



<b>To be completed by initiator of Policy/Policy owner:</b>	
1. <b>POLICY TITLE:</b>	<b>Research Ethics Policy</b>
2. <b>FIELD OF APPLICATION:</b> (All persons to whom policy applies)	Academic Teaching staff members, Administrative Staff Members
3. <b>COMPLIANCE OFFICER(S):</b> (Person/s responsible for ensuring policy implementation)	All Staff members
4. <b>STAKEHOLDER CONSULTATION</b> (State the stakeholder group/s consulted during policy formulation/revision)	Faculty Management Committee Faculty Research and Innovation Committees
5. <b>DESIGNATION OF POLICY OWNER:</b> (Person responsible for maintaining policy)	DVC: Research and Innovation, Teaching and Learning and Student Support
6. <b>NAME OF POLICY OWNER/S:</b>	<b>To be Appointed</b>
7 Link to the Research Ethics Policy	<a href="https://www.vut-research.ac.za/research-ethics-portal/">https://www.vut-research.ac.za/research-ethics-portal/</a>

<b>POLICY HISTORY (To be completed by policy owner)</b>						
<b>Decision Date</b>	<b>Status</b>	<b>Implementation Date</b>	<b>Approving Authority</b>	<b>Resolution Number</b>	<b>Policy Document Number</b>	<b>Pending date for next revision</b>
(Compulsory)	Revised	(Compulsory if "new" or "revised")	(If "new" or "revised". N/A if no changes)	<b>e.g.</b> 07/11-10.2 (Minute number. N/A if no changes)	(e.g. D/.../07 N/A if no changes)	(Compulsory)
9/11/2018	New	New	Senate			Nov 2021
24/01/2019	Revised	Revised	Senate			
19/10/2020	Revised	Revised	CREC			
28/10/2021	Revised	Revised	CREC			
20/05/2022	Revised	Revised	SENATE			
18/09/2023	Revised	Revised	CREC			
<b>For office use only</b>						
<b>SUBJECT</b>						
<b>SUBJECT NUMBER</b> (Refer to no. on Agenda)						
<b>CATEGORY</b> (Policy Field)						
<b>CATEGORY NUMBER</b> (As per date of approval by Council)						
<b>IPCP NUMBER:</b>						

# VAAL UNIVERSITY OF TECHNOLOGY

## POLICY ON RESEARCH ETHICS<sup>1</sup>

**This policy supersedes all other research ethics policies of the Vaal University of Technology, and that its rules, procedures, guidelines and definitions are binding from the date of acceptance by the Council of this university, as indicated on the cover to this policy.**

### 1. POLICY STATEMENT:

The Vaal University of Technology (VUT) declares that it is its policy to conduct all research and research related matters within the framework of national and international laws, regulations, and guidelines to the best of its ability. Such research has reference and application to humans, animals and/or the environment and the research ethical considerations are pertinent when such research places humans, animals and/or the environment in a state of vulnerability or invasiveness. As such, VUT subscribes to the research integrity standards set out in the Singapore Statement<sup>2</sup> on Research Integrity, Montreal Statement on Research Integrity<sup>3</sup> in Cross Boundary in Research Collaborations, WCRIs Hong Kong Principles<sup>4</sup> and support the Cape Town Statement<sup>5</sup> on fostering research integrity through fairness and equity.

### 2. DEFINITIONS:

**Animals** means all those beings that are non-human, are sentient, have the capacity to feel pain and suffering and a sense of well-being, and can interact with their surroundings in a reasonably deliberate manner.

**Central Research Ethics Committee (CREC)** means the highest committee that is established by VUT to independently approve and monitor research ethics, as defined below. Research projects, both for degree and non-degree purposes, that is undertaken by, and/or with duly constituted members of VUT, including registered students, visiting scholars and external research projects with humans, animals and in the environment under the control of VUT.

**Conflict of Interest (COI)** means a situation where one or more members of the particular research project has a vested, non-university wide interest in the results of the research project, where the situation holds no bearing on the course and scope of that member's appointment contract to the university, and where the situation makes it difficult for the member to act and decide impartially in the deliberations of the particular Ethics (or any other, relevant) committee.

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<sup>1</sup> The guidance and expertise of the *Revised Policy on Research Ethics* (Policy #: RIPPOL003) of the Tshwane University of Technology is gratefully acknowledged.

<sup>2</sup> Singapore Statement may be viewed at <http://www.singaporestatement.org>

<sup>3</sup> Montreal Statement: <https://www.wcrif.org/downloads/main-website/montreal-statement/123-montreal-statement-english/file#:~:text=The%20Montreal%20Statement%20on%20Research,the%20responsible%20conduct%20of%20research>.

<sup>4</sup> Hong Kong Principles: <https://media.tghn.org/medialibrary/2022/09/Moher The HK Principles 2020.pdf>

<sup>5</sup> Cape Town Statement: <https://www.wcrif.org/guidance/cape-town-statement>

**Departmental Research and Innovation Committee (DRIC)** (Also known as the Departmental Research Forum or RF) means that committee which duly appointed by the relevant VUT authority to manage and develop research, whether for degree or non-degree purposes, at the Departmental level.

**Environment** means a designated physical space that is construed to be able to develop and sustain life and the development of humanity.

**Expedited Review** means a review of a submission for ethical approval or waiver that carries research ethical concerns of humans, animals or the environment, or where such concerns are potentially present, they are of an extremely minimal state. In these cases, submitters may apply for expedited review, which is carried out by a sub-committee consisting of no less than two members of the CREC or FREC established on an *ad hoc* basis by the Chair of the CREC or FREC. Such an expedited review can be done electronically, but the decision of the ad hoc committee is noted in the following CREC and FREC minutes (where appropriate).

**Faculty Research and Innovation Committee (FRIC)** means a committee that is established by the relevant VUT authority with the purpose of scrutinising the research (scientific or scholarly) acceptability of projects (whether for degree or non-degree purposes), to recommend approval of said projects and related matters, and to direct such relevant research projects, at proposal stage, to the relevant research ethics committees.

**Faculty Research Ethics Committee (FREC)** means the Faculty-level Committee duly constituted according to the rules established below that has been mandated by the CREC to approve the research ethics of *minimal risk research*, as defined in the relevant Ethics documents, or to escalate the research ethics application to the Research Ethics Committee where this is required by this policy or where it seeks higher authority on the research ethics matters proposed.

**Human Subject or Research Participant** means an individual whose situation, opinions, ideas, documents and/or physical presence are targeted by the researcher in pursuit of data relevant to the research project, and who has the capacity to grant permission for the extraction and use of such data under conditions acceptable to that individual.

**Institutional Official (IO)** means that official who is appointed by Senate and is de facto responsible for the efficient, effective and sanctioned running of the Research Ethics Committee, and therefore oversees, develops and supports the Research Ethics Committee to enhance, protect and develop the committee as it carries out its mandated duties. The IO confirms the decisions made by the CREC, submits an annual report on the work of the CREC to Senate for ratification.

**Intellectual Property (IP)** means new knowledge, products and processes, including Copyright, Patents, Marks, Indigenous Knowledge Systems (IKS), Animal and Genetic breeding and development, and all other definitions of Intellectual Property as defined by the relevant Republic of South Africa Acts of Parliament, but also as defined by international benchmarking standards and laws, where applicable.

**Minimal Risk Research** means projects where the possibility/probability of vulnerability or invasiveness of and for participants and the environment might be of such a nature that this possibility/probability would not exceed the limits of possible harm (physical, emotional, economic or psychological) than which might occur to such participants and the environment in normal circumstances, as determined by the relevant Faculty Research Ethics Committees.

**Non-degree research (purposes)** means all research undertaken under the auspices of the university that is geared towards outputs that are not connected to formal degree processes, as these processes are defined by the university.

**Principal Investigator (PI)** means that person who will take primary responsibility for the development and execution of a research project, where such research is deemed to be for non-degree purposes.

**Promoter** means that person who is duly appointed (either internally, or externally as a Consulting Promoter) by VUT to guide a Doctoral candidate and a Doctoral research project through the development and execution of that project to its completion where such completion is determined by the university.

**Research** means all forms of investigation that follow a systematic approach to validate, extend, develop or invent ideas, processes or products with the purpose of placing such validation, extension, development or invention in the public domain in forms that are acceptable to the university, as defined by the university's Policy on Postgraduate Research.

**Research Ethics** means the application of nationally and internationally recognised principles and guidelines to oversee, monitor, and protect humans, animals and the environment, where such humans, animals and the environment are directly or indirectly affected by the potential invasiveness and vulnerability brought about by particular and defined research projects.

**Research Forum:** (See Departmental Research and Innovation Committee).

**Research Participant** (See Human Subject).

**Research Proposal/Research Protocol** means a document, submitted to the relevant Research and Innovation Committee, containing an acceptable justification for the validity of the proposed study, a clearly determined and justified plan to carry out the study, and all relevant annexures that support, add to and/or operationalise the proposed research.

**Serious Adverse Events (SAEs)** means those events that occur during the research process where such events run counter to the ethics expectations as approved during ethical review, have caused harm beyond the expected parameters of that review, have escalated vulnerability and invasiveness beyond those parameters, and have come about either through divergence by the researcher from the approved research plan, or by negligence on the part of the researcher, or by unforeseen circumstances. Such SAEs must be reported in full and with integrity, using the process laid out in the Standard Operating Procedures for Research Ethics as VUT.

**Standard Operating Procedures (SOPs) for the research ethics process** refers to all procedures that are to be followed and adhered to as laid out in the Standard Operating Procedures for the Research Ethics Committee of VUT.

**Standard Operating Procedures (SOPs) for specific operating procedures** refers to those procedures that are bound to be followed in the carrying out of research that involves the use of equipment, laboratories, the use of chemicals, hazardous materials and related matters, that require Standard Operating Procedures to be in place before they can be operationalised.

**Supervisor** means that person who is duly appointed (either internally or as a Consultant Supervisor) by VUT to guide, mentor and facilitate a Masters candidate and Masters-level research project (or Advanced Diploma candidate and project) through the development and execution of that project to its completion where such completion is determined by the university, as defined by the university's Policy on Postgraduate Research.

**VUT** means the Vaal University of Technology, as duly constituted in terms of the Higher Education Act, 1997 (Act No. 101 of 1997), as amended; and

**University** means the Vaal University of Technology, as duly constituted in terms of the Higher Education Act, 1997 (Act No. 101 of 1997), as amended.



### 3. GENERAL RULES:

- 3.1 The Vaal University of Technology's Research Ethics Committee (CREC) is a committee of the University's Senate, which reports to the Institutional Official (IO) appointed by Senate. The IO confirms decisions made by the CREC, and submits to Senate annual reports on the workings of the CREC, for ratification.
- 3.2 The VUT CREC will register with the relevant Research Ethics Committee of the National Health Research Ethics Council (NHREC) of the Department of Health.
- 3.3 The CREC independently reviews and grants ethical approval, ethical waivers or ethical rejection to and for research projects that are submitted to it for such review, by the FRIC's and by any other, non-VUT organisations that wish to conduct research with, in, on and/or about VUT, its staff, its students and its designated environments.
- 3.4 The CREC will also independently review any internal data gathering process undertaken by VUT that might not be for formal research purposes (as defined above) but might be for other purposes such as opinion gathering, various types of evaluations of systems and the like, and related matters. In the latter case as well, the critical evaluation criteria will engage with the potential vulnerability of all, and the potential for invasiveness in the lives of the participants.
- 3.5 In the case of formal research that is undertaken for non-degree purposes by members/staff of the non-academic departments, the CREC must scrutinise such proposed research or may refer it to a FREC that carries the closest academic relevance to the proposed project, for scrutiny.
- 3.6 The CREC does not evaluate the (scientific or scholarly) processes or procedures of the research process, except in as far as this affects the research ethics of the science. However, the CREC will not scrutinise submissions where the research process, as presented in research proposals, has not been scrutinised and approved by committees such as the Departmental Research Innovation Committee (DRIC) & Faculty Research and Innovation Committee (FRIC) that are appointed to undertake that task.
- 3.7 Where research project proposals are deemed to contain minimal risk<sup>6</sup> (not including the stipulated exclusions documented below) the CREC will grant the authority to the relevant FRECs to scrutinise the research proposal and grant ethical approval, with that provision that such an approval decision be noted in the minutes of the CREC. However, as the FRECs are sub-committees of the CREC, the CREC has the right to overturn decisions made by the FRECs.
- 3.8 Where research of any kind has to do with animals, as defined above, such research ethics approval shall be outsourced to a registered Animal Research Ethics Committee (AREC) for consideration, and such outsourcing shall be paid for by the research team who is conducting the research. The decisions of the outsourced CREC will be considered binding, except under the conditions of appeal as laid out, below.
- 3.9 All research submitted for research ethical approval shall follow the process laid out in the Standard Operating Procedures (SOPs) of the Research Ethics Committee.
- 3.10. All members of the CREC and the FRECs are fully indemnified by the university with regards to any decisions made by these committees. It is the task of the Institutional Official to make sure that this prerequisite is taken up in the University Statutes.

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<sup>6</sup> In the Terms of Reference (2.6.2) minimal risk "is defined as the potential harm that could be created for humans, animals and the environment where such harm is typically within the normal scope of their lives and conditions."

#### **4. MEMBERSHIP OF THE RESEARCH ETHICS COMMITTEE (CREC)**

- 4.1** The CREC will consist of the following members, where each appointment is formally confirmed, in writing, by the Institutional Official:
- 4.1.1 Each FREC shall nominate a primary and secondary member (*secundus*) from its faculty to serve on the CREC. The nomination will be confirmed by the Executive Dean of the Faculty and ratified, in writing, as duly appointed, by the Institutional Official. The *secundus* will represent the faculty when the primary member has indicated, in writing to the Chair, his or her unavailability to attend a specified meeting. Both members from a faculty, besides being experts in their fields, should either have demonstrated their expertise in the field of research ethics, have attended the mandatory two-day workshop for Research ethics upskilling and/or have indicated a desire and willingness to be upskilled within an acceptable passage of time in these matters. Such necessary upskilling must be financed by the university.
  - 4.1.2 One member of the committee, appointed by the IO, should be well versed in the laws of the country and in the regulations and procedures of VUT.
  - 4.1.3 One member, nominated by the Director of Research and appointed by the IO, should represent the Research Directorate.
  - 4.1.4 One member, nominated by the CREC and appointed by the IO, should have expert knowledge in the domain of Qualitative research methods.
  - 4.1.5 One member, nominated by the CREC and appointed by the IO, should have expert knowledge of Quantitative research methods, but also and particularly, statistical procedures relevant to research practice and used in such methods.
  - 4.1.6 Two community members who are not attached to VUT but will represent the interests and aspirations of the non-academic/non-research domain. Ideally, such members should be part of a particular community in which a fair amount of research is undertaken by VUT scholars so that these community members might better serve the protection of that community, and who, in the opinion of the CREC, will add value to the ethical review deliberations. The two members are nominated by the CREC and are appointed by the IO. These members are entitled to a set honorarium per meeting, financed by the Directorate of Research.
  - 4.1.7 Additional members may be nominated by the CREC and appointed by the IO, where these members carry specialist knowledge (such as the protection of Intellectual Property, or Indigenous Knowledge Systems). Such members are appointed for a full term and have full voting rights, but the number of additional members appointed may not exceed the number of primary members that come from the faculties.
  - 4.1.8 The Institutional Official, or his or her nominee (the nominee is officially appointed and subject to the same confidentiality agreements as all other members) is an *ex-officio* member of the CREC.
  - 4.1.9 The Directorate of Research shall appoint at least one full-time, non-voting administration officer.
  - 4.1.10 The CREC may, from time to time and on an *ad hoc* basis, draw on expertise that might be necessary for a particular project. Such *ad hoc* members are in an advisory capacity only, have no voting rights, and are subject to the same declarations of confidentiality as are incumbent on all members of the CREC.

#### **5. RULES OF THE RESEARCH ETHICS COMMITTEE (CREC)**

- 5.1 Each full voting member is appointed for a period of three years but may indicate his or her availability for further term(s) of appointment. However, each term needs to follow the same appointment procedure.

- 5.2 With the initial appointment (and subsequent re-appointments where this occurs) the appointee shall sign a declaration of confidentiality concerning the submissions to, and deliberations of, the committee. This declaration protects both the submissions and the committee.
- 5.3 At the commencement of each meeting the members present shall sign an abridged but binding declaration of confidentiality. Such a declaration may be included in the signed attendance register and therefore the attendance register must become part of the records of meetings.
- 5.4 The CREC shall appoint, by nomination and vote, its own Chairperson and Vice-Chairperson. Such an appointment must be ratified, in writing, by the Institutional Official, so that, in the case of expedited review, for example, the necessary gravitas to the appointment can be in place. The Vice-Chairperson shall chair the meeting in the case of the unavailability of the Chair or where the Chair indicates a potential Conflict of Interest and recuses himself or herself. The Chair should be a person who is seconded to the position of Chair of the CREC from his or her university appointment position (and thus relieved of his or her duties in that position) for the three-year term that he or she serves as Chair. All matters that go out from the CREC shall do so under the authority (and signature where necessary) of the Chair of the CREC.
- 5.5 The Institutional Official will make every effort to make sure that adequate attempts are made to ensure that membership of the committee reflects the diversity of the South African population.
- 5.6 The CREC should meet every month from February to November. Such meetings must be scheduled within the VUT calendar. Where necessary the Chair can set up additional meetings.
- 5.7 The quorum of each meeting should be 50% of the full membership, plus 1.
- 5.8 The CREC will only deliberate on and scrutinise a project where the research aspect (viz., the scientific or scholarly validity thereof) of the project has been deliberated on and approved (in writing) by a body or committee that is mandated to approve research. In the case of potential research that is to be generated for non-degree purposes by persons from the university who are not directly aligned with academic departments and programmes, it is incumbent upon that researcher to acquire the approval of the research processes to be undertaken.<sup>7</sup>
- 5.9 The CREC shall generate one of five possible decisions. (1) It may provide a waiver to the research, which indicates that there are no ethical considerations to be considered in the project. (2) It may approve the ethics of the project. (3) It may refer the application back for minor adaptations or clarifications (where such a decision may indicate a "provisional approval"), after which the reworked application may be submitted for expedited review or by full review (as decided upon by the CREC), (4) It may refer the application back for major revisions, after which the revised application needs to serve again at the full CREC; or (5) it may reject the application. In the last case, a full justification for this decision must be sent to the applicant.
- 5.10 The CREC will not entertain any application for research clearance where data gathering (except for such data that has been captured during the undertaking of the normal processes of generating a Literature Review or Survey of Scholarship) has already commenced. Where there is some doubt, the CREC will require a sworn statement/ declaration from the research team or PI that no data collection beyond the Literature Review or Survey of Scholarship has taken place. Upon receipt of such a declaration the review will recommence. Retrospective research ethics clearance will not be undertaken.

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<sup>7</sup> It is Recommended that the Directorate of Research, with the support of the Institutional Official establish such a body that has the same functions and responsibilities as the FRICs have, for non-academic staff members. If this cannot be arranged, the Directorate should be tasked with finding an equitable solution to the problem, as it is not the responsibility of the CREC to scrutinize and approve the research aspects of the project, but only the research ethics aspects.

- 5.11 Every effort shall be made to make decisions by consensus, except in situations where the application requires consensus, (i.e., high risk research) in which case consensus is compulsory (foot note). In cases where consensus cannot be reached, the matter shall be decided by vote of all present and in good standing. The approval will only be carried if there is a 75% (or the nearest percentage to that) of all eligible to vote in favour of approval. Abstentions will be included in the numbers eligible to vote and the calculation of the 75%. Those who vote against the matter shall have their objections minuted. Those who abstain shall also have this decision minuted. Declared Conflict of Interest and recusal shall not be included in the calculation of the 75%.
- 5.12 Potentially conflicted members of the committee shall declare their COI at the beginning of the meeting and have this minuted. The conflicted member will not have a vote for the matter being deliberated. Once the matter that has brought about the COI is up for deliberation, the Chair shall decide whether the conflicted member can remain in the meeting to add information that might be helpful for the deliberations and then ask the member to recuse himself or herself while the CREC makes a decision, or ask the conflicted member to recuse himself or herself for the entire time the matter is being discussed and a decision is made. The moment of recusal must be minuted.
- 5.13 An applicant may lodge an appeal against the *decision* made by the CREC with the Chair of the CREC. The Chair will attempt to resolve the appeal. Should this not occur, the Chair must approach an external Research Ethics Committee of good standing to review the application as a new submission. The decision of such an external CREC is final. Should the review of the appeal be successful VUT will carry the cost of such a review, should this be required. Should the review be unsuccessful and the decision of the VUT CREC be upheld, the applicant will be required to pay the cost of the external review.
- 5.14 An applicant may lodge an appeal against the *procedures* followed (as read against the VUT accepted Standard Operating Procedures), by the CREC in reaching its decision, with the Chair of the CREC. The Chair will attempt to resolve the appeal. Should this fail, the Institutional Official will be approached to adjudicate whether there were procedural aberrations or not. The decision of the Institutional Official is final in these matters.
- 5.15 The CREC shall be required to carry out monitoring processes of the ethical matters approved by the CREC and, where necessary, to proceed with investigations after the reporting of SAEs, or the discovery of potential SAEs.
- 5.16 The CREC shall undertake to abide by, and from time-to-time review, the Standard Operating Procedures that have been accepted that guide, provide strategy, and provide procedures for research ethical review.
- 5.17 The CREC shall provide each year, by March of the following year, a detailed report on the business undertaken by the CREC the previous year, to include information that is necessitated by the guidelines laid out in the Standard Operating Procedures of the CREC.
- 5.18 The CREC shall maintain a detailed and safe archive of all applications made, all decisions made, and all correspondence undertaken, in facilities provided for such a purpose by the Directorate of Research. Such an archive must be duplicated in a safe, off-campus, electronic location.
- 5.19 The CREC shall carry out an internal audit on the work undertaken by each FREC at least once a year.
- 5.20 The CREC must be correctly registered with the relevant national authority and must maintain this registration through sustained auditing as required by that body.
- 5.21 The CREC must drive research ethics education at VUT.



## **6. MEMBERSHIP OF THE FACULTY RESEARCH ETHICS COMMITTEE (FRECS)<sup>8</sup>**

- 6.1 The Faculty representative to the CREC will be the Chair of the FREC, and the *secundus* to the CREC will be the deputy chair.
- 6.2 Each department/programme in the faculty will nominate a primary member and a *secundus* to the FREC. The nominations will be ratified by the FREC of the relevant Faculty, and appointed, in writing, by the Institutional Official. The *secundus* will attend FREC meetings where the Primary member cannot. In the case of the departments from which the Chair and deputy chair come, such a department may nominate one more representative to the FREC, but such a representative will only serve at a particular meeting if the Chair or Deputy Chair is unable to attend. Members should be nominated as experts in their particular fields, and as persons either with current or burgeoning knowledge of research ethics or expressing a clear interest in being upskilled in this area, within an accepted time frame. In all cases the appointment will only be confirmed once the nominated member has completed a two-day research ethics course.
- 6.3 The Chair and Deputy Chair of the FREC will be elected by the relevant FREC and such appointments will be confirmed in writing by the Institutional Official.
- 6.4 The CREC may appoint other permanent members that bring specialist knowledge to the deliberations, such as experts in quantitative methods and statistics, or qualitative methods, or Intellectual property issues, or specialists in innovation. These added members have full voting rights.
- 6.5 The FREC may invite other specialists to attend meetings on an *ad hoc* basis where such invitees bring relevant knowledge to the discussion that is not present in the committee. Such invitees do not have voting rights.
- 6.6 The Chair of the CREC (or his or her permanent nominee) is an *ex-officio* member of the FREC.
- 6.7 The Executive Dean of the relevant faculty shall make available adequate administrative support in the appointment of an administration officer, who is a non-voting member of the FREC.
- 6.8 Each full voting member is appointed for a period of three years but may indicate his or her availability for further term(s) of appointment. However, each term needs to follow the same appointment procedure.
- 6.9 With the initial appointment (and subsequent re-appointments where this occurs) the appointee shall sign a declaration of confidentiality concerning the submissions to, and deliberations of, the committee. This declaration protects both the submissions and the committee.
- 6.10 All members of the FRECs are indemnified from the decisions taken by the FREC.

## **7. RULES OF THE FACULTY RESEARCH ETHICS COMMITTEE (FREC)**

- 7.1 The Faculty Research Ethics Committees (FRECs) are standing sub-committees of the Central Research Ethics Committee (CREC) and report directly to it. *As such, the CREC plays a deciding oversight role on the work of the FRECs and has therefore the right and obligation to scrutinise and, where deemed necessary, to rescind decisions made by the FRECs in high risk research.*
- 7.2 The FRECs scrutinise and grant research ethical clearance and research ethical waivers for research (for degree or for non-degree purposes) that is generated within the specific Faculty, for all no-risk or

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<sup>8</sup> Should the university decide to establish an ethics body to scrutinize research undertaken by non-academic staff, it is CREC recommended that similar procedures and responsibilities as presented here be used for that body.

minimal risk research as defined. However, the FRECs must escalate to the CREC research ethics submissions where the research falls into the following categories:

- 7.2.1 All research that, in the opinion of the FRECs, falls outside the definition of minimal risk research.
- 7.2.2 All research that uses minors (as defined by law)<sup>9</sup> as participants in cases where the FREC is of the opinion that the potential vulnerability of the participants is excessive.
- 7.2.3 All research that uses VUT students as participants and, in the opinion of the FREC, constitutes a significant risk to the students/participants in their academic progression.
- 7.2.4 All research that uses VUT staff members as participants and, in the opinion of the FREC, constitutes a significant risk to the staff members/participants in their employment situation.
- 7.2.5 All research that deals with medical matters.
- 7.2.6 All research that deals with deception as a critical methodological tool.
- 7.2.7 All research where the results might fundamentally challenge national interests.
- 7.2.8 All research whose results require an embargo; and
- 7.2.9 All research that, in the opinion of the FREC, needs comprehensive Intellectual Property protection for commercialisation, for example, or patent development.
- 7.3 At the commencement of each meeting the members present shall sign an abridged but binding declaration of confidentiality. Such a declaration may be included in the signed attendance register and therefore the attendance register must become part of the records of meetings.
- 7.4 All FREC meetings shall be chaired by the appointed Chairperson. The Vice-Chairperson shall chair the meeting in the case of the unavailability of the Chair or where the Chair indicates a potential Conflict of Interest and recuses himself or herself. All matters that go out from the FREC shall do so under the authority (and signature where necessary) of the Chair of the FREC and thus delegated authority from the CREC.
- 7.5 The FREC shall meet on an *ad hoc* basis, as determined by the request from the FRIC to meet to consider proposals that have been approved by that body. Nevertheless, the FREC shall meet at least 4 times a year and where there is no business to consider, the meeting shall be used for upskilling purposes.
- 7.6 The quorum of each meeting should be 50% of the full membership, plus 1.
- 7.7 The FREC will only deliberate on and scrutinise a submission where the research aspect (that is, the scientific and scholarly procedures) of the project has been deliberated on and approved (in writing) by a body or committee that is mandated to approve research.
- 7.8 When requested to do so, the FREC will scrutinise and grant ethical clearance for research projects that are presented to it by students who are in the Advanced Diploma or Post-Graduate Diploma.
- 7.9 The FREC shall generate one of five possible decisions. (1) It may issue a waiver, indicating that the research has not ethical matters to be deliberated upon. (2) It may approve the ethics of the project; (3) it may refer the application back for minor adaptations, after which the reworked application may

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<sup>9</sup> All children up to the age of 18 years of age are considered minors, except, occasionally and under certain circumstances, where the minor is head of a child-headed home.

be submitted for expedited review or by full review (as decided upon by the FREC); (4) it may refer the application back for major revisions, after which the revised application needs to serve again at the full FREC; or (5) it may reject the application. In the last case, a full justification for this decision must be sent to the applicant. The FREC might also decide that it is in the best interests of the university to escalate the submission to the CREC for a final decision, in which case the applicant needs to be informed in writing (with no justifications) about this decision.

- 7.10 The FREC will not entertain any application for research clearance where data gathering (excluding the development of a Literature Review or Survey of Scholarship) has already commenced. Where there is some doubt, the FREC may require a sworn statement/ declaration from the research team or PI that no data collection (beyond the Literature Review or Survey of Scholarship) has taken place. Upon receipt of such a declaration the review will recommence. Retrospective research ethics clearance will not be undertaken.
- 7.11 Every effort shall be made to make decisions by consensus (except in situations where the application requires consensus, in which case consensus is compulsory). In cases where consensus cannot be reached, the matter shall be decided by vote of all present and in good standing (with no COI). The approval will only be carried if there is a 75% (or the nearest percentage to that) of all eligible to vote in favour of approval. Abstentions will be included in the numbers eligible to vote and the calculation of the 75%. Those who vote against the matter shall have their objections minuted. Those who abstain shall also have this decision minuted. Declared Conflict of Interest and recusal shall not be included in the calculation of the 75%.
- 7.12 Potentially conflicted members of the committee shall declare their COI at the beginning of the meeting and have this minuted. The conflicted member will not have a vote for the matter being deliberated. Once the matter that has brought about the COI is up for deliberation, the Chair shall decide whether the conflicted member can remain in the meeting to add information that might be helpful for the deliberations and then ask the member to recuse himself or herself while the FREC makes a decision, or ask the conflicted member to recuse himself or herself for the entire time the matter is being discussed and a decision is made. The moment of recusal must be minuted.
- 7.13 An applicant may lodge an appeal against the *decision* made by the FREC with the Chair of the FREC. The Chair will attempt to resolve the appeal. Should this not occur, the Chair must forward the application to the Central Research Ethics Committee (CREC) to review the application as a new submission. The decision of the CREC is final but may then follow the same route as outlined for appeals on decisions made at the CREC.
- 7.14 An applicant may lodge an appeal against the *procedures* followed (as read against the VUT accepted Standard Operating Procedures for Research Ethical Clearance), by the FREC in reaching its decision, with the Chair of the FREC. The Chair will attempt to resolve the appeal. Should this fail, the Chair of CREC will be approached to adjudicate whether there were procedural aberrations or not. The decision of the Chair of the CREC is final in these matters.
- 7.15 The FREC may, following a request from the CREC, be required to carry out monitoring processes of the ethical matters approved by the CREC and/or the FREC. Where necessary, the FREC may then recommend, through a report, that the CREC proceed with investigations after the reporting of SAEs, or the discovery of potential SAEs. In the case of SAEs, the FREC may not be involved in the investigations.
- 7.16 The FREC shall undertake to abide by, and from time-to-time review, the Standard Operating Procedures that they have individually developed to accommodate the specific needs of the particular faculty (and which have been approved by the CREC) and that have been accepted to guide, provide strategy, and provide procedures for research ethical review.
- 7.17 The FRECs shall submit all their approved minutes to the CREC for ratification.

7.18 The FRECs shall submit to the CREC copies of the correspondence with researchers for archiving with the CREC.

7.19 The FRECs shall submit themselves to an internal audit undertaken by the CREC at least once a year.

## **8. PROCEDURES**

8.1 The Terms of Reference for the Central Research Ethics Committee and the Faculty Research Ethics Committee are contained in the relevant document.

8.2 The procedures undertaken by the CREC and the FRECs are contained in the Standard Operating Procedures (SOP).

8.3 The relevant documents, pro-forma, declarations, and the like are included as annexures to the SOP.

8.4 Research SOPs require for Research Ethics approval must be signed-off by a qualified Occupational Health & Safety Officer appointed by VUT or outsourced and must be aligned with the Occupational Health & Safety Act 58 of 1993 in order to sign-off the final approval of SOPs.

## **9. RESEARCH ETHICS GUIDANCE**

The following sources provide recommended guidelines and/or regulations in the development of research ethics thinking and practice.

Belmont report: <https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html>

Cape Town Statement: <https://www.wcrif.org/guidance/cape-town-statement>

Declaration of Helsinki: <https://www.wma.net/what-we-do/medical-ethics/declaration-of-helsinki/>

Hong Kong Principles: [https://media.tghn.org/medialibrary/2022/09/Moher\\_The\\_HK\\_Principles\\_2020.pdf](https://media.tghn.org/medialibrary/2022/09/Moher_The_HK_Principles_2020.pdf)

Human Research Council Code of Ethics: <http://www.hsrc.ac.za/en/about/research-ethics/code-of-research-ethics>

Medical Research Council: <http://www.mrc.ac.za/sites/default/files/attachments/2018-03-08/ReserchEthicsPolicy.pdf>

Montreal Statement: <https://www.wcrif.org/downloads/main-website/montreal-statement/123-montreal-statement-english/file#:~:text=The%20Montreal%20Statement%20on%20Research,the%20responsible%20conduct%20of%20research.>

Nuremberg Code: [https://research.unc.edu/human-research-ethics/resources/ccm3\\_019064/](https://research.unc.edu/human-research-ethics/resources/ccm3_019064/)

Singapore Statement may be viewed at <http://www.singaporestatement.org>