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**Animal Research Ethics Committee**

**TERMS OF REFERENCE**

**(“TORs”)**

**TABLE OF CONTENTS**

1. DEFINITIONS AND ABBREVIATIONS 3

2. INTRODUCTION 4

3. pURPOSE OF TORs 4

4. SCOPE 6

5. RESPONSIBILITIES 7

6 PROCEDURES 9

7 REFERENCES TO OTHER RELATED DOCUMENTS 15

8 ACKNOWLEDGEMENTS 15

9 Approval History of the TOR 16

All documents referred to as ANNEXURES are available on the Wits Website.

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| Wits Website | [Animal Research Ethics Committee (AREC) (wits.ac.za)](http://intranet.wits.ac.za/academic/uro/Pages/Animal-Research-Ethics--Committee-(AREC).aspx) |
| ANNEXURE 1 | Wits AREC member Code of Conduct |
| ANNEXURE 2 | University Research Integrity Policy and Research Integrity Procedure |
| ANNEXURE 3 | SOP for AREC |
| ANNEXURE 4 | AREC Research Classification of Severity Categories in Animal Research |
| ANNEXURE 5 | AREC Guidelines for the Use and Care of Animals in Teaching and Research at Wits |
| ANNEXURE 6 | Wits Code of Conduct for Researchers |

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**Terms of Reference for the Animal Research Ethics Committee**

# DEFINITIONS AND ABBREVIATIONS

Unless the context clearly indicates otherwise, the following terms will bear the following meanings:

|  |  |
| --- | --- |
| “Applicant” | members of staff, registered students and affiliates of the University, and external applicants |
| “DVC: R&I” | Deputy Vice-Chancellor: Research and Innovation |
| “AREC | Animal Research Ethics Committee |
| “National Guidelines 2015” | Department of Health: Guidelines – Ethics in Health Research: Principles, Processes and Structures, Department of Health, 2nd ed. 2015 |
| “National Health Act” | National Health Act 61 of 2003 |
| ”SANS 10386 : 2021” | South African National Standard in the care and use of animals for scientific purposes of 2008 |
| “ICLAS” | International Council for Laboratory Animal Science |
| ”CIOMS” | Council for International Organization of Medical Science |
| “NHREC” | National Health Research Ethics Council |
| “REC” | Research Ethics Committee |
| “SOP” | Standard Operating Procedures |
| “ToRs” | Terms of Reference |
| “University” / “Wits” | the University of the Witwatersrand, Johannesburg, a public higher education institution recognised as such in terms of the Higher Education Act 101 of 1997 |
| “UR&IC” | University Research and Innovation Committee, a committee appointed by the University Council |

# introduction

## The University of the Witwatersrand, Johannesburg (“University” / “Wits”) has established an Animal Research Ethics Committee (“AREC”) under the terms of the National Health Act 61 of 2003 (“National Health Act”) and the Department of Health, Ethics in Health Research: Principles, Processes and Structures, 2nd ed. 2015 (“National Guidelines 2015”).

## The Terms of Reference (“ToR”) are designed to ensure that the AREC at the University is compliant with the requirements of the National Health Act and with the National Guidelines 2015.

## The Animal Research Ethics Committee (“AREC”) is mandated to fulfil its function and mandate by the University Research Committee (“UR&IC”) and the Deputy Vice-Chancellor: Research and Innovation (“DVC: R&I”) of the University.

# pURPOSE OF TORs

## The overarching ethics guidance for the AREC will be the South African National Standard 10386:2008 (“SANS 2008”) and the National Guidelines 2015.

## Where relevant, major international guidelines (including, but not limited to International Guiding Principles for Biomedical Research (“CIOMS and ICLAS”) will apply. When strict compliance of a particular requirement of these declarations and codes is impossible, AREC will ensure that the proposed research is nonetheless in keeping with the spirit of the declarations and codes.

## The TOR is to provide guidelines and a minimum standard for the AREC operational management of the research process within the University.

## The essential purpose of the AREC in reviewing research is to contribute to safeguarding the welfare, safety, and well-being of all actual or potential animals in teaching and research conducted by the University and its researchers. The AREC will do this through independent, prospective and ongoing ethics review of all research projects involving animal participants undertaken by members of staff, registered students and affiliates of the University, and external applicants (“Applicants”).

## Research to be reviewed by the AREC will be in accordance with the provisions of the Veterinary and Para-veterinary Professions Act, 1982 (Act No 19 of 1982) and the amendment of this act, (Act No 16 of 2012) as well as the SANS 10386: 2008. This TOR must be read with the AREC Standard of Procedures (“SOP”) document, which is freely available on the AREC website, [Animal Research Ethics Committee (AREC) (wits.ac.za)](http://intranet.wits.ac.za/academic/uro/Pages/Animal-Research-Ethics--Committee-(AREC).aspx)and as Annexure 3 attached hereto.

## A significant proportion of research conducted at the University constitutes Health Research, as defined by the National Health Act, and it is therefore appropriate for the AREC to be registered with the NHREC. Once registered with the NHREC, as currently the AREC has a provisional registration, the AREC may advise the DVC: R&I to initiate disciplinary steps against researchers who violate either national or the AREC’s ethical guidelines and/or legislation.

## The Chairperson of the AREC is required to provide all necessary information in order to inform the University in adjudicating complaints of research ethics and integrity violations and/or research misconduct by researchers whose protocols have been approved by AREC.

## The AREC may have school sub-committees as categorised according to their specific faculty, school and field. These sub-committees will be referred to as “School sub-committees” of the AREC.

# SCOPE

## Any research undertaken by any Applicant involving animal participants must be submitted for review by the AREC.

## When reviewing research proposals, special attention will be given to research that includes certain species or categories of participants who may be vulnerable, for example, species listed as threatened or endangered, or animals that may generate emotive responses like non-human primates, dogs and cats.

## The AREC will uphold all the University’s necessary rules and regulations and in so doing reviewing applications for degree and non-degree purposes.

## The AREC will only under exceptional circumstances consider any applications for retrospective ethical acknowledgment, which is not ethical clearance, if it is apparent that the research has already commenced.

## The AREC will issue a waiver letter when historical data, collected on a previous ethics approval, will be used by a student to obtain a degree, or when any research involves most invertebrate species.

# RESPONSIBILITIES

## The NHREC stipulates the responsibilities of the AREC are as follows:

### The main responsibility of the AREC is to conduct rigorous ethics reviews of all research proposals involving animal participants to ensure to safeguarding the welfare, safety, and well-being of all actual or potential animals in teaching and research conducted by the University and its researchers, and that researchers are properly protected and that the research will be conducted in accordance with the required ethical norms and standards in terms of the SANS 10386: 2008 and the National Guidelines 2015.

### The AREC must confirm that research proposals stand up to ethical scrutiny as is appropriate to the discipline or field concerned.

### The review must ensure the maintenance of ethical standards to:

#### protect animal participants from harm by weighing the risk of harm against the prospect of benefits;

#### promote the four R’s of research (Replace, Refine, Reduce and Responsibility);

#### hold researchers accountable for their research actions;

#### promote the highest ethical standards and best available techniques or approaches for optimal wellbeing of participating animals; and

#### promote important environmental, social and ethical values to the research community.

## AREC must review research proposals prospectively and not retrospectively, to ensure that the research proposal meet the accepted ethical norms and standards before research commences, using the guidelines indicated in the National Guidelines 2015 as a minimum benchmark, of which one important aspect is, but which is not limited to:

#### the primary responsibility of each AREC member is to decide independently whether the proposed research study protects the interests of participants adequately and upholds the highest of standards.

## Such responsibility regarding participant interest will always take precedence over the interests of the research.

## The AREC will:

#### function according to its Code of Conduct as appropriate as attached hereto as Annexure 1;

#### operate in accordance with the University’s Research Integrity Policy and Research Integrity Procedure as attached hereto as Annexure 2 and amended from time to time;

#### follow the AREC procedures as set out in its SOP as attached hereto as Annexure 3,

#### in reviewing ethics applications, allocate a suitable level of severity classification for research studies whilst reviewing ethics applications which can be found as AREC Research Classification of Severity Categories in Animal Research as attached hereto as Annexure 4;

#### in reviewing ethics applications, and at follow-up site and study inspections confirm that the AREC Guidelines for the Use and Care of Animals in Teaching and Research at Wits as attached hereto as ANNEXURE 5, is adhered to

#### provide feedback on specific matters as requested by the UR&IC and /or the DVC: R&I;

#### ensure confidentiality of all information revealed to it;

#### ensure that all researchers applying for ethics approval sign the Wits Code of Conduct for Researchers, which is attached hereto as Annexure 6; and

#### ensure that all AREC members sign the AREC Code of Conduct as attached hereto as Annexure 1.

## The AREC will uphold the necessary University’s rules and regulations.

# PROCEDURES

## Formal Character of the AREC and School sub-committees” of the AREC:

### The AREC is provisionally registered with the NHREC registered committee, and the AREC will endeavour to be a fully registered REC. For further details of the AREC member selection, appointment and functioning, please see the AREC SOP as Annexure 3 attached hereto.

### Where Schools have research sub-committees, they have to follow the same processes and procedures as the AREC and as such they are bound by the AREC SOP, University Ethics Policy and this TORs. For further information, selection, appointment and function of these School sub-committees” of the AREC, please see the AREC SOP as Annexure 3 attached hereto.

## The AREC members will be expected beyond the Code of conduct to:

### agree to a term of office of five (5) years, which can be renewed for two (2) subsequent terms;

### familiarise themselves with the University’s relevant documentation as well as national and international research ethics guidelines;

### attend research ethics training sessions to keep abreast with the latest changes in this field and the AREC members will need to provide proof of evidence at least once every three (3) years to the AREC;

### always act with integrity in the capacity as members of AREC;

### regularly attend AREC meetings and provide a reasonable reason if they do not attend such meetings but they are permitted to still provide written reviews of applications if applicable;

### be punctual in the attendance of the AREC meetings;

### diligently perform all responsibilities delegated to them;

### maintain all of these responsibilities in compliance with the University’s internal policies, directives, rules and regulations, national and international ethical and regulatory requirements;

### consider and declare any prior interest, any conflict of interest and/or involvement in any matter being discussed at an AREC meeting to avoid potential conflict of interest, either personal or financial interest; and

### keep all matters coming to the AREC member’s attention during AREC meetings confidential.

## Relationship to Non-Affiliated Researchers / External Applications

### Researchers with no affiliation to the University or are considered to be external applications to the University can approach any of the NHREC-registered RECs of the University to review and approve their research proposals, where such a REC may on a case-by-case basis decide whether it is the appropriate REC to deal with the matter and whether the REC is willing and has proper expertise and capacity to evaluate the application.

## Accountability and Responsibilities of RECs

### The AREC is to function within the legislative framework of the National Health Act No. 61 of 2003 and the National Guidelines 2015, which requires a University at which research is being conducted to have an NHREC-registered REC. The REC is the single body vested with the explicit authority and legal accountability for the final determination regarding the ethical acceptability of the proposal.

## Mechanisms for Reporting by AREC

### The AREC, managed and supported by the UR&IC, function directly under the DVC: R&I. The University Research Office has oversight of all the RECs at the University. The Director: Research Development and the Legal Adviser and Research Compliance Manager conduct this function with the REC Chairpersons and the Research Office administrative officers and other support staff members. The AREC works in close collaboration with the University’s Faculties, the Faculty Deans and Assistant Deans for Research and Postgraduate Affairs structures involved in animal-related research. The Research Office also serves to internally audit the AREC in terms of their operational mandate and standards. The AREC must report annually on their activities to the NHREC and the UR&IC in the form of an annual report.

## Mechanisms for Remuneration of AREC Members

### AREC members who are on the payroll of the University are not remunerated for their services as AREC members, in order to reduce conflict of interest and increase independence, being a member of the AREC forms part of the University’s academic citizenship. Should the services of an AREC member not on the payroll of the University be required (e.g. layperson, attorney, and psychologist), then their services should be viewed as part of their contribution to their community but may be remunerated according to an honorarium negotiated before the appointment, where they are compensated for time, travel costs, inconvenience and expenses provided they are:

#### not employed and might lose the opportunity to earn income for the day by attending to certain AREC duties;

#### employed but have to add hours to their workday to serve on the AREC and do its work; or

#### in a private practice and their participation as a member of the AREC will lead to a loss, as they are not able to earn an income during the AREC meeting.

#### An honorarium has been introduced by the University to the Chairperson/s as a part of their academic service to the University as they may need to add hours to their workday to serve on the AREC and do its work.

## Authority of the AREC

### The Animal Protection Act, 1962 (Act No 71 of 1962) and its amendments in so far as they are relevant to animal-based research provides statutory authority for the governance of research through the registered RECs, as well as the necessary ethics regulatory infrastructure through the NHREC.

### The AREC receives its authority from the minimum standards and guidelines for research ethics of the NHREC, National Guidelines 2015, as well as from the UR&IC and the DVC: R&I of the University:

#### The National Health Act, which requires the University to establish AREC which are registered with the NHREC;

#### The South African National Standards for the use of animals in research and teaching for conducting responsible and ethical research.

#### The University Research Ethics Policy and the AREC SOPs.

### In all instances any amendments of animal welfare and related Acts, regulations or standards will take immediate effect as they are published or promulgated, where this TOR and the AREC SOP will then be amended as soon as reasonably possible to reflect the latest amendments.

### The AREC is supported by the University’s Research Office and the NHREC independently. If the AREC is dissolved for whatever reason, it must be reported to the NHREC, UR&IC and the DVC: R&I.

# REFERENCES TO OTHER RELATED DOCUMENTS

## National Health Act 61 of 2003;

## The Animal Protection Act, 1962 (Act No 71 of 1962) and its amendments in so far as they are relevant to animal-based research;

## The Animal Diseases Act, 1984 (Act No 35 of 1984);

## Animal Health Act, 2002 (Act No 7 of 2002);

## the Veterinary and Para-veterinary Professions Act, 1982 (Act No 19 of 1982) and the amendment of this act, (Act No 16 of 2012);

## Animal Improvement Act, 1998 (Act No 62 of 1998);

## the Medicines and Related Substances Control Act , 1965 (Act No 101 of 1065);

## Fertilizers Farm feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act No 36 of 1947);

## the South African National Standards for the Use and Care of Animals for Scientific Purposes (SANS 10386:2021);

## University Research Ethics Policy;

## Delegation of Authority Document (DOAD); and

## Department of Health, “*Ethics in Health Research - Principles, Processes and Structures* 2015” Guidelines (“2015 Guidelines”).

# ACKNOWLEDGEMENTS

## The following sources are acknowledged for their input into the development of this document:

### North West University Research Ethics Committee; and

### UCT

# Approval History of the TOR

|  |  |  |  |
| --- | --- | --- | --- |
| **STRUCTURE CONSULTED** | **Target date for discussion\*\*** | **Date approved/ discussed#** | **Date noted#** |
| AREC | 20 October 2017 | 20 October 2017 | - |
| AREC | 28 June 2022 |  |  |
| University Research and Innovation Committee | 09 November 2017 | - |  |
| UR&IC |  |  |  |

**\* Outline which structures will be consulted on this issue, and in which order**

**\*\* Indicate which meeting of each structure is being targeted.**

**# This date is only filled in when the specific body has dealt with the issue.**

## **SUBMISSION CONTENT**

## Proposal (Complete the sentence: This body is requested to approve the draft Standard Operating Procedures of the Animal Research Ethics Committee [AREC]:

### University Research and Innovation Committee (“UR&IC”) is requested to approve new Terms of Reference and Standard Operating Procedures for the AREC at the University of the Witwatersrand, Johannesburg (“University” / “Wits”).

## Motivation (Please put down the reasons why this decision should be reached, that is, why this should be supported):

### The proposed Terms of Reference and Standard Operating Procedures are designed to ensure that the Animal Research Ethics Committee [AREC] at the University of the Witwatersrand, Johannesburg is compliant with the requirements of the National Health Act 61 of 2003 (“National Health Act”) and South African National Standards for the use of Animals in research and teaching at the University, Johannesburg is compliant with the requirements of the National Health Act (Act 61 of 2003) and with the Department of Health Guidelines for Health Research (2004).

## Financial Implications (Outline what it will cost)

### Researchers with no affiliation to the University or are considered to be external applications to the University can approach any of the NHREC-registered RECs of the University to review and approve their research proposals, where such an REC may on a case-by-case basis decide whether it is the appropriate REC to deal with the matter and whether the REC is willing and has proper expertise and capacity to evaluate the application.

### The AREC can review research proposals / Protocols / applications of researchers that are not affiliated to University, or external applications subject to payment of a cost (“Review Fee”) levied for such service in the current amount of R15 000,00 (fifteen thousand Rand) plus VAT (currently at 15%) as per the Value Added Tax Act as amended from time to time, which Review Fee is payable upon submission. The Review Fee may change from time to time. The Review Fee is not for any Researchers within the University. The Review Fee is subject to the AREC Chairperson’s discretion, in consultation with the Secretariat and Research Office.

**ANNEXURE 1**

1. Wits AREC member Code of Conduct

**ANNEXURE 2**

1. University Research Integrity Policy and Wits Research Integrity Procedure

**ANNEXURE 3**

1. SOP for AREC

**ANNEXURE 4**

1. AREC Research Classification of Severity Categories in Animal Research

**ANNEXURE 5**

1. AREC Guidelines for the Use and Care of Animals in Teaching and Research at Wits

**ANNEXURE 6**

1. Wits Code of Conduct for Researchers