

RESEARCH INTEGRITY PROCEDURES

This is a set of Procedures related to Research Integrity and is approved by the URC.

These Procedures must be read in conjunction with the Policy on Research Integrity.

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1. **DEFINITIONS**

For the purpose of clarity the defined words and phrases are written in italics indicating their specific meanings in the context of this set of procedures. Thus pertinent definitions include, in alphabetical order:

- 1.1. '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* <u>before the research is initiated</u>.
- 1.2. '**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.
- 1.3. 'Institutional research' includes research conducted by *staff* and/or *students*, be it on or off the Wits campuses, where the *Principal Investigator* is a member of the *staff* or *student* body at Wits.
- 1.4. '**Principal investigator**' refers to the person who assumes responsibility for a research project, protocol or study the project leader.
- 1.5. '**Research Ethics Committee**' in the context of this policy refers to an independent review committee constituted with a reasonable number of members greater than



nine, who collectively have the knowledge and experience to review and evaluate the *ethics* of proposed research.

- 1.6. 'Research participants' including:
 - 1.6.1. '**Human participants**' that generally connotes individuals about whom an investigator conducting research obtains data through intervention or interaction with the individual or identifiable private information.
 - 1.6.2. '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, purposebred animals, farm animals, wildlife and higher invertebrates such the advanced members from the *Cephalopoda* and *Decapoda*".
- 1.7. '**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.
- 1.8. 'Vulnerable¹ Persons or Groups' refers to individuals or groups who have "... substantial incapacity to protect their own interests owing to such impediments as lack of capability to give informed consent, lack of alternative means of obtaining medical or psychological care or other necessities, or being a junior or subordinate member of a hierarchical group". (Anon., 2017) Although vulnerability must be decided on a case by case basis by the research ethics committee some guidelines include:
 - 1.8.1. Persons under the age of 18 years (children and adolescents)²;
 - 1.8.2. Persons with mental or physical incapacity;
 - 1.8.3. Persons traumatised due to exposure to physical, psychological and/or emotional abuse or trauma).
- 1.9. 'Wits Research Community' consists of:
 - 1.9.1. Wits '**staff'** members which refers to all categories of employees of Wits, including academic, professional and administrative, whether jointly appointed, permanently appointed, appointed on fixed term contracts or on a sessional basis, including postdoctoral fellows;

¹ See NHREC, 2015. Ethics in Health Research. Principles, Processes and Structures. Department of Health, Pretoria, 67pp.

² Even here the descriptor "under 18 years of age" should not be applied rigidly, but rather on a case by case basis. There are very often cases where minors are able to give consent independently of guardians, for instance, people under 18 who have no guardians.



- 1.9.2. '**Students'** includes all persons registered full time or part time for a degree, diploma, licentiate or certificate of the University, which includes undergraduate and postgraduates; and
- 1.9.3. '**Researchers**' who are people who undertake research at and/or through Wits and may include external researchers, external collaborators, partners, external supervisors, non-*staff* research associates, non-*staff* research assistants, and so on.

2. **RESPONSIBILITY FOR ETHICS**

It is the responsibility of individual *staff*, *students* and *researchers* to ensure they uphold the principles of research integrity described in this policy and as guided by the Singapore Statement on Research Integrity (see Appendix). Part of this commitment is to have all research that directly or indirectly, deliberately or accidentally involves *human* and/or *animal participants*, especially *vulnerable people and groups*, considered by a *research ethics committee* and approved as *ethical* <u>before it is implemented and / or conducted</u>. No data involving human or animal subjects can be collected until the correct ethics clearance has been obtained.

It is the responsibility of the University to ensure that there is an accredited structure in place to promptly and independently review research that directly or indirectly, deliberately or accidentally involves *research participants*, especially *vulnerable people and groups*, to declare it *ethical* in accordance with the above principles and relevant legislation. Although the University retains responsibility the task of assessment is delegated to the *Research Ethics Committees* by the Deputy Vice-Chancellor for Research and Postgraduate Affairs (DVC-R&PGA). The administration supporting the *Research Ethics Committees* is managed normally by the University Research Office. To this end, the University Research Office has a dedicated function called the Office of Research Integrity, headed by the Research Integrity Officer, which is responsible for the stewardship of research integrity and *ethical* approvals in the University.

The University is further responsible for providing a mechanism that allows appropriate and relevant training in respect of *staff* and *students* and members of the *research ethics committees.* Provision of this means of training does not remove the responsibility of the individual researcher for breaches or violations of research integrity.

3. ORGANISATIONAL STRUCTURES AND THEIR RESPONSIBILITIES

In order for the University to fulfil its responsibilities regarding the *ethical* conduct as described in this policy and, in particular, the formal review of the *ethics* of proposed research studies, the University constitutes the following committees which are appointed and are answerable to the URC:

3.1. **The Advisory Committee on Ethics** (ACE): This committee has a threefold responsibility:



- 3.1.1. It provides knowledgeable advice to the DVC-R&PGA on all matters related to maintaining *ethical* standards for research and scholarly endeavour at Wits. The ACE reports to the Senate Graduates Committee for *student* related matters and to the URC for research related matters or both when *student* related matters cannot be separated from *research* matters.
- 3.1.2. It considers and pronounces on appeals raised against the decisions of the *Research Ethics Committees* brought by aggrieved *staff, students, researchers*, or external parties; and
- 3.1.3. When requested it will provide support for the *Research Ethics Committees* in the form of providing scholarly, legal and philosophical inputs into their deliberations.
- 3.1.4. The ACE is normally constituted with a suitably qualified lawyer; philosopher; bioethicist; sociologist; a representative from one of the humanities; the Head of the Research Integrity Office; and one external person and the DVC-R&PGA who chairs the ACE or his/her delegated representative. Decisions should preferably be made on the basis of consensus but where this is not possible they will be based on a simple majority of the quorum (75% of membership). The Chair can break deadlocks with a casting vote. The ACE will meet quarterly or as necessary with special meetings called by the Chair giving members a notice period of at least five working days.
- 3.2. **Research Ethics Committees**: Four independent *Research Ethics Committees* are responsible for the review of the *ethical* considerations related to *institutional* and *external research* involving the *Wits research community*. The committees and their sub-committees are listed below:
 - 3.2.1. Human Research Ethics Committee (HREC) focused on '**Medical**' matters (**HREC-M**) assumes responsibility for the review of the *ethical* considerations related to medical processes—including basic scientific research of human anatomy, physiology and pathologies and clinical research and clinical trials—which investigate *human participants* including *vulnerable groups*. The HREC-M has one sub-committee, namely:
 - 3.2.1.1. The Biobanks Ethics Committee (**BEC**) that considers the ethical principles of storing biological samples and associated biological data sourced from *human participants*; and the ethical principles of sharing of biological samples and biomedical data for collaborative research;
 - 3.2.2. Human Research Ethics Committee (HREC) focused on '**Non-Medical**' matters (**HREC-NM**) assumes responsibility for the review of the *ethical* considerations related to research involving *human participants* in all non-medical situations, more specifically in research in social, behavioural, economic and educational situations. As an illustrative example, research conducted in government and a non-governmental medical facility that does <u>not involve in-patients</u> should be



referred to the HREC-NM. HREC-NM has several sub-committees, based at school or departmental level, whose role is to manage the ethics applications submitted by students on taught programmes including Honours/4th year and Masters by Coursework and Research Report. Detailed guidelines and procedures for this process are given on the HREC-NM website. Ethics applications for Non-Medical research undertaken by all Wits staff and students on Masters by Dissertation and PhD programmes are submitted to the University HREC-NM committee.

- 3.2.3. The Animal Ethics Control Committee (**AECC**) that oversees all *ethical* decisions related to the use of *animals* in research. It has one subcommittee:
 - 3.2.3.1. The Animal Research Ethics Committee (**AREC**) is charged with monitoring the treatment of *animal participants* used in research and teaching at Wits, reviewing all protocols involving animal use in order to ensure that they are in accordance with acceptable ethical standards, and ensuring that all aspects of the care and use of animals in research and teaching comply with national and international standards and norms and relevant national laws.
- 3.2.4. Institutional Biosafety Committee (**IBC**) focused on all issues related to the identification of risks related to bio-hazards.
- 3.3. The ACE and the four *Research Ethics Committees* are organised and administered at the central University level while some of the sub-committees are administered at the School level. Each committee has its own terms of reference, which defines its mandate, purpose and scope arising out of this Policy. The procedures of these committees are defined in appropriate standard operating procedures.
- 3.4. During the review of *ethical* considerations a *research ethics committee* may make recommendations to the *Principal Investigator* with a view to strengthening the scientific quality or selected methodology of a proposed study. However, these recommendations that are unrelated to *ethical* considerations should not be converted into mandatory instructions nor should they prevent the research from being undertaken through the withholding of an ethical clearance certificate.

4. **PROCESS**

The responsibility for obtaining *ethics* clearance is described by the following statements:

4.1. *Ethics* clearance is required for all *institutional* and *external* research through the appropriate structures outlined above prior to the commencement of data collection and cannot be issued retrospectively³. This assessment process by definition introduces a bottleneck to the research process and therefore the *Research Ethics*

³ See section 1.6.9 of DOH2015 which states that "Ethics Retrospective review and approval or clearance is not permitted" <u>http://www.nhrec.org.za/index.php/grids-preview</u>



Committees commit to a four week turn around assuming that the application is fully compliant and appropriate⁴

- 4.2. All research proposals/protocols and treatises/dissertations/theses should include a section on ethical considerations, where appropriate.
- 4.3. In line with the mandates and the terms of reference of the four *Research Ethics Committees*, researchers are required to adhere to the procedures set out by these structures and provide all relevant documentation to inform the review of an application for *ethics* clearance.
- 4.4. The responsibility for the submission of an application rests with the *Principal Investigator*. A *student* supervisor may submit an application for an overarching project involving a number of student participants. However, on occasion the *student* can fulfil the role of *Principal Investigator*. In such cases the *student's* supervisor bears responsibility for making the *student* (as *Principal Investigator*) aware of the policy and procedures for obtaining the necessary *ethics* clearance for research to be undertaken.
- 4.5. The *Principal Investigator* is responsible for completing and submitting the relevant documentation as per the rules and procedures with the approval of the research supervisor. The *Principal Investigator* is furthermore responsible for his/her conduct in relation to the final implementation of the research process for which approval has been granted.
- 4.6. In the event of any material deviation from the approved protocol or research project that impacts on the ethical nature of the proposed research, it is the responsibility of the *Principal Investigator*, or in the case of a *student* as *Principal Investigator* the joint responsibility of the *student Principal Investigator* and supervisor to bring such amendments to the attention of the relevant *Research Ethics Committee* as soon as possible.
- 4.7. Suspected breaches of research integrity must be reported either to the Chair of the relevant ethic committee or to the Research Integrity Officer either directly or preferably via the University Integrity Hotline (email: <u>Wits.Integrity@Wits.ac.za</u> or telephone: 082 938 45 59/69).
- 4.8. The Research Integrity Officer will take all such reports seriously and investigate them thoroughly using the resources available with the University, including but not limited to: the ACE, the Legal Office, the Employee Relations Office, the Gender Equity Office, the Senate and Faculty committee structures and the University Research Office.

⁴ In other words where all the relevant information is provided in the correct form.



4.9. Should the principles of research integrity described in the policy be breached or violated then the Research Integrity Officer will invoke the University disciplinary procedures.

5. ACKNOWLEDGEMENTS

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APPENDIX: SINGAPORE STATEMENT ON RESEARCH INTEGRITY

Preamble. The value and benefits of research are vitally dependent on the integrity of research. While there can be and are national and disciplinary differences in the way research is organized and conducted, there are also principles and professional responsibilities that are fundamental to the integrity of research wherever it is undertaken.

> PRINCIPLES Honesty in all aspects of research Accountability in the conduct of research Professional courtesy and fairness in working with others Good stewardship of research on behalf of others

RESPONSIBILITIES

 Integrity: Researchers should take responsibility for the trustworthiness of their research.
 Adherence to Regulations: Researchers should be aware of and adhere to regulations and policies related to research.

3. Research Methods: Researchers should employ appropriate research methods, base conclusions on critical analysis of the evidence and report findings and interpretations fully and objectively.

4. Research Records: Researchers should keep clear, accurate records of all research in ways that will allow verification and replication of their work by others.
5. Research Findings: Researchers should share data and findings openly and promptly, as soon as they have had an opportunity to establish priority and ownership claims.

6. Authorship: Researchers should take responsibility for their contributions to all publications, funding applications, reports and other representations of their research. Lists of authors should include all those and only those who meet applicable authorship criteria.

7. Publication Acknowledgement: Researchers should acknowledge in publications the names and roles of those who made significant contributions to the research, including writers, funders, sponsors, and others, but do not meet authorship criteria.

8. *Peer Review:* Researchers should provide fair, prompt and rigorous evaluations and respect confidentiality when reviewing others' work.

9. Conflict of Interest: Researchers should disclose financial and other conflicts of interest that could compromise the trustworthiness of their work in research proposals, publications and public communications as well as in all review activities.

10. Public Communication: Researchers should limit professional comments to their recognized expertise when engaged in public discussions about the application and importance of research findings and clearly distinguish professional comments from opinions based on personal views.

11. Reporting Irresponsible Research Practices: Researchers should report to the appropriate authorities any suspected research misconduct, including fabrication, falsification or plagiarism, and other irresponsible research practices that undermine the trustworthiness of research, such as carelessness, improperly listing authors, failing to report conflicting data, or the use of misleading analytical methods. 12. Responding to Irresponsible Research Practices: Research institutions, as well as journals, professional organizations and agencies that have commitments to research, should have procedures for responding to allegations of misconduct and other irresponsible research practices and for protecting those who report such behavior in good faith. When misconduct or other irresponsible research practice is confirmed, appropriate actions should be taken promptly, including correcting the research record. 13. Research Environments: Research institutions should create and sustain environments that

encourage integrity through education, clear policies, and reasonable standards for advancement, while fostering work environments that support research integrity.

14. Societal Considerations: Researchers and research institutions should recognize that they have an ethical obligation to weigh societal benefits against risks inherent in their work.

The Singapore Statement on Research Integrity was developed as part of the 2nd World Conference on Research Integrity, 21-24 July 2010, in Singapore, as a global guide to the responsible conduct of research. It is not a regulatory document and does not represent the official policies of the countries and organizations that funded and/or participated in the Conference. For official policies, guidance, and regulations relating to research integrity, appropriate national bodies and organizations should be consulted. Available at: www.singaporestatement.org