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| **POLICY** **DOCUMENT** |

AREC INCIDENT / ADVERSE EVENT / NON-COMPLIANCE

WITS POLICY

Version Control

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| Policy Title | AREC INCIDENT/ADVERSE EVENT/NON-COMPLIANCE |
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| Last Updated |  |

# CONTEXT

The University of the Witwatersrand, Johannesburg (Wits or the University) is a research intensive university that strives for excellence in research and scholarly endeavour and hereby commits itself to conducting such activities with the utmost integrity. This *Policy* recognises the inherent academic and intellectual freedom associated with institutions of higher learning which enables the University to fulfil its core mission of sharing (teaching), transferring (using) and generating (research) knowledge. However, the *Policy* also commits such scholarly endeavour to comply with internationally accepted ethical standards, principles and practices whilst conducting research with both human and animal subjects.

This Policy is to be read in conjunction with the *Wits* *Code of Conduct[[1]](#footnote-1)*.

# PURPOSE OF THE POLICY

A guide for formal reporting of welfare violations, adverse events, adverse reactions and deviations (non-compliance) from approved applications of animal-based research linked to Wits

The following incidents should be monitored and reported as well as any:

1. shortcomings to Wits Occupational Health and Safety SOP’s that jeopardise the health and wellbeing of any and all personnel including Staff and Students involved in animal-based research;
2. shortcomings in the WRAF programme of animal care;
3. non-compliance with operating policies of Wits, WRAF and AREC; and
4. Action that may harm or compromise the reputation of Wits or the WRAF or interfere with the academic programme.

# DEFINITIONS

* 1. **‘A Deviation’** is an unplanned / unintentional change from the protocol not to be implemented as a systematic change to the protocol. Measured as a less serious non-compliance.
  2. **’An Adverse Event (AE)’** can be any unfavourable or unintended change in the structure (signs) or function (symptoms) in an animal after an intervention (product administration or intervention for study purpose),
  3. **‘An Adverse Reaction (AR)**’ can be all unwanted and unintended responses to any product administered, related to any dose administered. This definition also covers medication errors and uses outside what is foreseen in the protocol, including misuse and abuse of the product.
  4. **‘An Incident’** is an occurrence of any of the events described above.
  5. ‘**Animal**’ **(‘Animal Participants’** SANS, 2008) refers to “live sentient non-human vertebrate, including eggs foetuses and embryos that is: fish, amphibians, reptiles, birds and mammals, and encompassing domestic animals, purpose-bred animals, farm animals, wildlife and higher invertebrates such the advanced members from the *Cephalopoda* and *Decapoda[[2]](#footnote-2)”*.
  6. **‘****An Irregularity’** meansany unlawful act or omission committed by any person responsible for upholding the protocol, ethics and husbandry that could impact the study.
  7. **'AREC’** means the University’s Animal Research Ethics Committee.
  8. **‘A Violation’** is an intentional or unintentional change from the protocol that with expected impact on the study outcome, the welfare of the animals and impacts on safety of people or environment.
  9. **‘Ethics’** is a branch of philosophy that deals with moral issues and is concerned with “moral principles that govern a person's behaviour or the conducting of an activity” (Anon., 2018). In the context of this policy, the word ethics (and its adjective) is seen as part of the broader concept of research integrity but is used here with a focus on the independent assessment and approval of research (conducted by staff, students and researchers) as ethical before the research is initiated.
  10. **‘External research’** includes any research that may involve staff and/or students, be it on or off the Wits campuses, where the Principal Investigator is not a member of the Wits staff or student body.
  11. **‘Primary Investigator (PI)’** refers to a qualified person that applies for and thereafter oversees the scientific, technical and day-to-day management of the research. The PI refers to the person who assumes responsibility for a research project, protocol or study – the project leader.
  12. **‘Protocol Violation (PV)’** is intentional or unintentional divergence from the protocol that materially reduces the quality or completeness of the data. Non-compliance with directions of animal numbers, procedures, timelines or experimental design as stipulated in the protocol (approved application).
  13. **'Research Ethics Committee’** in the context of this Policy refers to an independent review committee constituted with a reasonable number of members, who collectively have the qualifications and experience to review and evaluate the ethics of proposed research.
  14. **‘Research for degree purposes’** connotes all research undertaken by Students and / or Staff of Wits for the purpose of attaining a qualification or degree.
  15. **‘Research for Non-Degree Purposes’** pertains to research undertaken by individuals or collaboratively by groups of researchers and includes contract research, institutional research and research by external bodies or individuals.
  16. **‘Research Impropriety (RI)’** is non-compliance with laws, regulations or policies regarding animal welfare as well as research, Staff and Student safety or the security of the facility.
  17. **Research Misconduct’** includes but is not limited to plagiarism, fabrication or falsification of performing, reviewing or reporting research results.
  18. **‘Researchers’** includes all staff and students and others who undertake research at and/or through Wits and maybe regarded as collaborator, partner, external supervisor, research associate, research assistant, etc.
  19. **'SANS 2008'** refers to the South African National Standards Guidelines 2008.
  20. **‘Staff’** refers to all categories of employees of Wits, including academic professional and administrative, whether jointly appointed, permanently appointed, appointed on a fixed term contract, contract or on a sessional basis, including postdoctoral fellows.
  21. **‘Stakeholders’** include all parties who have a vested interest in the implementation and outcome of research conducted at/or through Wits. They include at least the communities in which research is undertaken, specific participants in studies, sponsors, donors, alumni, etc.
  22. ‘**Student’** includes all persons registered full time or part time for a degree, diploma, licentiate or certificate of the University, which includes undergraduate and postgraduate students registered at Wits on a part-time or fulltime basis.
  23. **‘Welfare Violation (WV)’** The welfare of an animal is compromised if attention to its health, comfort, nourishment, and safety is not provided and it is therefore suffering from unpleasant states such as pain, fear, and distress.
  24. ‘**WRAF’** means the Wits Research Animal Facility.

# PRINCIPLES

National and international ethics and regulatory guidelines, require the Animal Research Ethics Committee (AREC) to have a standard operating procedure (SOP) which clearly defines the review and management process required for reviewing applications for animal research as well as reporting any welfare (WV) and compliance violations (CV) including adverse events (AE) or reactions (AR) during an AREC approved study.

# RESPONSIBILITY

All AREC members, WRAF Staff and Researchers of the University that have an interest in the wellbeing of the animals used for research and teaching as well as the reputation of Wits and WRAF must take any and all responsibility with their research and the animals that are used for such research especially in terms of the welfare of such animals, any compliance violations, any the adverse events or reactions that may arise.

# ORGANISATIONAL STRUCTURES AND THEIR RESPONSIBILITIES

In order for the University to fulfil its responsibilities regarding protocol violations, non-compliance and adverse effects or events as described in this Policy and, in particular, the formal review of such happenings, the University grants protection from reprisal to all Staff and / or Students arising from good faith reporting of incidents as per the University’s internal Whistle-blowers policies and procedures.

# PROCESS

**NOTE**: *All information gathered, people involved and outcome of any enquiry will be handled with discretion and confidentiality in line with Wits disciplinary rules (Document C2017/627A).*

*AREC and the Head of School / Department will be kept informed at the end of each stage of the investigation*.

* 1. **Incident Report** (ANNEXURE A: Incident Report Form)

Any information included in the Incident Report Form, should be factual and arise from personal observation or experience. The Incident Report Form should be sent to the Chairperson of the AREC for review.

* 1. **Initial Investigation** (ANNEXURE B: Initial Investigation Form)

The AREC Chairperson together with the Director: WRAF will do an initial investigation to decide whether a formal inquiry is required. If either of the parties are implicated in the report, it should be sent to the Deputy Vice-Chancellor: Research and Postgraduate Affairs (DVC: R&PGA), Director: Research Development and the Legal Adviser and Research Compliance Manager / Research Integrity Officer. The AREC Chairperson must advise the DVC: R&PGA and the Director: Research Development if a formal inquiry is required*.*

If the deviation is assessed to be *minor*, without expected impact on the study outcome, personnel occupational health and safety, or the welfare of the animals involved, no further action, apart from noting it as such, is required. It is the responsibility of the PI to report the matter in the next study report to AREC. Any person with repeat (1 previous) minor transgressions, may be suspended from being involved with the animal study (future studies), pending a formal investigation, inquiry and their findings.

* 1. **Formal Inquiry** (ANNEXURE C Formal Inquiry Form)

7.3.1 The following individuals may be required to submit reports addressing the allegations to the Chairperson of the Independent Commission of Enquiry for the initial investigation:

7.3.1.1 The Principal Investigator / PI;

7.3.1.2 The Area Manager where the animal is kept;

7.3.1.3 The Director: WRAF;

7.3.1.4 The WRAF Veterinarian;

7.3.1.5 The Head of the relevant Research Group/Unit;

7.3.1.6 The Head of the relevant School/Department; and

7.3.1.7 The chairperson of the AREC.

* 1. **Formal Enquiry** 
     1. The panel composing of at least five (5) people will be appointed by the Chairperson of the AREC. Two (2) people with no link to the person involved or the incident itself or members of the AREC and / or no person from the WRAF have to be included. A veterinarian, a representative of animal welfare and finally someone from the University’s Research Office or their nominee must be represented. The panel will select a chairperson.
     2. An additional member, with special expertise required to evaluate technical aspects of the substance of the complaint, may be invited while ensuring that the impartiality of the panel is not compromised.
     3. The panel chair has to draw up timelines for submission of documentation and the investigation phase of the matter and then set a date for the delivery of the panel’s decision.
  2. **Powers of the Enquiry Panel**
     1. Request further information to assist with their task;
     2. Interview parties who can contribute information to provide insight into the incident to the panel;
     3. Uphold the complaint and in consultation with the chair of the University’s Advisory Committee of Ethics (ACE) to the DVC: R&PGA and the Chair of AREC. They will decide on an appropriate disciplinary procedure to be followed in line with the Wits disciplinary policy and procedures. They have to determine at this point to cease all experimentation for this study, or to have it continue with the assistance of a qualified supervisor until such time as any possible appeal procedure is complete;
     4. Refer the complaint to the University’s Advisory Ethics Committee to the DVC: R&PGA (ACE); and
     5. Dismiss the complaint.
  3. **Appeal Procedure** 
     1. Any person involved and not satisfied with the outcome of the inquiry, may appeal in writing to the University’s Advisory Ethics Committee to the DVC: R&PGA, motivating the reason for appeal.
     2. An appeal to the finding has to be lodged within fourteen (14) days in writing.
     3. If the matter has been referred to the ACE and upheld, the decision is final.

# ACKNOWLEDGEMENTS

The following sources are acknowledged for their input into the development of this *Policy*.

* Medical Research Council. *Guidelines on Ethics for Medical Research*. Books 1-5. MRC SA (refer <http://www.sahealthinfo.org/ethics/ethics.htm>)
* Guide for the Care and Use of Laboratory Animals, Institute for Laboratory Animal Resources, National Research Council, National Academy Press
* South African Bureau of Standards. South African National Standard: The Care and Use of Animals for Scientific Purposes. SANS 10386: 2008
* Stellenbosch University, *Framework Policy for the Assurance and Promotion of Ethically Accountable Research*, March 2009
* Reporting of Protocol Deviations and Unanticipated Problems; Standard Operating Procedures, Animal Ethics Committee, Faculty of Health Sciences, University of Cape Town.
* Vancouver Protocol. Accessed 22 May 2010 <http://www.authorder.com/index.php?option=com_content&view=article&id=28&Itemid=47>
* https://www.research.va.gov/vacentralirb/sop/default.cfm: scire-lb.org/wp-content/uploads/2016/.../Reporting-Research-Events-5-05-16-1.docx
* https://www.ucl.ac.uk/jro/documents/jro\_inv\_sop\_05: Standard Operating Procedure for the Recording, Management and Reporting of Adverse Events by Investigators
* https://ctsi.wakehealth.edu/ar-reporting-procedures: Animal Research Reporting Procedures
* <http://www.health.uct.ac.za/sites/default/files/image_tool/images/116/FHS_AEC_Protocol_Violation_June_2012.docx>:
* Wits code of conduct for researcher or research ethics members (2018)
* Wits policy document; Research Ethics (2018)

## Wits logo1ANNEXURE A: Incident Report in Animal Research

Fallible Form (FOR OFFICIAL USE ONLY)

To be completed for reporting any incident or non-compliance during research. *This should reach the AREC Chairperson within 24 (twenty-four) hours after the incident has occurred.*

*This form needs to be completed electronically.*

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| AREC number: | | | Enter Number | | | | Date of Incident: | | | | | Select Date |
| Name of PI of Study: | | | Enter Name | | | | Time of Incident: | | | | | Enter Time |
| Study Title: | Enter Title | | | | | | | | | | | |
| Location of Incident: | | | | Enter Place | | | | | | | | |
| Person/s reporting the incident Name/s and staff or student number if applicable: (this information is confidential) | | | | Enter Name | | | | | | | | |
| Enter Number | | | | | | | | |
| School/Department/External | | | | Enter Entity | | | | | | | | |
| Email for person/s above: (this information is confidential) | | | | Enter Email | | | | Cell Number: | | | Enter Number | |
| Office Number: | | | Enter Number | |
| Person/s implicated in the incident (Name/s): | | | | Enter Name | | | | | | | | |
| Person 1st reported to (Name) and indicate if external or internal to the University: | | | | Enter Name | | | | | | | | |
| Species involved: | | | | Enter Species | | | | Age range: | | | Enter Age | |
| Number of Animals: | | | | Enter Number | | | | Sex: | | | Choose an item. | |
| First reporting action (select): | | | | **Verbal** | **Written** |  | | | | | | |
| Provide a short, factual description of the nature of the incident you personally observed: | | | | Enter Details | | | | | | | | |
| Any other relevant information: | | | | Enter Information | | | | | | | | |
| Names of other people associated with the incident: | | | | Enter Name/s | | | | | | | | |
| Signature | | Shape  Description automatically generated with low confidence | | | | | | | Date | Select Date | | |
| (FOR OFFICE USE ONLY)Incident Reference Number: *Click or tap here to enter text.* | | | | | | | | | | | | |

## Wits logo1ANNEXURE B: Initial Investigation of Incident and/or Non-Compliance in Animal Research

Fallible Form (FOR OFFICIAL USE ONLY)

To be completed by the Animal Research Ethics Committee (AREC) Chairperson or the Wits Research Animal Facility (WRAF) Director [who received the incident report in order to determine whether to call a formal investigation and / or enquiry].

Date Complaint Received: Select Date

Complaint Received by: Enter Name

AREC Clearance Certificate Number: Enter Number

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Date of incident: | Select Date. | | Time of incident: | | tap here to enter time. | |
| Where incident happened | Enter Text. | | PI staff/student number: | | tap here to enter text. | |
| PI Name: | Enter Text. | | Department / School / External: | | Enter Text. | |
| Persons notified: | Enter Text. | | Date notified: | | Select Date. | |
| Enter Text. | | Select Date. | |
| Enter Text. | | Select Date. | |
| Indicate your selection | | **Deviation** [unplanned change] | Choose an item. | **Violation** [change with impact on outcome] | | Choose an item. |
| Classification of the violation / incident | | | Choose an item. | | | |
| Click or tap here to enter text. | | | | | | |

**FINDINGS OF INITIAL REVIEW OF INFORMATION** (FOR OFFICE USE ONLY)

|  |  |
| --- | --- |
| Panel Finding | Choose an item. |

**Proposed corrective actions to be considered includes, but is not limited to:**

[click on block/s to select choice]

* No action required
* Modification of the protocol
* Additional education and training
* Refer for Formal Inquiry
* OTHER [e.g. Suspend study/individual]

Enter recommendations not in list provided

If a FORMAL INQUIRY is required, the appointed panel members should be appointed and in possession of the required documentation and reports no later than 7 (seven) working days after the incident has taken place. Incident Reference Number: Click or tap here to enter text.

## Wits logo1ANNEXURE C: Formal Inquiry of Incident and / or Non-Compliance in Animal Research

Fillable Form (FOR OFFICIAL USE ONLY)

To be completed by the Inquiry Panel

Date of Inquiry: Select Date Incident Reference Number: Enter Number

Date of Incident: Select Date AREC Number: Enter Number

Reported to Initial Investigator: Select Date PI Name: Enter Name

PI Staff or Student Number: Enter Number

Department / School / External: Enter Name

Non-Compliance Classification: Select an item.

|  |  |  |  |
| --- | --- | --- | --- |
| Panel members: | 1 Enter Name | Position/Role in panel Composition: | 1 Enter Position |
| 2 Enter Name | 2 Enter Position |
| 3 Enter Name | 3 Enter Position |
| 4 Enter Name | 4 Enter Position |
| 5 Enter Name | 5 Enter Position |
| 6 Enter Name | 6 Enter Position |
| Additional information requested | 1 Request Information | | |
| 2 Request Information | | |
| 3 Request Information | | |
| 4 Request Information | | |
| 5 Request Information | | |
| Person(s) who submitted reports addressing the allegations: | 1 Enter Name | Report Reference: | 1 Reference |
| 2 Enter Name | 2 Reference |
| 3 Enter Name | 3 Reference |
| 4 Enter Name | 4 Reference |
| 5 Enter Name | 5 Reference |

**FINDINGS OF FORMAL INQUIRY PANEL** (FOR OFFICE USE ONLY)

|  |  |  |
| --- | --- | --- |
| Motivate Findings | | |
| Panel Finding | Choose an item. |

**Proposed corrective action/s to be considered includes, but is not limited to:**

Click on box/s next to selection/s

* Modification of the protocol
* Additional education and training
* PI work under strict supervision and frequent reporting
* Limit research activities, use of facilities, use of data.
* PI restricted to work as co-investigator only
* Research on approved protocol allocated to new PI
* Complete cessation of the study – AREC to advise on the fate of the animals
* OTHER (to be indicated by the panel)

Choose an item.

Enter recommendations not in list provided

**Dated:** Select Date **Signature: Shape

Description automatically generated with low confidence**

Inquiry Chair

1. HRG/26, C2006/482, 8 December 2006 (<http://intranet.wits.ac.za/exec/registrar/Policies/HRG26%20-%20Code%20of%20Conduct.pdf#search=code%20of%20conduct>) [↑](#footnote-ref-1)
2. South African National Standards Guidelines 2008 [↑](#footnote-ref-2)