Standard Operating Procedures

Wits HREC-Medical

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Version Control

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Version numbering scheme:
0 = early rough drafts
1 = drafts that contain inputs from Wits HREC-Medical
2 = final drafts that are ready for approval
3 = Approved versions

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1. Objective of this Standard Operating Procedure

The overarching objective of this Standard Operating Procedure (SOP) is to contribute to the promotion of a culture of ethically responsible research in the clinical, medico-social and biomedical sciences at the University of Witwatersrand, Johannesburg (hereafter referred to as the University or Wits). More specifically the SOP will create a framework in which the Wits Human Research Ethics Committee - Medical (Wits HREC (Medical) or Committee) can operate. This will, in turn, enable the Committee to provide a consistent and quality rich service of reviewing research proposals against an ethically responsible framework. The work of the Committee is informed by the University Research Integrity Policy and the Wits HREC (Medical) Terms of Reference (ToR).

2. The Context in which the Wits HREC (Medical) Performs it Duties

Wits will ensure that the Wits HREC (Medical) is able to make independent decisions related to the assessment and review of the ethics of proposed research projects, without interference. Wits will ensure that this independence of decision making is protected, especially in the ambit of the University. Outside interference is not in Wits' domain but Wits must oppose such interference. In its structure and functioning, and in the execution of its duties and responsibilities, the Committee will follow the principles and guidelines stipulated in:

- The Constitution of South Africa, Act 108 of 1996;
- The Children's Act, Act 38 of 2005;
- National Health Act, Act 61 of 2003;
- Promotion of Access to Information Act, Act 2 of 2000;
- Protection of Personal Information Act, Act 4 of 2013;
- ICH (Good Clinical Practice / GCP) and Declaration of Helsinki (2017)
- South African Good Clinical Practice / SAGCP (2020)
- Department of Health, Ethics in Health Research: Principles, Processes and Structures, 2nd Ed. 2015 ("National Guidelines 2015") – soon to be updated to the Department of Health, Ethics in Health Research: Principles, Processes and Structures, 3rd Ed. 2023 ("NDoH 2023 Guidelines");
- The National Health Research Ethics Council, insofar as it is relevant to research in the health sciences, biomedical and medical;
- The University Research Integrity Policy;
- The University Code of Conduct for Researchers and/or REC members; and
- Official documents of professional bodies and scientific organisations, in so far as they

are relevant to research in the medical sciences, broadly construed.

3. Composition of the Wits HREC (Medical)

3.1. Committee Membership

The Wits HREC (Medical) must have a minimum of 9 (nine) members including the Chairperson, to be properly constituted. The membership should ideally include, noting that all categories below are neither exhaustive nor intended to be exclusive of 1 (one) another, at least 1 (one):

- Layperson, preferably from the community in which the research is to take place. A layperson is viewed as an ordinary person with no specific qualification in a given profession and/or does not have specific knowledge of a certain discipline / field, for example, a member of the community or someone with an interest in spiritual care;
- Members with knowledge of, and current experience in, the professional care, counselling or health-related treatment of people. Such a member might be, for example, a medical practitioner, psychologist, social worker or nurse;
- Member with professional training and experience in qualitative and quantitative research methodologies including statistics;
- Member with expertise in molecular biology and human genetics;
- Member with expertise in radiology;
- Representative of local Government health structures;
- Member with expertise in epidemiology;
- Member with experience of health communication and education;
- Member with expertise in mental health;
- Member who holds a legal qualification or is legally qualified.

The Committee should 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 Committee must include members of both genders, although not more than 75% (seventy five percent) should be either male or female.

The Committee can co-opt other members:

- Specialist advisors to help review research proposals where the content of the proposed research is not within the areas of expertise of the Committee membership; and or
- Emeritus advisors, namely, people with experience whose terms of membership have ended, but who can help with mentorship and capacity development.

Such co-opted advisors are not regarded as full members and will not be able to vote or to be counted in the quorum.

- All Wits HREC (Medical) members including co-opted members and layperson / external members must: Protect the interests (rights and welfare) of the research participants who volunteer to take part in scientifically sound research.
- Decide independently whether the proposed research protects the interests of participants adequately and keep to exemplary standards in research activities
- Act in the best interests of the University and the Wits HREC (Medical). This obligation must be observed over any duty a member may owe to those electing or appointing him or her.
- Participate in the deliberations and decisions of the Wits HREC (Medical) with the object of promoting the best interests of the University and the Wits HREC (Medical), drawing on his or her knowledge and experience.
- Act in good faith, honestly and for a proper purpose.
- Exercise appropriate care and diligence in decision-making.
- Preserve the dignity of the research participants, the University and the Wits HREC (Medical) and respect and abide by and the Wits HREC (Medical) decisions.
- Spend as much time as is required to diligently perform their duties (this will normally mean devoting more time over and above that required for attending and the Wits HREC (Medical) meetings).

3.2. Quorum

A minimum of 50% (fifty percent) plus 1 (one) of members must be present for a Wits HREC (Medical) meeting to constitute a quorum. For a Sub-Committee, a minimum of 3 (three) members must be present to constitute a quorum.

3.3. Duration of Membership

Members including the Chair and Co-Chairs of the Wits HREC (Medical) are appointed for a period of 5 (five) years and can be re-appointed for a second 5 (five) year term. The maximum period of service is therefore 10 (ten) years.

3.4. Recruitment and Appointment of Members

Each year a call for new members will be published in the University through the Deans, Heads of School, Faculty HR Managers and the Wits News channel. The number of new members to be recruited each year will depend on the needs of the Committee and the number of members resigning or retiring. Applications, including a brief motivation and CV, must be submitted to the Wits HREC (Medical) Secretariat. These applications, including those from people seeking re-appointment, will be reviewed by a sub-committee of the Wits HREC (Medical) chaired by the Chairperson of the Committee. The selected candidates will be approved and appointed by the Deputy Vice-Chancellor for Research and Innovation (DVC: R&I). Any potential members are to attend a minimum of 2 (two) Wits HREC (Medical) meetings as observers before being appointed

to the Wits HREC (Medical).

Each new member and reappointed member will receive an appointment letter, signed by the DVC: R&I, referring to the ToR, this SOP, Confidentiality Declaration, Code of Conduct and Declaration of Interest. The appointment letter will also provide the assurance by the University that the Committee members are indemnified from any personal liability against claims that may arise in the course and scope of ordinary business of the Committee.

3.5. Induction of New Members

All the new members will take part in a formal induction programme that will introduce them to the functioning of the Committee and their responsibilities. The induction programme will be arranged by the Chairperson of the Committee. They will receive an introductory pack of information which will include the following, but not limited to: Letter of Appointment, University Research Ethics Policy, Wits HREC (Medical) ToR and SOP, Wits Code of Conduct, Confidentiality Declaration (to be signed by the members and returned to the Secretariat), National Guidelines 2015 (NdoH 2023 Guidelines, SAGCP (2020) and other documents that maybe required. After an initial briefing training will be achieved through observation, mentoring and "on the job" experience.

All members are required to complete an accredited ethics content and GCP training course and provide proof of completion to the Chairperson within 6 (six) months of joining the Committee. This training is to be renewed every 3 (three) years.

Upon appointment to the Wits HREC (Medical), new members must sign applicable confidentiality declaration, the University's Code of Conduct, Conflict of Interest Declaration and any other relevant documentation that may be required in future.

All Wits HREC (Medical) members will receive an acknowledgment of service at the end of each year that they have served. This certificate will indicate the member's involvement with the Committee and serve as evidence of their academic citizenship in the University.

3.6. Appointment of the Chairperson and the Co-Chairpersons

The Chairperson of the Wits HREC (Medical) is a paid position normally at the level of 50% (fifty percent) of a full-time professorial equivalent. The recruitment of the Chairperson will follow normal University recruitment processes and policies, including advertising of the position. The selection committee for the recruitment process will include 2 (two) representatives of the Wits HREC (Medical), 2 (two) members of the academic leadership within the Faculty of Health Sciences, a Chairperson from another Wits research ethics committee and 2 (two) members of the University Research Office. Additional members may be required by the Wits Human Resources Department as per their policies. The selection criteria will include, at least, a deep knowledge of ethically responsible research and experience on an ethics review committee.

The appointment of the Chairperson will be for a period of 5 (five) years. In the fifth year the position will be advertised, and the incumbent can reapply. No 1 (one) person will be allowed more than 2 (two) 5 (five) year terms as Chairperson and Co-Chairperson. Previous terms as a member will not impact on this term. Once a Chairperson has served their full term as a Chairperson, they are not permitted to be appointed as Co-Chairperson.

The Chairperson will be regarded as a member of the Wits HREC (Medical) and will carry the responsibilities of presiding over the Committee's work and responsibilities, ensuring the smooth and efficient running of the Committee and to provide leadership both on a strategic and operation level. To this end, the incumbent will work closely with the Secretariat and with the University Research Office tasked to administer the Committee.

The Wits HREC (Medical) will have several Co-Chairpersons, at least 2 (two), but more if necessary. They will be selected from the membership by the Committee, through a nomination and decision-making process by the Wits HREC (Medical). The Co-Chairpersons remain members of the Committee and have the additional responsibility of supporting the Chairperson and representing the Chairperson during periods of absence. The role of the Co-Chairpersons is seen in a development light, thus preparing them to compete competently for the role of Chairperson as described above. Their membership term is as for normal members of the Committee.

3.7. Termination of Membership

If a member, including a Co-Chairperson, is absent from 3 (three) consecutive scheduled Committee meetings without an apology and explanation, then the absence must be addressed by the Chairperson in writing and may result in the termination of the membership. Virtual attendance by members is acceptable.

In situations where a member is on sabbatical leave, maternity leave, is seriously ill, or under circumstances where they cannot fulfil the requirements of membership, the membership of the person concerned can be put into abeyance until they are able to continue serving normally.

Membership can be terminated for good cause including but not limited to poor performance or inappropriate performance.

For purposes of this paragraph good cause includes *inter alia* decision-making in bad faith or failure to declare a conflict of interest. Such decisions must be decided by a specially constituted independent sub-committee chaired by the Chairperson of the Wits HREC (Medical) and communicated in writing to the member. People whose membership is terminated in this manner may appeal the decision by writing a motivation to the University Research and Innovation Committee (UR&IC). The UR&IC will consider the matter and call for all necessary inputs before making a decision. The decision of the UR&IC in this matter will be regarded as full

and final.

Should the Chairperson miss 2 (two) consecutive scheduled meetings without explanation or if the Committee considers the Chairperson's performance less than adequate, then they can bring this to the attention of the UR&IC in writing. The UR&IC will consider the matter and call for all necessary inputs before making a decision on the way forward. If they uphold the decision, then the DVC(R&I) will refer the matter to the University's Employee Relations to institute disciplinary procedures against the Chairperson using the University's normal disciplinary procedures and in line with the Labour Relation legislation.

3.8. Managing Conflicts of Interest

Wits HREC (Medical) members must disclose all conflicts of interest, no matter how small or apparently insignificant, before they have a bearing on decision making which is in line with the University's Conflict of Interest Policy.

Wits HREC (Medical) members are required to declare any conflict of interests at the start of every year by signing a declaration of interest. Members are to further declare any conflicts of interests before and in meetings. Members should not review or make decisions about research proposals in which they are involved personally or financially or where they may receive any benefit from the approval of the ethics related to a research proposal. When such a proposal is discussed, the member concerned must declare the potential conflict and must then recuse himself / herself from the meeting while that matter is being discussed. This absence must be minuted. The specific member will be invited back to re-join the meeting after the review has been complete. Members are required to declare if they have a relationship with an applicant in order for the Committee to decide if there are any conflicts that need to be addressed.

In the case of a conflict impacting on the Chairperson, a Co-Chairperson will preside over the meeting and the Chairperson must recuse himself / herself while the matter is being discussed and decided upon. This absence must be minuted. The Chairperson will be invited back to re-join the meeting after the review has been complete.

4. Sub-Committees within the Wits HREC (Medical)

The Wits HREC (Medical) can form sub-committees to enable its work. One example is the Biobanks Ethics Committee (BEC). The delegation by the Wits HREC (Medical) Chair, of responsibility to a properly constituted sub-committee will not include delegation of authority. The Committee remains accountable for all decisions related to ethically responsible research. Thus, all decisions taken by a sub-committee need to be ratified at a Wits HREC (Medical) meeting.

Membership regulations of sub-committee are the same as for the Committee. A member of the sub-committee may also serve as a member of the Wits HREC (Medical), but this is not mandatory. As with Wits HREC (Medical) members, sub-committee members must also attend research ethics training sessions to keep abreast with the latest changes in this field. Evidence of this training must be lodged with the Secretariat at least once every 3 (three) years.

The sub-committees of the Wits HREC (Medical):

- Will comply fully with this SOP and any others subsequent SoPs and / or relevant documents;
- Will be required to keep good records of their meetings, decisions and clearance certificates for auditing purposes and will therefore be supported by the University Research Office Secretariat;
- May review on their own recognizance applications which are of no risk or of minimal, low or negligible risk provided always that the recommendation is noted at the next monthly meeting of the Wits HREC (Medical);
- Will be monitored and may be audited by Wits HREC (Medical) as per DoH Guidelines 2015 (NDoH 2023 Guidelines).

Ad hoc sub-committees may be constituted by the Wits HREC (Medical) to consider and report back on any particularly contentious or difficult application for ethics clearance to the Wits HREC (Medical).

5. Application Requirements and Submission Procedures

5.1. Application Forms

Requirements for applying for ethics clearance from the Wits HREC (Medical) are determined by the Committee and should be reviewed at least annually. The application form and the associated documents (e.g. participant information and informed consent forms) providing further information and or evidence of certain requirements should be in English and must include all necessary information that enables informed decision making. The application form must contain a checklist that will guide the applicant in submitting a complete application.

Different application forms can be provided for different situations including, but not limited to the following: waivers, case reports, laboratory studies, sub-studies, full studies, amendments and corrections.

The Committee through the Chair must ensure that the Secretariat communicates the application requirements clearly and transparently to all potential applicants, so that applicants are well informed of the requirements and there is no confusion of what is to be submitted.

The application form must be signed by the applicant(s) and where appropriate by the applicant's supervisor(s) (in the case of a student applicant) and where appropriate by the research co-ordinator in the applicant's School, Department, Unit or Research Entity. The signing of the application will indicate full compliance and the accuracy of the application.

5.2. Submission of Applications

Applications for the review of the ethics of proposed research should be submitted by researchers with a record of independent research, or by researchers in training (i.e. under and post-graduate students) that must be supported by an appropriately qualified supervisor. The research proposals submitted by students must have been approved by the relevant Postgraduate Degree Committee before being submitted for review by the Wits HREC (Medical).

All researchers who wish to undertake research that requires ethics approval must attend research ethics content training, either online or face-to-face, at least once every 3 (three) years and provide proof of such training to the Committee along with their application.

The Secretariat must clearly advertise appropriate mechanisms for submissions, either online or in hard copy delivered to the Secretariat office. The deadlines and meeting dates must all be easily accessible by applicants.

5.3. Service Level Agreement

The Committee, working with the Secretariat, should develop and publish a service level agreement in the form of separate SoPs that commits the Committee and the Secretariat to providing specified turnaround times for communication of decisions after a scheduled meeting of the Wits HREC (Medical). Part of this service level agreement is a provision that revisions of applications, addressing reviewer comments, which are not submitted within 6 (six) months of the date of the first communication of the reviewer's comments shall be declared null and void. Should the applicant want to proceed with the study then a new application must be submitted for review by the Committee.

6. Committee Procedures and Responsibilities

The task of the Wits HREC (Medical) is to review the ethics of proposed research projects that are presented to it. To this end, the Committee is required to review application forms, research proposals, and supporting documents.

Special attention must be given to the recruitment of potential participants in health research, the status and characteristics of participants, (for example, whether they are regarded as vulnerable or not), and the informed consent process and the documentation provided to research participants.

The following must be considered in the review of research ethics, as applicable:

- The risk-benefit profile of the proposed research;
- Ethical Principles as per DoH Guidelines 2015 (NDoH 2023 Guidelines) such as beneficence, maleficence, justices, respect and so on.
- The criteria for withdrawing research participants before completion of the research;
- The measures of support provided at no cost or reasonable cost to participants if they need it during or after the research;
- The adequacy of provisions made for monitoring and auditing the conduct of the researchers, including considerations related to data safety, and what happens to the data upon completion of the research; and
- The manner in which the results of the research will be reported and published; in particular it should not be possible to identify individual participants.

6.1. Procedures

The Wits HREC (Medical) will function according to this SOP, within the context of the ToR.

The procedures of the Committee should follow normal parliamentary procedures with decisions being made based on consensus. Where consensus cannot be reached, decisions are made by members' votes, cast by a show of hands, with a simple majority (50% (fifty percent) of present members plus one (1)) carrying the decision. The Chairperson will have a casting vote in the case of a vote that does not realise a majority.

The membership must ensure that it is adequately informed on all aspects of the research proposals it is called to review before making decisions related to the ethics of the proposed research. This can include the research methodology, but only in the case where the methodology is flawed with respect to the proposed objective of the research. The Committee may also provide researchers with methodological comments to improve the potential for a more productive outcome and study design, but this will not lead to withholding an ethics clearance certificate. The study's design and methodology are vital for research integrity, regardless of the discipline. Sound design and methodology are likely to result in reliable and valid data and outcomes that address the research objectives. Poor design and inappropriate methods may expose participants to unnecessary risk of harm and burden with little or no compensating benefit in the form of useful knowledge gained.

At least 2 (two) members of the Committee are assigned by the Chairperson(s) and Secretariat to review each application (i.e. the reviewers) with the Chairperson, although all members should have access to all applications. The selected reviewers must diligently consider the application and provide written reports, using the reviewer template and reviewer scoring system, on the Monday before the meeting to the Secretariat. The selected reviewers will lead the conversation

regarding the application in the meeting. If, for some reason, all the reviewers are absent from the meeting, then written reviews will be presented by the Chairperson or Co-Chairperson and then considered by the Committee and provide the basis for the decision-making. If, however, the Committee regards these reports as unsuitable then the decision must be delayed until at least 1 (one) reviewer can explain the review/s.

Decisions taken by the Committee (see below regarding types of decisions available to the Committee) must be made in such a manner to ensure that all research proposals are conducted in accordance with National and International guidelines, principles and standards for ethically responsible research. In making these decisions the members must focus, in particular, on:

- Actual or potential risks related to research proposals to participants as well as investigators;
- Measures to avoid or minimize such risks;
- The balance between risk to potential participants and the potential for benefit to society arising from the proposed research.

After careful and diligent review and assessment, the Committee is empowered to make the following decisions regarding the proposed research:

- Approved pending other permissions;
- Minor changes at discretion of secretariat;
- Minor changes at discretion of reviewers;
- Major changes requiring review of whole committee;
- Rejected and resubmitted;
- Rejected but should not be resubmitted due to fundamental ethical flaws.

In case of concerns on the part of the Wits HREC (Medical) or the Applicant, a meeting will be arranged between the Applicant(s) and either the Chairperson, Co-Chairperson(s) or a sub-committee of the Wits HREC (Medical) to discuss the concerns. This meeting may be held face to face or virtual.

In addition to the above, the Wits HREC (Medical) can, after due consideration, take the following actions at any point in time during the research, including but not limited to:

- Monitor the research regularly;
- Request further training of the researcher(s) under certain circumstances.
- Inspect a research site(s);
- Request an immediate report on the ethical aspects of a research project;
- Temporarily suspend a research project with good reason; and / or
- Investigate an allegation of a breach of ethics in the research being conducted.

6.2. Meeting Schedules

During the last Wits HREC (Medical) meeting of the year, members will be provided with a schedule of meetings dates for the following year. This schedule will also be posted on the Wits-HREC (Medical) website. The Wits HREC (Medical) meetings may be over more than 1 (one) day if necessary.

Submissions by Applicants should be received by the Secretariat by the last day of the month preceding the meeting.

The agenda and documentation for scheduled meetings will be circulated to the membership at least 7 (seven) days prior to the meeting.

Extraordinary meetings may take place under special circumstances and notification of such meetings will be provided to the Wits HREC (Medical) members at least 3 (three) days before such a meeting.

6.3. Minute Taking and Other Necessary Records

The meetings of the Wits HREC (Medical) will be recorded by means of minute-taking, and where possible with the aid of electronic recording.

Draft minutes of the previous meeting will be included in the agenda of the next meeting of the Committee for correction and approval and to deal with matters arising. The agenda will include a section on noting conflicts of interest. These must be captured in the minutes and attendance register of that meeting.

The Secretariat will keep records of all applications submitted for review and the resulting decisions. The records must provide a reliable and authoritative record of the business of the Committee that will stand up to scrutiny in the event of queries, conflicts of interest and audits. Electronic records are acceptable if they are securely stored.

The record should include, at least, the following:

- Name of Principal Investigator or Researcher(s);
- Participant Information Leaflets Informed Consent forms and relevant correspondence;
- Protocol identification number;
- Title of the project;
- Ethics Content Training;
- Date of approval or rejection;
- Conditions of approval, if applicable;
- Whether approval was expedited;
- Copy of the signed final proposal or protocol approved;

- Whether and how consultation occurred;
- Records of amendments;
- Reports of adverse and especially serious adverse events and actions taken;
- Other relevant information such as complaints from participants and whistle-blowers.

The Wits HREC (Medical) should correspond primarily with the Principal Investigator, but if the need arises for the Committee to correspondence with any relevant stakeholders including but not limited to the Faculty, School, Sponsors, or even the study participants, then the Chairperson will be permitted to do so with good reason.

6.4. Scope of Responsibilities of the Committee

Not all applications for ethics approval need to be considered by the full Committee as set out herein.

6.4.1. Sub-Studies and Case Reports

Sub-studies (i.e. studies that re-interrogated data collected under an existing ethics clearance by another researcher with the formal permission of the original Principal Investigator) and case reports (i.e. reports focusing normally on a patient with a rare condition being treated in a hospital or clinic) are considered usually by the Chairperson and 1 (one) other Committee member. The level of care and attention paid to these studies should be commensurate with that applied by the full Committee.

6.4.2. Repetitive Survey Techniques

Some laboratories, particularly in the National Health Laboratory Services (NHLS), use deidentified remnant biological samples, usually, but not exclusively, from a hospital, for repetitive testing purposes. This might include validating new analytical techniques or testing of equipment. Another variant is repetitive survey techniques, for example, where the incidence of a disease is surveyed in different settings, most commonly in health facilities, often by the National Institute for Communicable Diseases (NICD). In this category, the original application must follow the normal route of review (see 7.1 above), but thereafter variations on that common theme are presented in a letter to the Secretariat. These are then reviewed by the Chairperson and 1 (one) other Committee member with full care and diligence.

6.4.3. Waivers

Waivers, where no ethics clearance is needed because there are no human participants involved in the research, are reviewed by the Chairperson. If the Chairperson deems that a waiver is not appropriate, then the applicant must follow the normal process of application. If a waiver is deemed appropriate, then the applicant will be provided with a waiver letter. All waiver letters will be ratified at the next Wits HREC (Medical) meeting and minuted as such.

6.4.4. Expedited Reviews

To ensure efficient and effective review of research proposals the Wits HREC (Medical) should, where appropriate, use an expedited review procedure.

Such a procedure requires the formation of an *ad hoc* sub-committee consisting of the Chairperson or Co-Chairperson and 2 (two) other members to undertake the review without the need for a formal meeting. Each member of this sub-committee will review the application and prepare a written report. The Chairperson or Co-Chairperson will then consolidate the 3 (three) review reports into 1 (one) document and, based on consensus, decide about the ethics of the proposed research. If it is not possible to find consensus the application must be forwarded to the full Committee for consideration.

Such a review process will need to comply with the service level agreement that specifies turnaround time.

The expedited applications will be listed on the agenda and ratified at the next formal Wits HREC (Medical) meeting for ratification and minuted as such.

Expedited reviews will apply only to research that poses no more than minimal risk of harm.

6.5. Who can Apply to the Wits HREC (Medical)

The Wits HREC (Medical) may review research proposals submitted by researchers from all faculties in the University and from researchers working at organisations affiliated to the University so long as the proposed research falls in the appropriate domain.

Any non-Wits affiliated researchers, that are not collaborating with Wits researcher on the proposed research, will be charged a reasonable fee[1] to cover the costs of the review. This review fee is set by the University Research Office in consultation with the Chairperson and reviewed annually. The review fee is payable upon submission of the application but may be waivered by the Chairperson for strategic reasons that advantage the University and ethical research.

Researchers who wish to do research on students, staff or alumni of the University, must obtain institutional permission (see Appendix 1) for the research from the Wits Deputy Registrar: Academic Administration.

6.6. Additional Services offered by the Wits HREC (Medical)

The Wits HREC (Medical) will be available to render expert advice regarding research ethics to researchers, upon request. Advice regarding application procedures and similar operation matters will be addressed on an informal and *ad hoc* basis by the Chairperson and the Secretariat

[1] In 2023/2024 the reviewer fee is set at R17 000,00 inclusive of VAT

within the University Research Office.

The Wits HREC (Medical) is also responsible for reviewing applicants' annual progress reports. To this end, Principal Investigators / Researchers are required submit these reports yearly on or before the anniversary of the clearance certificate.

6.7. Attendance of Researchers, Applicants and Other Parties at Wits HREC (Medical) Meetings

The Chairperson may invite applicants to attend a meeting to provide insight into their proposed research.

The Chairperson may invite research specialists to attend a meeting to provide insight or present on a specific research methodology, ethical conundrum or any other issues that requires specialised skills and expertise to assist the members to decide on an application.

Any member of the UR&IC, including the DVC: R&I or his / her nominee, may attend a meeting as an observer.

In all these cases, non-members should not compromise the independent decision making of the Committee related to the review of ethical research proposals. They will also need to complete and sign a confidentiality agreement before joining the meeting.

7. Research Project Amendments

An amendment to an approved research project can be submitted to the Secretariat by the Principle Investigator / Researcher in the event of material changes in the research project. The request for an amendment of the research project must be accompanied by a motivation for the proposed change and an explanation of why it will not impact negatively on the ethical standards of the research.

Such requests are reviewed by the Chairperson or Co-Chairperson and the original reviewers, where possible. Should those reviewers no longer be Committee members then the Chairperson will allocate the matter to 2 (two) other suitable members to review the amendment request.

All amended applications will be listed on the agenda and sent to the next suitable Committee meeting for ratification and minuted as such.

8. Appeals, Complaints and Whistleblowing

8.1. Appeals

Applicants have the right to appeal the decisions of the Wits HREC (Medical). Such appeals must be addressed in writing to the Chairperson of the Wits HREC (Medical) via the Secretariat. They should consist of a clear and concise description of the grounds for the appeal and the desired outcome.

The Chairperson is obliged to consider all appeals objectively and must communicate the decision to uphold or reject the appeal to the applicant in writing within 7 (seven) working days of receipt. A meeting between the Chairperson or a sub-committee of the Committee and the applicant maybe arranged if so required.

If the applicant is still aggrieved, the second phase of the appeal process can be activated by submitting the written appeal to the University's Head of the Office of Research Integrity. This official must investigate the appeal and will provide a report to the Advisory Committee on Ethics (ACE), an independent Standing Committee. The ACE will consider the evidence and make a recommendation to the DVC: R&I. The DVC: R&I will take the final decision and implement the necessary action within the polices of the University.

8.2. Complaints

Should anyone observe what they perceive as unethical research, they are encouraged to lodge a complaint. The complaint should be submitted in writing according to the guidelines provided on the Wits website[2].

All complaints will be reviewed and investigated by the Secretariat, Wits Legal Advisor, Research Compliance Manager, and the Chairperson of the Wits HREC (Medical). The outcome will be communicated to the complainant in writing within 15 (fifteen) working days.

8.3. Whistleblowing

Any person within or without the University is encouraged to use the Wits Integrity Hotline to report any alleged infringement, misconduct or offence committed by a Wits HREC (Medical) member, the Chairperson or Co-chairperson, member of the Secretariat, researcher, research participant, or any University personal linked to research or any other person that may have committed such an offence.

Whistle-blowers should use the dedicated email address (wits.integrity@wits.ac.za) or by calling the hot line (082 938 45 59/69). The matter will be dealt with confidentiality as per the

[2] https://www.wits.ac.za/media/wits-university/research/documents/Ethics%20complaint%20structure.pdf

University's Whistle-blowers Policy. The report will remain anonymous as far as possible in law. The DVC: R&I will consult with the University's representatives to find a way forward to process such report and to resolve such report.

9. Serious Adverse Events (During Implementation)

Incidents leading to adverse events especially serious adverse events that occur during research studies must be reported immediately on detection to the Wits HREC (Medical) via its Chairperson of the Wits HREC (Medical) telephonically, or any other means of communication. If the Chairperson is not available to receive the communication, then the communication must be addressed to a Co-Chairperson. Ongoing communications must take the form of written electronic messages, which does not exclude the use of telephonic messages in emergencies. The Chairperson / Co-Chairperson must notify all members of the Wits HREC (Medical) and the University Research Office of the incident within 24 (twenty-four hours).

9.1. Responsibilities

It is the responsibility of the Principal Investigator to effectively manage the incident, as described below, with the guidance and direction of the Wits HREC (Medical), the University Research Office and in particular circumstances the Sponsor and / or the relevant Regulatory Authority. To this end, the Chairperson / Co-Chairperson must rapidly constitute a sub-committee suitably constituted to provide useful and informed advice and direction to the Principal Investigator on managing the incident. If additional expertise is required for the incident management strategy, experts from outside the Wits HREC (Medical) should be co-opted onto the sub-committee. The Legal Adviser and Compliance Manager in the University Research Officer must be included in the sub-committee and will keep the DVC: R&I informed of progress. Clear and continuous communication between the sub-committee and the Principal Investigator is important for the successful management of the incident. On the other hand, confidentiality is important so that external communication of the incident can be communicated in an appropriate manner.

Serious adverse events often relate to unforeseen reactions to trial drugs and must also be reported to the Sponsor(s), Applicant(s) and South African Health Products Regulatory Authority according to the study protocol provided.

9.2. Management Strategy

When an incident arises as a direct outcome of a research study the Principal Investigator, as guided and directed by the sub-committee, must take all reasonable and appropriate measures to prevent any further harm and / or injury. If successful, then the study may proceed in order not to disturb the research. If this is not possible, then the Principal Investigator, as guided and directed by the sub-committee, must stop the study immediately and take all reasonable and

appropriate steps to avoid further occurrences.

All decisions made in relation to the incident must be made collaboratively by the Principal Investigator and the sub-committee.

9.3. Reporting

Once the incident event has been satisfactorily dealt with, the Principal Investigator must provide a written report addressed to the DVC: R&I, the appropriate Dean of the Faculty, Head of School and the Wits HREC (Medical). The report must describe the incident, how it was contained, how the matter was resolved, and the steps to be taken to prevent further occurrences of the incident. This report must be reviewed and endorsed by Chairperson of the sub-committee and entered into the formal University records (Registry). The Secretariat will place the incident report on the agenda of the next meeting of the full Wits HREC (Medical) for discussion and noting. The Wits HREC (Medical) will report the incident event to the NHREC is required in the following Annual Report submitted by the Wits HREC (Medical).

10. Record Keeping and Archiving

The following processes will apply to the record keeping and subsequent archiving of all materials related to applications, the deliberations of the Wits HREC (Medical), and their decisions.

- The Secretariat, which is organisationally housed in the University Research Office, is responsible for creating the record of the Committee deliberations concerning all applications, thus ensuring that a complete history of the workings of the Committee is safe and secured;
- All relevant documentation will be dated, labelled and filed so that it can be recalled should the need arise;
- After a research study is completed the relevant documentation must be archived according to standard University procedures, which includes submitting them to the Registry Office on the 4th Floor in Solomon Mahlangu House in digital format;
- These documents will normally be archived for a minimum period of 15 (fifteen) years following the completion of a study., depending on University policies, the Promotion of Access to Information Act No. 02 of 2000, the Protection of Personal Information Act No. 04 of 2014 and any other legislation that may be applicable.

Documents that should be filed and later archived include, but are not limited to:

- The ToR, this SOP, and regular (annual) reports prepared by the Wits HREC (Medical) and submitted to the NHREC;

- The published guidelines for submission established by the Wits HREC (Medical);
- The records of Wits HREC (Medical) meetings, including agendas and minutes;
- All applications for ethics clearance including all the documents submitted by the applicant, the correspondence provided by the Wits HREC (Medical) in response to the application, and the decision and certificates awarded;
- Notification of the completion, amendments to the original study, premature suspension, or premature termination of a study and the final summary or final ethics report on the study.

11. Adoption and Amendments to these SOP

Changes to this SOP must be discussed at any ordinary meeting of the Wits HREC (Medical) and then suggested to the UR&IC. The UR&IC will consider the proposed changes and either refer unapproved changes back to the Committee for further consideration or approve them. In the latter case, the SOP then becomes the adopted set of procedures.

The Wits HREC (Medical) must review the SOP at least once a year at a normal meeting to ensure they are relevant, effective and appropriate.

12. Auditing and Accreditation of the Wits HREC (Medical)

To maintain the necessary accreditation required by the NHREC, the Wits HREC (Medical) will:

- Provide annual progress reports to the NHREC. These reports will also be tabled and discussed at the next UR&IC meeting.
- Be audited regularly by the NHREC audit team and it will apply the recommendations provided by the NHREC audit.

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13. Appendix 1: Institutional Permissions

For research to take place in various settings it may be necessary to be granted permission to perform the research in that setting. These are referred to as institutional permissions.

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

In some cases, the Wits HREC (Medical) may require that an institutional permission is required.

Permission letters should be in written form on an official letterhead, signed and dated, specifically mentioning the applicant, the title of the applicant's research project. Email correspondence is not an acceptable form of institutional permission.

Instances where permission is not required must also be confirmed in writing by the Committee.