about the functioning of Research Ethics Committees

b) Hear a complaint from a researcher who believes that a Research Ethics Committee has discriminated unfairly against him

c) Refer matters involving allegations of violation of ethical or professional rules or standards by a health care provider to the relevant statutory health professional council or body

d) Institute remedial measures and disciplinary action where warranted, to facilitate compliance with legal, ethical and professional norms and standards as required for responsible conduct of research.

2.2 Statement of principles

The following principles[1]inform a CADC investigation of a complaint:

(i) Fairness

Requires the investigation to be carried out fairly in accordance with constitutional and statutory rights and interests of those involved. In particular, fairness requires that procedural processes be clear, transparent and in accordance with the principles of justice.

(ii) Integrity

Requires that procedures be established and publicized and that parties involved, including committee members involved in an investigation, conduct themselves responsibly and as objectively as possible. CADC members who have a conflict of interest must declare it.

(iii) Confidentiality

An investigation must treat personal information of parties and the nature of complaints as confidential. This means that members of CADC (and NHREC) do not publicise information beyond committee (and Council) boundaries, except on a need-to-know basis.

Complainants may remain anonymous in accordance with whistleblower protection, subject to other legal requirements. Limitations to protection may apply, particularly if the investigation finds the complaint to be malicious.

(iv) Prevention of consequential harm

Once the investigation is complete, the NHREC must take reasonable steps to prevent consequential harm to parties involved in the process, unless such harm is unavoidable as part of a formal disciplinary procedure.

2.3 Role of Research Ethics Committees

Ordinarily, the institutional REC should be the first body to consider a complaint.

RECs are expected to provide adequate opportunity for any interested person, including but not limited to research participants, research assistants, researchers and members of the wider community, to express a concern or to lodge a complaint or grievance that may arise during the research process. RECs must include complaints and appeals procedures in their written standard operating procedures.

[1]Statement of principles adapted in part from *Procedure for the Investigation of Misconduct in Research.* August 2008. UK Research Integrity Office

3. MANAGEMENT OF COMPLAINTS

3.1 Complaints Administration Officer

The NHREC Secretariat receives written and verbal complaints on behalf of the NHREC, either directly or by way of referral from third parties. The Secretariat designates at least one person, the Complaints Administration Officer (CAO), to receive complaints and to communicate with complainants to ensure receipt of all relevant information by completion of the NHREC Complaints Form (Appendix 1).

3.1.1 Duties of the Complaints Administration Officer

(i) The CAO receives a complaint, written or verbal.

(ii) The CAO must acknowledge receipt of the complaint by the NHREC within 10 working days of receipt.

(iii) The CAO notifies the Chairperson of CADC that a complaint has been received.

(iv) The CAO ensures that the complainant completes the NHREC Complaint Form, requesting that all relevant information and supporting evidence be provided.

(v) Upon receipt of the completed form, the material is channelled to the Chairperson of CADC.

3.2 Completion of the NHREC Complaint Form

The complainant must provide information, including the following:

(i) Name, address and contact details (even if she requests anonymity)

(ii) Name, address and contact details of respondent (if known)

(iii) Details of the research project, including its title, the name of the Principal Investigator or Project Leader and the name of organization, as applicable

(iv) Name and contact details of the REC that reviewed or approved the project (as the case may be)

(v) A description of the nature and supporting evidence of the complaint

3.3 Respondent's rights

In line with the principles of procedural fairness, a respondent has the right to

(i) Respond to allegations made by a complainant

(ii) Have the response considered before a decision or finding is reached

(iii) Receive all relevant information before having to respond.

(iv) A reasonable period of time within which to respond (see Appendix 2), taking into account the urgency, gravity and complexity of the matter.

(v) A written response from the CADC or NHREC, as the case may be, that includes the outcome of deliberations, a summary of reasons that informed the finding, provided that confidentiality is preserved as appropriate.

3.4 Pre-investigation screening

The CAO must screen the NHREC Complaint Form and accompanying documentation to ensure they are adequate for onward transmission to the Chairperson of CADC. In particular, the CAO must ensure the presence of relevant factual information like contact details and timelines in relation to the complaint details.

3.5 Investigation of complaints

3.5.1 Referral of complaint documents

The CAO refers the complaint to the Committee after establishing the completeness of the documentation. Referral should occur within 10 working days of receipt or as soon as the completed form and supporting documentation are available.

The Committee must conduct a preliminary review of the complaint and its supporting documentation to decide whether to

(i) Refer the matter for further investigation, based on the prima facie evidence supporting a violation of norms and standards
(ii) Regard the matter as unfounded based on the lack of prima facie evidence supporting a violation of norms and standards
(iii) Suspend the research project pending further investigation based on the prima facie supporting a serious violation of norms and standards

3.5.2 Preliminary review criteria

Before deciding to proceed with processing of a complaint, the Committee must ensure that

(i) Substantial and credible prima facie evidence supports the complaint

(ii) Violation of a legal or ethical norm or standard is consistent with the prima facie evidence

3.5.3 Investigation by CADC

Documentation must be sent to Committee members by email (preferable) or courier. The CADC Chair must include a covering letter in which he or she outlines the substance of the complaint, the nature of the supporting evidence and the preliminary view formed. In addition, the CADC Chair must brief members as to particular aspects requiring close attention.

The CAO must arrange a teleconference of the CADC members to discuss the complaint in light of the Chair's briefing letter, whether further evidence gathering is

needed, the nature of the required evidence and whether the parties should be interviewed.

When the CADC has decided on whether and how to proceed, the respondent must be notified in writing of the complaint and be requested to respond on the NHREC Respondent's Form within 15 working days. The response should address the allegations outlined in the complaint and should provide further information as appropriate.

In addition, the CADC may refer the matter to the institutional REC concerned if it believes that the REC is better placed to resolve the matter or to provide an opinion. It may also confer with the institution's management officials if necessary. The CADC may request documentation from the complainant, the respondent, the institutional REC as needed. It may request additional relevant information, including legal opinions, from third parties as needed.

3.5.4 Decision-making at CADC level

After all requested information has been received by the CAO, documented and organised into a portfolio (hardcopy and electronic), it must be forwarded to all CADC members for their consideration.

Tele-conferences or face-to-face meetings must be carefully minuted to ensure accuracy and comprehensiveness in the event of a query or challenge.

The CAO in consultation with the Chair of CADC must arrange follow-up tele-conference of CADC members to discuss their deliberations, after which the CADC must make a determination as follows:

(i) The investigation has revealed sufficient factual evidence to support a finding of wrong-doing by the respondent and the CADC recommends further action in a report to the full NHREC to be tabled at the next NHREC meeting or, if urgent action is required, the report must be considered in a tele-conference

OR

(ii) The investigation has not revealed sufficient factual evidence to support a finding of wrong-doing by the respondent. The CADC determines no further action is required by the NHREC. The complainant and the respondent are notified of the finding which is also reported by the Chair of CADC to the full NHREC at its next meeting

OR

(iii) The investigation has revealed factual evidence but not sufficient to support a confident finding of wrong-doing. The CADC refers the matter to the full NHREC for discussion and finalisation at its next meeting by way of a report drawn up by the Chair of CADC.

3.5.5 Decision-making at NHREC level

When a matter is referred to the full NHREC, the CAO in consultation with the CADC Chairperson must ensure that all relevant information is made available to NHREC members *prior* to the meeting with sufficient time for members to familiarise themselves with the facts.

At the NHREC meeting or during the teleconference, as the case may be, the Chair of CADC must present the findings and recommendations of the CADC to the NHREC and open the matter for discussion, indicating the main points for deliberation.

The NHREC may decide to

(i) uphold the CADC findings and implement its recommended action

OR

(ii) uphold the CADC findings but implement additional or alternative action

OR

(iii) refer the matter back to CADC requesting that the investigation be re-opened and further evidence obtained following the process in 3.1.4.2

OR

(iv) (in rare circumstances) convene a formal hearing of the matter before the full NHREC to finalise the matter. All parties including the NHREC should have representation which may include legal representation

3.6 Possible action by NHREC

On completion of its decision-making process and having made its finding and recommendation, the NHREC may

(i) conclude the matter by communicating its findings to both parties, with no further action deemed necessary

(ii) conclude the matter by communicating its findings to both parties; request remedial action or follow-up by one or both of the parties; issue a warning to the relevant party

(iii) conclude the matter by communicating its finding to both parties and the institution or professional body; request remedial action; request disciplinary action in appropriate circumstances

(iv) refer the REC to its institutional superiors e.g. Deputy Vice Chancellor: Research, for further investigation and possible remedial action including, where appropriate, disciplinary action

(v)

(vi) refer the matter to any other forum or statutory body including but not limited to the SA Police Service for further investigation and action, as appropriate

3.7 Communication of Findings

The letter informing the parties of the outcome of the investigation must be signed by the Chairperson of the CADC and the Chairperson, or Deputy Chairperson of the NHREC. The CAO must co-ordinate this communication process in a timeous manner.

4. RECORD KEEPING

4.1 The CAO must ensure that all records of complaints, investigations and decision-making processes are updated regularly and appropriately and that the documents are securely filed in both hard and electronic copies.

4.2 RECs are encouraged to keep a record of complaints lodged with them directly, and to include this information in annual reports submitted to the NHREC.

4.3 The NHREC must retain the information regarding complaints in accordance with legislative provisions, and must submit relevant information to the Minister of Health, if requested.

5. APPEALS

5.1 Any person or entity that is aggrieved or believes that rights have been adversely affected by a decision of the NHREC, may appeal against such decision to the EXCO within sixty (60) days of the decision being communicated to the parties (see Appendix 3).

5.2 An appeal is usually heard on the basis of written submissions only, i.e. no oral evidence is led. The parties, with the assistance of the CAO, must therefore ensure that all relevant information from their respective points of view is before the Ad Hoc Appeal Committee. Parties may make submissions to augment the existing record in accordance with the time lines set out by the Chair of the Appeal Committee

5.3 The appellant must provide relevant information including

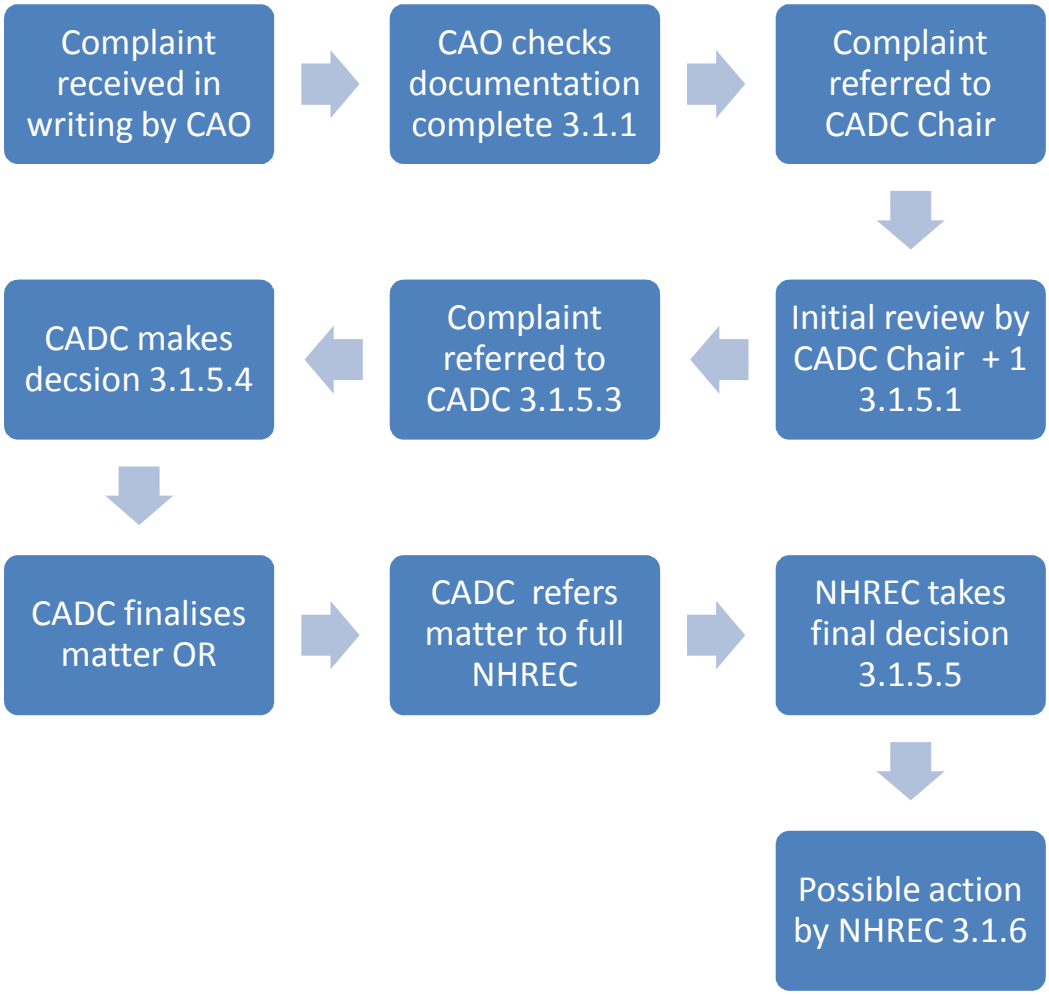
- the decision against which the appeal is being lodged
- the grounds on which the appeal is being lodged
- information supporting the basis of the appeal.

5.9 The NHREC EXCO is empowered

- to request further information if needed
- to interview the parties
- to require the parties to seek to resolve the matter through mediation or seek some other route as to a possible resolution of the dispute and
- to uphold the appeal OR
- to dismiss the appeal.

5.10 The NHREC EXCO must keep careful minutes of the appeal proceedings and must draw up a report to support its finding at the conclusion of proceedings. The decision of the Appeal Committee is final and can only be taken on review in the case of a procedural irregularity.

6. COMPLAINTS PROCESS FLOW CHART



APPENDIX 1

National Health Research Ethics Committee

Complaints Form

1. Complainant:

Name				
Postal Address				
Residential Address				
Telephone				
Fax				
Email				
Do you wish to remain anonymous?	YES		NO	

2. Details of person or entity against whom/which the complaint is lodged:

Name:	
Postal Address	
Residential Address	

Telephone	
Fax	
Email	

3. Nature of the Complaint.

3.1 If the complaint pertains to a particular research project, please provide the following information (if available):

Title of research study or clinical trial[2].	
Name of Principal Investigator	
Name of Sponsor	
Institution or site where research project is being conducted.	
Contact details of Principal Investigator	
Name of the research ethics committee that approved or reviewed the study.	

3.2 Please provide comprehensive details of the complaint with supporting evidence (if available).Use additional pages if necessary, including measures taken so far.

[2] Please attach full research proposal/protocol, proof of ethical clearance and other relevant documentation if available.

I hereby declare that the above submission is accurate and true to the best of my knowledge.

Signed this _____ day of _____ 20..

Signature: _____

Full Name: _____

(Please print)

APPENDIX 2

National Health Research Ethics Committee

Response Form

1. Respondent

Name	
Identity Number	
Postal Address	
Residential Address	
Telephone	
Fax	
Email	

2. Details of REC that granted ethics approval or clearance

Name:	
Postal Address	
Residential Address	
Telephone	

Fax	
Email	

3. Details of person or entity conducting the research

Title of research study or clinical trial[3].	
Name of Principal Investigator	
Name of Sponsor	
Institution or site where research project is being conducted.	
Contact details of Principal Investigator	

4. Details of research project

Please provide comprehensive details of the research project, including the protocol/proposal, proof of ethics clearance, status of the study as at the date of submission of this response and any other information pertinent to the matter, with supporting evidence (if available).Use additional pages if necessary.

[3]Please attach full research proposal/protocol, proof of ethical clearance and other relevant documentation if available.

I hereby declare that the above submission is accurate and true to the best of my knowledge.

Signed this _____ day of _____ 2015

Signature: _____

Full Name: _____

(Please print)

APPENDIX 3

National Health Research Ethics Committee

Appeal Form

1. Appellant:

Name	
Identity Number	
Postal Address	
Residential Address	
Telephone	
Fax	
Email	

2. Nature of the Appeal

Please provide comprehensive details of the appeal with supporting documentation. Use additional pages if necessary.

I hereby declare that the above submission is accurate and true to the best of my knowledge.

Signed this _____ day of _____ 20..

Signature: _____

Full Name: _____

(Please print)