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**University of the Witwatersrand, Johannesburg**

**(“University” / “Wits”)**

**Animal Research Ethics Committee**

**(“AREC”)**

**Standing Operating Procedures**

**(“SOP”)**

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**Standard Operating Procedures for the Animal Research Ethics Committee (AREC)**

# OBJECTIVES

## The overarching objective of this Standard Operating Procedures (“SOP”) is to promote and ensure a culture of ethically responsible research at the University in animal-based research.

## The specific objective of this SOP is to contribute to the promotion of quality, transparency and consistency of ethics applications submitted to the AREC and in reviewing the ethical aspects related to animal-based research conducted at the University by upholding a high standard of ethical practice and research integrity. The AREC is informed by the University Research Integrity Policy and its Terms of Reference [ANNEXURE 6].

# THE PURPOSE OF THE AREC

## The 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 research conducted by the University and its researchers, balancing it with the innately intrusive nature of such research.

## Also, the purpose of the AREC is to facilitate sound ethical practice by Applicants and students through training and support.

## The AREC provides independent, competent, and timely reviews of the ethical risks related to research proposals and can recommend measures aimed at avoiding or minimizing these risks – acknowledging that the ethical dimensions of research can never be fully separated from the scientific dimensions of research (that include, amongst others, methodological, theoretical and institutional aspects). The AREC can also require that certain measures be taken by the Applicants to minimise or avoid potential ethical risks. The AREC has a classification of severity categories document [ANNEXURE 1] for research in order to provide guidelines for the Applicants to follow.

## The AREC is responsible for acting in the full interest of potential research animals and affected communities, taking into account the interests and needs of the Researchers, and having due regard for the requirements of applicable professional bodies and academic societies, relevant regulatory agencies, applicable laws, and relevant institutional requirements.

## The AREC will maintain a record of all the research proposals, protocols, reviewer reports, emails and correspondence that have been considered in ethical terms, including those:

### approved by Research Ethics Committees (“REC”) of other institutions that were submitted to the AREC for commentary and / or endorsement.

# SCOPE OF THE AREC

## Any research undertaken by any students or staff of the University (“Researchers” / “Applicants”) involving non-human vertebrates, their foetuses, embryos, and cephalopods, must be submitted for review by the AREC after pre-approval of the research proposal from School research-committees. The AREC will uphold all the University’s necessary rules and regulations and in so doing reviewing applications for teaching, degree and non-degree purposes.

## When reviewing research proposals, special attention will be given to research that includes certain species that may be endangered or fall within highly emotive groups (e.g. companion animals or non-human primates).

# CONSTITUTING THE AREC

## In executing its duties the AREC will ensure that it is free from bias and influence that could affect its independence. In its structure and functioning, and in the execution of its duties and responsivities, the AREC will follow the principles and guidelines stipulated in:

### The National Health Research Ethics Council in so far as it is relevant to animal-based research.

### 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).

### the Animal Health Act, 2002 (Act No 7 of 2002).

### the Animal Improvement Act, 1998 (Act No 62 of 1998).

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

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

### the 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).

### Medical Research Council’s Guidelines on Ethics for Medical Research Book 3.

### Guidelines for the Care and Use of Animals for Research and Teaching at Wits.

### Any relevant legislation, regulations and guidelines, including international guidelines and standards in so far as they are applicable to animal-based research.

### Official documents of professional bodies and scientific organisations, in so far as they are relevant to animal-based research.

### The University Research Integrity Policy; and

### The University, AREC member and Researcher Code of Conduct.

### Department of Health - *Ethics in Health Research - Principles, Processes and Structures 2015* Guidelines

# COMPOSITION

## **MEMBER COMPOSITION OF THE AREC**

### The representatives of the broader community are identified according to the ARECs needs, they are approached and upon agreement, appointed by the Deputy Vice Chancellor:Research and Innovation (DVC: R&I) or his / her nominee as follows:

#### .Members of the AREC are appointed for a period of four (4) years;

#### Members of the AREC may be re-appointed for a second and subsequent third (3rd) four (4) year term in succession;

#### The AREC must be representative of the research communities it serves within the University and, increasingly, reflect the demographic profile of the population of the Republic of South Africa as best and reasonably as possible;

#### The AREC must include members of both genders, although not more than 70% (seventy percent) should be either male or female;

#### The AREC must have at least nine (9) members in order to be constituted as a AREC, including the Chairperson. At an AREC meeting, a minimum of five (5) members, at least one (1) from each category, must be present in order to constitute a quorum.

### Membership should consist of:

#### at least one (1) layperson (Category D), preferably a person not previously involved animal -based research. A lay person is viewed as an ordinary person for example, a member of the community, with no specific qualification in a profession and/or does not have specific knowledge of a certain discipline / field;

#### at least one (1) person from a nationally recognised animal welfare organisation (Category C). A person that will further the welfare of animals, who is not employed or otherwise associated with the University and is not currently involved with the use and care of animals for scientific purposes;

#### at least one (1) scientist (Category B). A person with substantial and recent experience and knowledge in the use of animals for scientific and experimental purposes. This person shall have a higher degree, or equivalent experience in research from a nationally approved academic institution;

#### at least one (1) South African Veterinary Council (SAVC) registered veterinarian (Category A). A person with experience relevant to the animal facility’s activities or has the ability to acquire relevant knowledge.

#### Alternate members to above categories may be appointed by the AREC. A category member and the alternate may not count toward a quorum at the same time. Alternate members have to undergo the same training as regular AREC members.

#### The proposed membership of the AREC for the following year is sent to the University Research and Innovation Committee (UR&IC) and the DVC: R&I annually in order for the DVC: R&I to approve and the UR&IC to note such memberships in line with the University’s rules and regulations.

#### All the new AREC members will receive a formal induction and introduction into the AREC. The main way of training being a formal Research Ethics training course on the authority, composition, regulation and function of the AREC, as well as on how to review applications. Secondary training is through workshops, observation and “on the job” experience. More experienced members on the AREC will be able to provide any guidance that maybe required by any new members.

#### The AREC members must attend research ethics training courses at least every three (3) years to keep abreast with the latest changes in this field. All AREC members are required to complete an accredited ethics content course. They need to provide proof of attendance to the Chair / Co-Chair of the AREC. This is to be renewed every 3 (three) years.

#### AREC members will receive an introductory pack electronically, which will consist of the following, but not limited to: Letter of Appointment, University Research Ethics Policy [ANNEXURE 5], AREC Terms of Reference [ANNEXURE 6], AREC Standard Operating Procedures, Wits AREC member and Researcher Code of Conduct [ANNEXURES 3 & 4], Non-Disclosure Declaration [ANNEXURE 7] (to be signed by the members and returned to the Secretariat), Guidelines for the Use and Care of Animals in Research and Teaching at Wits (ANNEXURE 1), National Guidelines and other documents that maybe required.

#### AREC members will receive a certificate of service at the end of their term that they have served on the AREC. This certificate will support the member’s involvement with the AREC and their academic citizenship in the University.

## **5.2 MEMBER PARTICIPATION**

* + 1. Functioning of Members, Chairperson, Co-Chairperson/s and Deputy Chairperson/s of the AREC

5.2.2 Chairperson and Deputy Chairperson/s

6.2.3 A Chairperson will either hold the Chair individually

5.2.4 Subject to the University’s requirements, a Chairperson of the AREC should be elected at the last meeting of year by the members of the AREC. The Chairperson of the AREC serve a term of 1 (one) calendar year, and may be re-elected annually for a maximum period of 5 (five) years in succession.

### 5.2.5 The Chairperson must be assisted by at least 1 (one) Deputy Chairperson/s as this will promote succession planning for the AREC. The Deputy Chairperson/s is to be elected at the last meeting of year by the members of the AREC. The Deputy Chairperson/s of the AREC serves a term of 1 (one) calendar year, and may be re-elected annually for a maximum period of 5 (five) years in succession.

### 5.2.6 The Deputy Chairperson/s will be elected by the members and be expected to assist the Chairperson with responsibilities and inter-meeting matters as well as to step into the role of the Chairperson when necessary.

5.2.7 Once the Chairperson, and Deputy-Chairperson/s of the AREC are elected as above, and then their respective identities are to be reported to the DVC: R&I for approval and the UR&IC for noting.

## **APPOINTMENT AND REAPPOINTMENT OF MEMBERS**

### 5.3.1 Appointment and reappointment of the AREC members are subject to approval by the Chairperson of the AREC and then approved by the DVC: R&I and the UR&IC. The term of office for members is as set out in clause 5.1.1.1 above.

### 5.3.2 If a member, including Chairperson, and Deputy-Chairperson/s is absent from a meeting for four (4) consecutive meetings without an apology, his or her absence will be addressed by the Chairperson/s, or in their absence the DVC: R&I or their nominee, in writing to the specific member, after which the Chairperson can make a recommendation, and in this context, has the authority to remove such member reported as non-attending from the AREC and propose another representative for the remainder of the disqualified member’s term, such appointment to be confirmed by the UR&IC and the DVC: R&I.

### 5.3.3 Resignation from the AREC can be initiated by the committee member, Chairperson or any other member of the AREC, and must be in writing to the AREC Secretariat and the Chairperson.

### Upon appointment to the AREC new members must sign applicable non-disclosure agreements [ANNEXURE 7], the AREC Code of Conduct [ANNEXURE 3], Conflict of Interest Document and any other relevant documentation that may be required.

### The AREC can co-opt members with appropriate expertise and/or training, when needed.

### **ROLES AND RESPONSIBILITIES**

### The AREC will function according to this set of Standard Operational Procedures (SOP) formulated in this document and under the AREC ToR [ANNEXURE 6], AREC member Appointment Letter and Code of Conduct [ANNEXURE 3].

### The AREC must ensure that it is adequately informed on all aspects of a research protocol, including its scientific validity, that are relevant to deciding whether the protocol is both acceptable on ethical grounds and conforms to the principles of this document.

### The AREC will have the responsibility to ensure that research conducted in the non-human vertebrates, their foetuses, embryos, and cephalopods by the University is in accordance with National and International guidelines and standards for ethically responsible research.

### In making these decisions the AREC focuses in particular on:

### the comparison of the benefit to society and/or animals versus the potential harm or suffering that may occur to research animals as described in the proposal;

### the consideration and implementation of the 4R’s (reduction, refinement, replacement, responsibility); and

### scientific merit and/or the advancement of student knowledge and experience.

### The AREC may review protocols for projects of other organisations that collaborate with the University and any affiliated Applicants:

### where studies or teaching activities, or parts thereof, are conducted at a NHREC registered research institution outside the University, ethical approval from one (1) of the institutions need to be obtained, on condition that a confirmation letter indicating this approval be shared with the researcher as proof to the other REC’s ethics approval;

### requests for amendments, modifications and/or extensions to approved projects, will need to be reviewed and approved at the school level before submission to the AREC Exco;

### AREC Exco, a subcommittee of AREC, comprising of the Chairperson and a representative from each of the categories (A to D), may approve amendments, modifications and extensions to approved projects, electronically, between formal ethics meetings. The full committee may then endorse the approval at the next formal meeting.

### The AREC will be available to render researchers, upon formal request, with expert opinion regarding research ethics, and advice regarding application procedures will be addressed on an informal and ad hoc basis by the Chairperson and /or Co-Chairperson/s with the University Research Office. The AREC also provides Applicants with methodological comments in order to assist in making the research better.

### The AREC has to notify Applicants in writing regarding their decisions within fifteen (15) to 20 (twenty) working days after the AREC monthly meeting. This will be dealt with in more detail herein.

### The AREC will review applicant’s annual reports yearly. The report must reach AREC by 25 January each year. AREC. A final report must be submitted indicating the end of the study.

# APPLICATION REQUIREMENTS FOR AREC REVIEW

## Requirements for submitting an application to the AREC are available to prospective applicants 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 include the following aspects:

## **DOCUMENTATION REQUIRED**

### An application to the AREC for review, the following documentation is required:

#### a fully completed Application Form dated and signed by the applicant, their Supervisor (if applicable) and Head of School/Department.

#### a detailed drugs list stating dose, route and frequency of application.

#### The name, qualification and signature of the veterinarian taking responsibility of any scheduled drugs to be used

#### the Application Form should include:

#### a harm versus benefit motivation, as defined by the AREC;

##### species, strain, gender and number of animals to be used in the project;

##### the need for permission letters and permits are required, but may be on reasonable terms be supplied after approval, but before starting any research activities [See 7.6 ];

##### research instruments, i.e. welfare observation score sheet and experimental design flow charts.

#### appropriate references in support of and relating to scientific and/or procedural information relevant to the planned study.

### SUBMISSION AND PROCESSING OF APPLICATIONS

#### The application form has a checklist as a preamble. The following guidelines apply to the submission and processing of applications:

##### An application for review of the ethics of proposed research should be submitted by a qualified researcher, or a researcher (student) in training supported by an experienced applicant, a researcher (student) in training supported by a qualified supervisor responsible for the ethical and academic conduct of the research (undergrad students may not be the main applicant);

##### Along with their application, Applicants must attend research orientation and ethics content training either online or face-to-face and to provide proof of evidence of qualification of such training at least once every three (3) years to the AREC, as described on the completed application form;

##### If the Applicant is a student, the application must be pre-approved by the relevant supervisor and/or school/ department/unit or must have been submitted to the specific Higher Degrees Committee;

##### All applications must be submitted electronically through the online submission system found 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) including uploading all supporting documents that are required for the application;

##### The proposal must be submitted in English and written so a layperson can understand it.

##### The application form has to be completed in full and must be signed by all relevant parties.

##### The submission deadlines and meeting dates of the AREC will be published 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 submissions must reach the AREC Secretariat before the listed submissions deadline of the appropriate meeting of the AREC;

##### Applicants will be notified in writing about the outcome of the application within 15 (fifteen) to 20 (twenty) working days after the regular meeting of the AREC has taken place. If there are any delays, then the AREC will inform the relevant Applicants/ Applicants of such and will indicate a new timeline;

##### The procedure and requirements for any amendments required after review by the AREC to the research application/ proposal / protocol, the recruitment material or the potential research animal information will be made available in writing to the applicant(s) and on the website. The amendment procedure is set out below;

##### The responses from Applicants to the AREC will normally be processed within 14 (fourteen) days of receipt by the AREC Secretariat;

##### If a revised version of the original submitted application has not been received, addressing the reviewers’ comments, within five (5) months of the original decision letter, the application shall be considered to be null and void. A new application must then be submitted for review;

##### In all instances, Applicants must submit a detailed letter indicating what changes have been made in response to the reviewers’ comments. If a student, the applicant must confirm that the supervisor(s) has seen and approved the revised submission.

# AREC FULL REVIEW

## **MEETINGS**

### Meetings will be scheduled to be held on a monthly basis, unless decided otherwise by the Chairperson of the AREC. Meetings will normally take place once a month from January until November of each year, inclusively. The applications submitted during December will be reviewed during the next meeting in January. No meetings will take place take place if no applications have been submitted during the time period specified.

### Late applications not submitted by the given deadline will be stood over until the next month’s meeting.

### The scheduled dates of all meetings and deadlines are available on the website of AREC, [Animal Research Ethics Committee (AREC) (wits.ac.za)](http://intranet.wits.ac.za/academic/uro/Pages/Animal-Research-Ethics--Committee-(AREC).aspx).

### With the permission from the AREC committee members, meetings of the AREC will be recorded by means of minute-taking, electronic recording and electronic record keeping.

### Minutes of meetings will be included in the agenda of the next meeting of the AREC for approval and to deal with matters arising. The agenda will include a section on conflict of interest of reviewers and confirmation that reviewers do or do not have any conflict of interest. These must be captured in the minutes and attendance register of that meeting.

### The agenda and documentation for scheduled meetings will be circulated to the AREC at least 10 (ten) business days prior to the meeting.

### Extraordinary meetings may take place under special circumstance and notification of such meetings will be provided to the AREC members at least three (3) days before such meeting.

## **CONFLICT OF INTEREST OF MEMBERS**

### AREC members should disclose information that may lead to perceptions of conflict of interest.

### AREC members should not review or make decisions about research proposals in which they are involved personally or financially. When such a proposal is to be discussed, the member concerned should declare the potential conflict and offer to recuse himself / herself from the meeting for that time. Should the member be permitted to remain for the discussion at the discretion of the Chairperson or Co-Chairperson then the member may not participate in the final decision-making on the application in question.

## **MINUTE TAKING AND KEEPING**

### The AREC will keep written records of all research applications / protocols / proposals for review, including information sheets, consent forms and relevant correspondence, as in the form provided for by the electronic submission system. Electronic records are acceptable by the AREC, provided that signatures, especially on the finally approved documentation, are properly documented on the hard copy of the application and included in the record and an applicant is to request that a hard copy be printed by the Secretariat.

### The AREC records must provide a reliable and authoritative record of the business of the AREC that will stand up to scrutiny in the event of queries, conflict and audit.

### The AREC should correspond primarily with the principal investigator but if the need arises for the AREC to correspondence with the Faculty, School or with participants then the AREC chair will be permitted to do so with good reason.

### The record should include at least the following:

#### Name of principal investigator / Researcher;

#### Protocol identification number;

#### Title of the project;

#### comments submitted;

#### Date of approval or rejection;

#### Conditions of approval, if applicable;

#### Copy of the signed final protocol approved;

#### and through the life cycle of that protocol the following:

##### Records of adverse events;

##### Record of expedited Amendment/ Modification and extension applications;

##### Reports of adverse and serious adverse events and action taken;

##### Other relevant information such as request for extension of time;

##### Post approval monitoring Records; and

##### Annual Reports.

## **ATTENDANCE OF APPLICANTS/ OTHER PARTIES**

### Any member of the UR&IC, the DVC: R&I or his / her nominee and any member of the University Research Office, the Researcher, Supervisor, Dean of a Faculty or Head/Chairperson of a School or a Department, or any other University personnel can attend a meeting of AREC as an observer to hear their own application being considered or for good reason, following the procedure given in the documentation 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) the Research Office website. Attendance as an observer can only take place following the notification of the AREC Secretariat at least twenty-four (24) hours before the AREC meeting and written confirmation or rejection must be given by the Chair or a Co-Chairperson of the AREC. If a rejection is provided then good reason must be provided for such a rejection. If such a request is granted, then that person will need to complete the same non-disclosure agreement that the AREC members complete at the meeting. These observers will need to complete the same non-disclosure agreement that the AREC members complete.

## **ELEMENTS OF THE REVIEW**

### **REVIEW PROCESS**

#### **REVIEW BY THE AREC**

##### The primary task of the AREC lies in the ethics review of research proposals. In this review, the Application Form and research proposal, as well as all supporting documents are considered, The AREC takes into account guidelines, where appropriate, provided by professional bodies as well as the requirements of applicable laws and regulations. The following is considered in particular in the ethics review, as applicable:

## **INSTITUTIONAL PERMISSION**

### The following will be considered with respect to obtaining institutional permission: If a central authority/ies are involved, copies of the institutional permission that was obtained, or, if such institutional permission is still pending at the time of submitting the application, proof that institutional permission was requested.

### The research is not permitted to be undertaken at any institution without previously obtaining permission from that institution, if required by the AREC.

### Permission should be in written form on an official letterhead, signed and dated, specifically mentioning the Applicant, the title of the Applicant’s project by name. Email correspondence is not an acceptable form of permission.

### Instances where permission is not required must also be obtained in written form.

## REGISTRATIONAL REQUIREMENTS

### According to the Veterinary and Para-veterinary Professions Act of 1982, no person may do any procedure unless conducted by a veterinarian or para-veterinarian, and the researcher will have to apply to the South African Veterinary Council (“SAVC”) for conditional approval to do the procedure themselves.

### If the researcher selects to do such a procedure, they are required to undergo training and to be found competent in that procedure by veterinarian.

### The researcher will then apply to SAVC for conditional approval to do the procedure and be required to pay an annual maintenance fee for this approval.

# Amendments / Modifications process to be followed by Applicant

## The procedure and requirements for any amendments required to the research application / proposal / protocol, (ANNEXURE 8 AREC Expedited Applications SOP) the recruitment material or the potential research animal information, will be made available in writing to the applicant(s) as well as on the website, https://www.wits.ac.za/research/researcher-support/research-ethics/ethics-committees/.

## An amendment(s) to an approved protocol can be submitted to the Secretariat of the AREC in the event of a change(s) in the research project of instrument/s used or methods of data collection or analysis or participating groups or research site(s). This can be done in writing to the Secretariat of the AREC using the appropriate form found on the website, [Animal Research Ethics Committee (AREC) (wits.ac.za )](http://intranet.wits.ac.za/academic/uro/Pages/Animal-Research-Ethics--Committee-(AREC).aspx) indicating the relevant change(s) including the updated documents etc. Same is then reviewed by the Chairperson / Co-Chairperson and 4 (four) interim reviewers One (1) from each category A to D (AREC Exco).

## If approved by the AREC Exco, any amendments, modifications or request for extension of time, must be considered and endorsed at the next AREC meeting and be minuted as such.

## If the revised version of the original submitted application is not submitted to the AREC before the due date of submission for the next AREC meeting then that revised version will be considered at the next meeting as per the AREC due dates.

# Waiver for Protocol by the AREC

## The AREC has established procedures for waiver of applications (ANNEXURE 8 AREC Expedited Applications SOP). This process is for research being carried out which does not have contact with living animals, or using data collected from previous animals studies.

## The Applicant would apply for a waiver by submitting a letter containing all relevant information required regarding the data and/ or information to be used. This letter must have attached all supporting documents if so required in order for the AREC to provide a full review of such waiver.

## Once the waiver request is received by the Secretariat then such application for waiver will be sent to the AREC Chairperson / Co-Chairperson. S/he reviews such waiver application and s/he will determine if the application should be waivered or not. If it is waivered, then the Applicant will be provided with a waiver letter.

## The waivered letters will be endorsed at the next AREC meeting and minuted as such.

# DECISION-MAKING WITHIN THE AREC AND SCHOOL SUB-COMMITTEES

## In making decisions on applications for the ethics review of research, the AREC will make use of the following procedures and considerations:

### Any conflict of interest of a committee member should be indicated to the Chairperson / Co-Chairperson prior to the review of the application and recorded in the minutes at the AREC meeting;

### Applications from members of the AREC are considered by AREC in absence of the applicant in line with the Conflict of Interest Guideline.

### Decisions should only be made at meetings where a quorum is present. In cases where a quorum is not present, the AREC can make recommendations of decisions on individual applications, but that these decisions cannot be confirmed and must be held over to a subsequent meeting at which a quorum is present;

### The documents required for a full review of the application should be complete and the relevant elements mentioned above should be considered before a decision is made. If a significant proportion of documents are missing from the application, then the application is considered to be incomplete and the application is returned to the Application for resubmission.

### Decisions at meetings of the AREC are arrived at through consensus, where possible. If consensus is unlikely to be reached, the AREC should explore with the applicant, ways to modify the point of contention in such a way that may lead to consensus. When a consensus still appears unlikely, it is recommended that a vote is taken, in which a simple majority of 51% (fifty one percent) is required.

### Voting will take place by a show of hands or electronically, unless indicated by the Chairperson / Co-Chairperson;

### In cases of conditional decisions, such as where permission letters are needed, the nature of these conditions must be made clear;

### The decisions of resubmission, major, moderate or minor revisions on an application must be supported by clearly stated reasons and suggestions to amend the application and/or supporting documents;

### An approval is valid for two (2) years from the date of the clearance certificate. In order for the three (3) years approval to be valid, the Applicant is obligated to provide the AREC with annual report/s, at the anniversary of the approval reporting the progress of the research as well as any incidents and / or adverse event that may have taken place which must include how this was resolved. Such annual reports are vital to allow for post-approval evaluation and national reporting to the NHREC.

### If a research project stretches more than two (2) years, it is the responsibility of the Applicant to apply to the AREC for an extension of not more than two (2) years of the approval before the validity of the approval has lapsed. If there are no fundamental changes to the research project, this request for extension must be motivated on the required form, supported by a short report on the ethical aspects of the research, stating whether any new or unforeseen ethical issues were encountered during the initial two (2) years, and how they were addressed. If there are substantive changes to the research project, a full application will have to be submitted again as the nature of the initial project would have changed.

## Decisions that the AREC can make, include:

### The AREC can make the following decisions, including but not limited to:

#### The approval of a research proposal as submitted with no amendments (APPROVED);

#### Minor amendments (MINOR AMENDMENTS), Moderate amendments (MODERATE AMENDMENT) required before approval by AREC Exco and be endorsed at the next scheduled AREC meeting;

#### or Major amendments (MAJOR AMENDMENTS) with recommendation for RESUBMISSION (RESUBMISSION); or

#### Approval based on receiving permits / letters of permission or actions to be fulfilled (CONDITIONAL APPROVAL)

#### Rejection of the application will be based on it being unethical and/or it cannot be scientifically justified.

### In addition to the above, the AREC can in terms of the National Guidelines 2015 and SANS, after due consideration, take the following actions at any point in time during the research, including but not limited to:

#### Monitoring the research;

#### Inspecting a research site;

#### Requesting an immediate report on the ethical aspects of a research project;

#### Temporarily suspending a research project with good reason;

#### Suspending a research project with good reason; and / or

#### Investigating an allegation of a breach of ethics in the research being conducted.

## **COMMUNICATING OF A DECISION AND DECISION ON RESUBMITTED REVISED APPLICATIONS (REVISION PROCESS)**

### The decision of the AREC after reviewing an application will be communicated in writing to the applicant, normally within 15 (fifteen) to 20 (twenty) business days after the AREC meeting at which the decision was made or the decision of revised applications which were resubmitted. The content of the communication will be generated from the details provided in the application and revised applications, but will at least, include the following:

#### The exact title of the research proposal reviewed;

#### The name and title of the applicant;

#### The date of the decision;

#### The name of the AREC;

#### A clear statement of the decision reached;

#### Any advice by the AREC;

#### In the case of a conditional decision, any requirements by the AREC, including suggestions for revision and the procedure for having the application re-reviewed; and

#### In the case of a decision of RESUBMISSION, clearly stated reason(s) for the decision.

#### In the case of a decision of REJECTION, clearly stated reason(s) for the decision.

# REVIEWS OF RESEARCH PROPOSALS OF APPLICANTS NOT FROM THE UNIVERSITY OR EXTERNAL APPLICATIONS

## The AREC can review research proposals, Protocols or applications of Applicants that are collaborating with a Wits researcher or staff member. This collaboration research should benefit the University through either co-authorship or financially.

# Post approval monitoring

## Active Monitoring:

## 12.1.1 AREC members may inspect activities of any study post approval either by arranging the inspection with the Principal Investigator (“PI”), or without any notification.

## Active and in person monitoring of Cat D research is required by a panel of three AREC members and the PI at least once a year.

## Studies identified by the research veterinarian or have been identified for possible animal welfare or non-compliance concerns may be evaluated unannounced

* + 1. Monitoring of Cat A to C may be in person (active), or electronic meeting (off site studies) involving two AREC members and the PI, at least once every two years.

## Passive Monitoring:

### All PI’s need to submit an Annual report listing any and all study activities of the preceding year. If the study was completed or discontinued during the preceding year, a final report needs to be submitted. The deadline for these reports is no later than 25 January of each year.

### In the case where Field studies requires surgery in an informal environment, a Field Surgery Feedback form has to be sent to AREC within ten (10) to fifteen (15) business days after the end of the last surgical intervention of that session.

# COMPLAINTS AND APPEALS PROCEDURES

## For applicants who wish to complain about the workings, procedures or decisions of the AREC:

### The complaint or appeal must be in writing to the Advisory committee on Ethics to the DVC: R&I (“ACE”) via the AREC Secretariat and Chairperson and / or Co-Chairperson of the AREC, and must contain a clear motivation as to the reasons for the appeal or complaint.

### The ACE will consider the appeal or complaint and will communicate a decision to the applicant in writing within ten (10) to fifteen (15) working days after the next scheduled ACE meeting, or after calling an ad hoc meeting.

### If the Applicant is still aggrieved, the second phase in the Standard Operating Procedure can then be activated by submitting a further appeal or complaint in writing to the Head: Office of Research Integrity which falls under the DVC: R&I.

### The Head: Office of Research Integrity will investigate such appeal or complaint and will provide a report to the DVC: R&I in order for the DVC: R&I to make a determination in order to refer the matter in accordance with the University’s Disciplinary Procedure for Staff or for Students .

### Guidelines can be found in the University Research Integrity Policy and AREC Whistleblowing in Ethical Research (ANNEXURE 2).

## For complaints about the ethical conduct of a Researcher who has received ethics clearance from the AREC, or any person involved with animals in research, the process to follow is described in AREC Policy Incident Adverse event\_Non-compliance , [Animal Research Ethics Committee (AREC) (wits.ac.za)](http://intranet.wits.ac.za/academic/uro/Pages/Animal-Research-Ethics--Committee-(AREC).aspx)

### The complainant should complete the COMPLAINTS FORM 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 submit the completed form following the procedures outlined on the website.

### A meeting will take place between the Secretariat, Legal Advisor and Research Compliance Manager, Chairperson or Co-Chairperson of 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 the researcher or the supervisor about whom the complaint has been made. The outcome of this meeting will be communicated to the complainant in writing within fifteen (15) working days.

### If the complainant is not satisfied, the APPEALS FORM 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) should be completed and submitted, following the procedures outlined on the website. The appeal will be adjudicated by the ACE chaired by the DVC: R&I or his/her nominee. The outcome of this adjudication will be communicated to the complainant in writing within fifteen (15) working days.

# Whistleblowing

## Any person externally or internally to the University will be able to report any infringement or offence in relation to research by an AREC member, Chairperson, Co-chairperson, Deputy Chairperson, Secretariat, administrator officer, researcher, applicant, research participant, any University personal linked to research or any other person that may have committed such an offence. See AREC Whistleblowing in Ethical Research (ANNEXURE 2).

## **14.2** Such reporting must be sent to the ACE in writing, who will deal with the matter with confidentiality as per the University’s internal Whistle-blowers procedures. The report will remain anonymous as far as possible in law. The DVC: R&I will consult with the ACE and the relevant University’s representatives in order to find a way forward to process such report and to resolve such report.

# Serious INCIDENTS

## All Applicants conducting research that encounter incidents or serious adverse events should report it to the AREC and the University Research Office within 24 (twenty four) hours (See ANNEXURE 9, AREC Incident\_Adverse event\_Non-compliance Policy). Care should be taken to describe how the incident / adverse event was contained and how the matter will be resolved. The Applicant then electronically reports the incident / adverse event and how it will be resolved, as well as the steps to be taken to prevent further incidents / adverse events of this nature to the AREC and University Research Office.

## The policy for reporting and the processes to follow for incidents, adverse events and non-compliance can be found on the Wits website, [Animal Research Ethics Committee (AREC) (wits.ac.za)](http://intranet.wits.ac.za/academic/uro/Pages/Animal-Research-Ethics--Committee-(AREC).aspx)

## The Secretariat / administrator officer will place the incident / adverse event on the agenda of the next AREC meeting, during which the Chairperson / Co-Chairperson will give a very brief description of the incident / adverse event and the manner in which it was dealt with.

## Should any Wits personnel or infrastructure be threatened / hurt / damaged within the boundaries of the Republic of South Africa they should immediately contact the Chairperson / Co-Chairperson for facilitation of this emergency situation.

# DOCUMENTATION AND ARCHIVING

## The following guidelines will apply to the documentation and archiving of submissions and applications, and the decisions of the AREC:

### The Secretariat of the AREC which resides in the Research Office is responsible for all documentation with regard to submissions and applications, as well as the archiving of reports and decisions of the AREC.

### All documentation and communications of the AREC will be dated, filed, and archived according to standard procedures applicable to the administration of AREC.

### The documentation and archive of the AREC is administered and governed according to the standard procedures and policies of the University, as applicable; i.e., submit documentation to the Registry Office, 4th Floor in Solomon Mahlangu House.

### Records of the AREC will normally be archived for a minimum period of 15 (fifteen) years following the completion of the project– depending on the University policies, the Promotion of Access to Information Act, 2 of 2000, the Protection of Personal Information Act 4 of 2014 (also plays a role in this regard) and any other legislation that may be applicable.

### Online submissions will be stored directly on the database of the online submissions system and via email archiving.

## Documents that should be filed and archived include, but are not limited to.

### The Research Integrity Policy, written terms of reference and standard operating procedures of the AREC, and regular (annual) reports.

### The published guidelines for submission established by the AREC.

### The agendas of the AREC meetings.

### The minutes of the AREC meetings.

### One (1) copy of all materials submitted by an applicant to the AREC.

### The correspondence by AREC members with applicants or concerned parties regarding an application, the decision on it, and follow-up.

### A copy of the decision and any advice or requirements sent to an applicant by the Secretariat or the AREC.

### All written documentation or correspondence received during the processing of the application.

### The notification of the completion, premature suspension, or premature termination of a study.

### Annual reports.

### The final summary or final ethics report on the study.

# ADOPTION OF, AND CHANGES TO, THIS STANDARD OPERATING PROCEDURE

## Changes to this Standard Operating Procedure can be made at any ordinary meeting of the AREC and any such changes must be noted by the UR&IC. The AREC must assess the efficacy of its Standard Operating Procedure at least once a year, and minute the results of this assessment at one (1) of its ordinary meetings.

# AUDITING AND ACCREDITATION OF THE AREC

## The AREC will be registered with the National Health Research Ethics Council (“NHREC”). It will be regularly audited by the NHREC. The University Research Committee and / or Research Office may be entitled to carry out check audits at any point in time without prior notification.

# REGULATORY FRAMEWORK

## This AREC functions within the framework of all relevant promulgated Acts legislation of Parliament and international treaties and conventions to which the Republic of South Africa is a signatory, interpreted in a manner appropriate to animal-based research. Examples of relevant Acts, treaties and conventions include, but are not limited to:

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

### The Constitution of South Africa, Act 108 of 1996;

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

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

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

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

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

### National Health Act, Act 61 of 2003;

### Promotion of Access to Information Act, Act 2 of 2000.

# POLICIES AND GUIDELINES

## In addition to the regulatory framework, the AREC functions within the framework of the following documents:

### South African National Standards for the Care and Use of Animals in Research and Teaching (SANS 10386:2021); and

### Department of Health, Ethics in Health Research - Principles, Processes and Structures 2015 guidelines

### National Health Act 61 of 2003.

# DEFINITIONS

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

|  |  |
| --- | --- |
| Amendments | Amendments are made post-clearance and may include changes to final approved application and attachments to the application to improve the study |
| “Applicant” | any student or staff of the University or any third party undertaking any research involving animal subjects |
| Clearance | Clearance is a certificate to conduct research in the knowledge that it is regarded as ethical by the committee |
| “Confidentiality” | Committee member may not share, discuss information and / or details regarding applications with persons outside the committee without permission of the applicant |
| “Conflict of Interest” | Incompatibility of duties, responsibilities or interests (personal or professional) of a person or an institution as regards ethical conduct of research so that one cannot be fulfilled without compromising another |
| “Data” | Data may be destroyed after use, but preservation in an archive or personal collection may also be appropriate, desirable or even essential. For instance, data sets that contain historically important information or information that relates to national heritage must be preserved and should be placed in a public archive where possible and appropriate.  All data should be preserved in a way that respects the nature of the project |
| “Days / days” | Refers to business days i.e. any day which is not a Saturday, Sunday or official public holiday in the Republic of South Africa. |
| Endorse | Declare public approval or support by the AREC |
| “Ethics” | are defined as the rules of conduct recognised in respect to a particular class of human actions or a particular group, and are concerned with how morally accepted outcomes can be achieved in specific situations |
| Exco | The AREC Executive Committee for the purpose of expedited approval of amendments. |
| Modify | To make minor or slight changes to aspects of the study |
| “Permission” | Obtaining permission is necessary when conducting research within the premises of a particular site where the animal species involved is found. |
| Reduction | Minimising the number of animals used per study, while enabling comparable levels of information with fewer animals, or to gain more information by using the same number of animals. |
| Refinement | Improve methods or techniques that will reduce distress, suffering or pain, the animals may be exposed to. |
| Replacement | Using methods that will replace or avoid using animals in a situation/study, they would otherwise have been used. |
| Responsibility | To adhere to all aspects and guidelines, governing the ethical use of animals in research and thereafter presenting the true outcomes from the data collected in a scientific manner that will add to the current knowledge base and or benefit man or animal or both. |
| Waiver | An ethics waiver (that is no clearance is needed) can only be awarded for studies where there is no active animal participation, e.g., in vitro lab studies, database studies, literature reviews, etc., or in lower groupings of invertebrates such as protozoans, annelids, and insects, where the risk of participant harm is low |

# REFERENCES

## Council for International Organizations of Medical Sciences (CIOMS) (2002);

## International Ethical Guidelines for Biomedical Research involving Human Subjects. Geneva;

## Department of Health, Ethics in Health Research: Principles, Processes and Structures, 2nd ed. 2015;

## Department of Health (2006). Good Clinical Practice (GCP). Pretoria.

## Human Sciences Research Council (HSRC) (n.d.). Research Ethics Committee Terms of Reference;

## South African National Standards for the Care and Use of Animals in Research and Teaching (SANS 10386:2021);

## ARENA/OLAW Institutional Animal Care and use Committee Guidebook (2nd edition 2002);

## Medical Research Council: (2000). Guidelines on Ethics for Medical Research: General Principles. Cape Town; and

## The North West University Research Ethics Committee.

# ACKNOWLEDGEMENTS

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

### North West University Research Ethics Committee; and

### University of Cape Town Research committee.

# Approval History of the sop

|  |  |  |  |
| --- | --- | --- | --- |
| **STRUCTURE CONSULTED** | **Target date for discussion\*\*** | **Date approved/ discussed#** | **Date noted#** |
| AREC | June 2022 |  | - |
| University Research Committee |  |  |  |

**\* 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 the Department of Health, Ethics in Health Research: Principles, Processes and Structures, 2nd ed. 2015 (“National Guidelines 2015”).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) and the South African National Standards for the Care and Use of Animals in Research and Teaching.

# SUPPORTING DOCUMENTATION

# All supporting and referenced documentation can be found on the Wits intranet site:

# [Animal Research Ethics Committee (AREC) (wits.ac.za)](http://intranet.wits.ac.za/academic/uro/Pages/Animal-Research-Ethics--Committee-(AREC).aspx)