RHODES UNIVERSITY
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Research Ethics Policy: Research Involving Human Participants

Policy Volume	Research and Postgraduate Studies
Policy Chapter	Research Policies
Responsible Committee/Unit/Division/Faculty	Rhodes University Research Ethics Forum (RUREF); Rhodes University - Human Research Ethics Committee (RU-HREC); Faculty Research Ethics subcommittees (F[X]-RE); Departments; Research Units; Faculties; Senate; Council
Responsible Chairperson/Director/Manager	Chairpersons of RU-HREC, RUREF; F[X]-RE; DVC: R&I
Dates of First and Subsequent Council Approvals	Commencement Date: 2 November 1984 Date of Approval of Last Policy (Inclusion of Animal Ethics Policy) by Council: 4 December 2014
Policy Approval Pathways (e.g. committee, Senex, Senate, Council)	Faculty Boards; RU-HREC, RUREF; Senate Research Committee; Senate; Council
Revision History: Approved Reviews	Revision History: 1st revision 26 November 1986; 2nd revision (informal) March 2008; 3rd revision December 2014; 4th revision 2021.
Review Cycle (e.g. every 2/5/7 years etc)	Five Years
Next Review Date	2026

Abbreviations

RU-AREC	Rhodes University - Animal Research Ethics Committee
DVC: R&I	Deputy Vice-Chancellor: Research and Innovation
ERAS	Ethical Review Application System
[X]-REC	[Faculty] - Research Ethics Committee
RU-HREC	Rhodes University - Human Research Ethics Committee
NHREC	National Health Research Ethics Council
RUREF	Rhodes University Research Ethics Forum
[X]HDC	[Faculty] Higher Degrees Committee

1. POLICY PARTICULARS

1.1.Policy Title	Research Ethics Policy: Research Involving Humans
1.2.Policy Statement (State in a single paragraph the policy mandate and how this relates to the University Mission and Vision)	Research involving humans is essential for the advancement of knowledge. Conducting studies in an ethical manner, including protecting the rights and dignity of those involved, is of utmost importance for Rhodes University. In this regard, staff members, students, post-doctoral fellows and research associates conducting and supervising research (henceforth RU researchers) have the responsibility to ensure that studies are performed in an ethical manner. The University has the responsibility of supporting researchers in reaching ethically sound decisions concerning the conduct of research. In this policy, Rhodes University sets a clear statement for the consideration of ethics requirements, and corresponding procedures to meet those requirements, in research involving humans. This policy succeeds previous Rhodes policies in relation to studies involving humans and the role of the Rhodes University Research Ethics committees. It is complemented and extended through generic and discipline-specific ethics texts and guidelines written by various bodies and scholars.
1.3. Reason for Policy (What this policy aims to achieve)	The Research Ethics Policy: Research Involving Humans aims to provide a sound basis for contextually and disciplinary relevant ethical conduct of studies involving humans. The policy described herein outlines the formal procedures for endorsement of research projects involving humans at, or in conjunction with, Rhodes University. Further aspects of institutional ethics, ethical conduct, and ethics as an academic discipline, or part thereof, are not covered by this policy. This policy does not relieve a University member or associate of any obligations acquired as a result of membership of a professional or other association.
1.4. Policy Objective/s (What are the measurable objectives of this policy)	The objectives of this policy are to lay out the following: • Rhodes University's broad approach to research ethics involving humans; • Rhodes University's alignment with relevant legislation regarding research ethics; • The people affected by and implementers of the policy; • Related documents, forms and tools; • Policy definitions and abbreviations; • The Committees responsible for ethics support and clearance; • The processes involved in ethics clearance, including the allocation of "risk" categories, the review process, settling disputes or conflicts of interest, retrospective applications, and appeals; • Dealing with adverse events in relation to the ethical conduct of research involving humans; • Internal audit processes; • The roles and responsibilities of all parties involved; • The constitution of the relevant committees in relation to research conducted with human participants.
1.5. People affected by this Policy (e.g. All units of the University)	The people affected by this policy are: research participants; researchers employed by or associated with Rhodes University, including students and post-doctoral fellows, who are conducting, or plan to conduct, research involving humans (RU researchers); peer reviewers of ethics protocols for research involving humans; and members of the various committees.
1.6. Who should read this Policy (People who need to heed this policy to fulfil their duties)	The people who should read this policy are: all RU researchers studying human participants or topics involving humans; supervisors; peer reviewers of ethics protocols for research involving humans; the chairs and other members of the relevant committees listed below.
1.7. Implementers of this Policy (Who will manage the implementation of this policy)	The implementers of this policy are: all RU researchers studying human participants or topics involving humans; supervisors; ethics reviewers; and relevant committees listed below.

1.7 Website address/link for this Policy	https://www.ru.ac.za/institutionalplanningunit/policies/policiesa-z/ https://www.ru.ac.za/researchgateway/ethics/.

2. RELATED DOCUMENTS FORMS AND TOOLS

(University Policies, Protocols and Documents (such as rules/policies/protocols/guidelines related to this policy)

Relevant Legislation (Legislation/Regulatory requirements/Organisational Reports – name these)

- National Health Act 61 of 2003 and Regulations Relating to Research with Human Participants (R. 719 19 September 2014) (https://www.gov.za/sites/default/files/gcis_document/201409/38000rg10268gon719.pdf)
- Children's Act 38 of 2005 (https://www.justice.gov.za/legislation/acts/2005-038%20childrensact.pdf)
- Protection of Personal Information Act 4 of 2013 (https://www.gov.za/documents/protection-personal-information-act#)
- Promotion of Access to Information Act 2 of 2000 (https://www.gov.za/documents/promotion-access-information-act#)

Related Policies

- Common Faculty Policy and Procedures on Plagiarism: ethical concerns regarding plagiarism are dealt with through this policy
- Rhodes University Research Ethics Policy: Animal Subjects: all research involving animals is regulated through this policy
- Staff Disciplinary Code and Procedure: where staff members engage in unethical conduct of research that violates Rhodes regulations, it is dealt with through this policy
- Student Disciplinary Code: where students engage in conduct during the course of conducting research that violates Rhodes regulations, it is dealt with through this policy
- The Rhodes University Policy onTeaching and Learning: pedagogical processes are guided through this policy – see later discussion of using student data

Related Protocols

Researchers should be well-versed in their disciplinary-specific and general ethics principles. Some relevant guidelines are:

- Department of Health (2015). Ethics in Health Research: Principles, processes and structures (2nd ed.) Pretoria: Department of Health.
- Macleod, C. I., Marx, J., Mnyaka, P., & Treharne, G. J. (Eds.). (2018). The Palgrave Handbook of Ethics in Critical Research. Palgrave Macmillan.
- Other relevant general and specific guidelines can be accessed at: [https://www.ru.ac.za/media/rhodesuniversity/content/ethics/documents/educationfacultyrec/Ethics_Procedures_and_Practices_an_Orientation_V2.pdf]

Forms and Tools (documents to be completed in support of this policy implementation)

All applications for ethics clearance are to be submitted through the relevant formal channels (currently the online Ethical Review Application System (ERAS) that can be accessed from the website (https://www.ru.ac.za/researchgateway/ethics/).

3. POLICY DEFINITIONS

(Technical or Conceptual terms used in the policy)

No	TERM	DEFINITION
3.1	**Accreditation**	The process by which a body is officially recognised as being qualified to perform a particular activity (in this case a committee constituted by Rhodes is qualified (accredited) by the National Health Research Ethics Committee (NHREC) in the activity of supporting and approving ethics clearance and the ethical conduct of research).

3.2	**Applicant and co-applicants:**	The applicant and co-applicants take the responsibility for conducting the research. In the case of postgraduate student research that will result in a qualification, the student may be the applicant in circumstances where they have conceptualised the project, work alone on collecting data, and write-up the results independently, but the supervisor must be co-applicant for ethical clearance (even if not a co-investigator). In other cases and in the case of staff research, the researcher leading the study is the applicant. If students form part of a larger staff project, the staff member is the applicant and the students are co-applicants.
3.3	**Data**	Information generated through interactions with human participants (through, for example, interviews, questionnaire responses, observations) or collected from a source concerning human participants (e.g. social media, newspaper articles, medical records).
3.4	**Ethics clearance**	The authorisation by the accredited research ethics committee for researchers to undertake the research activities proposed in the ethics protocol; ethics clearance (also referred to as approval) is normally expressed in the form of a letter with a unique identifier (number) which can be provided by the researcher when proof of clearance is needed, and tracked back to the authorisation by the issuing body (the accredited research ethics committee).
3.5	**Ethics principles**	Basic understandings of ethical research practice including (but not necessarily restricted to): • Respect for autonomy: Researchers acknowledging the right of people to control over their own life and body; • Beneficence: The obligation to take positive steps to prevent, remove, or undo harm, and rather to promote good; • •Non-maleficence: Not inflicting harm; • Justice: Being fair and acting with a sense of fairness and equity; • Respect for persons: All humans have the right to be treated with dignity.
3.6.	**Ethics protocol**	The document or set of documents describing the ethics considerations pertinent to the research activity being carried out. The ethics protocol (also referred to as an application) normally consists of a form and supporting documents completed through formal channels (currently online through ERAS), and appendices.
3.7.	**Ethics review**	The process whereby peers review an ethics protocol or application and provide guidance to the accredited research ethics committee on ethics clearance. These reviews are used by the ethics committee to provide guidance, where necessary, to the applicant(s) concerning ethics of the proposed study, and to issue ethics clearance decisions.
3.8.	**Human participants**	Persons about whom or from whom a researcher obtains data, or specimens, or identifiable private information, through intervention or interaction with that person and/or the texts/specimens produced by and about them. This may include: i. humans partaking in data collection that involves methods such as observation, surveys, interviews, or focus group discussions; ii. collection of personal information from or about a human participant, including use of personal documents or personal records of an institution; iii. humans undergoing experimental psychological, physiological, health, educational or medical testing, intervention or treatment; iv. humans providing identifiable tissue or other identifiable personal matter for the purpose of research; v. humans whose information (in individually identifiable, re-identifiable form) is accessible as part of a published or unpublished source, whether data are collected directly from individuals, or data of

		individuals or collectives have been aggregated previously; this excludes non-identifiable publicly available data.
3.9.	**Quality assurance check**	Unbiased assessment of the processes, policies and procedures engaged in by ethics committees; internal quality assurance checks are carried out by non-partisan internal individuals; external quality assurance checks (called an audit by the NHREC) are carried out by independent external parties (in this case NHREC).
3.10.	**Methodology**	This policy uses the term 'methodology' as a broad understanding of the conceptual and the empirical frameworks of the research, acknowledging that these may be discipline-specific
3.11.	**Research**	Research is a scholarly activity involving rigorous methods and processes to generate new knowledge. The scope of this policy is newly planned research involving human participants conducted by RU researchers.
3.12.	**RU Researchers**	: All staff members, students, post-doctoral fellows, research associates and visiting researchers conducting and supervising research under the auspices of Rhodes University involving human participants or that potentially affects currently living humans.

4. PRINCIPLES GOVERNING THIS POLICY

OVERVIEW
Rhodes University strives to carry out the following, as far as is reasonably practicable:
4.1. Ethics principles are a foundation of research integrity, and form the basis of a collegially adopted set of values for conducting research. The reputation of Rhodes University as a scholarly institution is dependent on demonstrable adherence to quality standards in the generation and dissemination of new knowledge. Peer reviewed ethics clearance is an inherent part of undertaking good quality research and ensuring research integrity, and is inherent to the knowledge creation processes.
4.2. It is important for researchers to have guidelines that can be referred to when making decisions about the ethics of research with human participants. There are multiple texts to which researchers can refer in thinking through ethics decisions in their study. Researchers and research supervisors should ensure that they refer to these.
4.3. The Research Ethics Policy: Research Involving Human Participants and any associated Guidelines developed by Faculties and approved by RU-HREC are aligned with the National Health Research Ethics Council (NHREC) principles and criteria for processes and structures (Department of Health [DoH], 2015). Although the NHREC framework is not legally binding within the context of most (non-medical) research conducted at Rhodes University, the institution supports the spirit and intention of the NHREC to provide quality assurance for ethical research taking place at and involving South Africa's higher education institutions. Of particular relevance to this policy is the NHREC advisory (DoH, 2015, p.75) which states that: "While researchers may refer to discipline- or paradigm-specific ethical norms and frameworks, adherence to national research ethics guidance is also required … RECs must consider any ethical tensions arising from specific methodologies and analytic approaches competently, fairly and without prejudice."
4.4. In line with this, Rhodes University recommends a situated approach to research ethics. This approach combines principlist (adherence to agreed-upon overarching ethics principles) and contextual and/or discipline- or professional-specific understandings of ethics. Recognised cross-cutting ethics principles, including respect for autonomy, beneficence, non-maleficence, and justice, should be balanced with contextual ethics understandings that include consideration of social, cultural, and discipline-related issues.

5. DIRECTIVES FOR IMPLEMENTING THIS POLICY

(Actions and processes by which the objectives of the policy will be achieved.)

5.1. Committees

Support and clearance regarding research ethics at Rhodes University is implemented by: (1) The Rhodes University Research Ethics Forum (RUREF); (2) Rhodes University Human Research Ethics Committee (RU-HREC), accredited with NHREC; (3) Rhodes University Animal Research Ethics Committee (RU-AREC), accredited with NHREC; (4) Faculty

Research Ethics Committees where faculties have decided to form their own committees ([X]-REC). The Department of Health's National Health Research Ethics Council (NHREC) has accredited RU-HREC and RU-AREC to independently conduct the transactional processes of research ethics clearances. RUREF and [X]REC are not accredited committees, but support RU-HREC and RU-AREC in their functions. An organogram outlining this structure is contained in Appendix 1.

At Rhodes University research ethics clearance relating to humans is conducted by an independent standing committee, the Rhodes University Human Research Ethics Committee (RU-HREC). RU-HREC is an independent committee, not controlled by any superior University body in terms of its decisions regarding research ethics. RU-HREC reports directly to the NHREC but submits reports, at least annually, to Rhodes University Senate via the DVC: R&I and Research Committee. Its functions are supported by the Research Office and the Rhodes University Ethics Forum (RUREF) and [X]RECs.

RU-HREC, together with its [X]-REC subcommittees, commits itself to national and international ethics principles and standards, to this policy and related documents and guidelines, and to Rhodes University rules and standards for all administrative issues.

The [X] Higher Degrees Committees may liaise with the RU-HREC, but formally remain separate committees with their own Chairs or Coordinators. As scientific integrity is a principle of ethical research, dialogue across Higher Degrees Committees and the RU-HREC is useful in ironing out any concerns relating to the ethics of methodology.

5.2. Applications for research ethics clearance

RU researchers who intend to perform research involving human participants shall obtain ethics clearance prior to data collection or, on rare occasions retrospectively (see Section 5.7). An ethics protocol must be completed through formal channels, currently through the online Ethics Research Application System (ERAS). Ethics clearance will take different paths depending on the researcher's faculty affiliation and the level of risk associated with the study as described below (see Appendix 2 for summary). Ethics clearance is valid for a year, after which application for extension is required. Extensions may be applied for through student progress reports, the ERAS system and/or correspondence with the relevant chair.

5.2.1. Researchers in faculties with [X]-REC have their ethics protocols reviewed initially by the respective [X]-REC where the studies pose a low level of risk (see Section 5.4 regarding assigning risk status). Each Faculty REC will decide whether and how proposals and protocols should serve at departmental level prior to submission to the [X]-REC. The Faculty Ethics Chair will assign ethics reviewers in accordance with the Faculty requirements and NHREC guidelines. In the case of postgraduate students whose research proposals must serve at the relevant[X]HDC, this assignment can be made in consultation with the relevant Faculty Higher Degrees Committee Chair.

Studies categorised as medium and high risk will be referred to RU-HREC for processing. The RU-HREC Chair may consult with the [X]-REC Chair regarding such applications, but is fully responsible for the process.

5.2.2 Students and staff in Faculties without a Faculty Research Ethics Committee will have their research ethics protocol reviewed by the RU-HREC directly. The Chair of the RU-HREC will assign ethics reviewers directly.

5.2.3 The RU-HREC and [X]-RECs will appoint ethics reviewers with the necessary expertise in various areas. Criteria for ethics reviewers are outlined in Section 5.3. Reviewers do not have to be members of the relevant committee but should be academic staff preferably within the same or cognate fields of study (may be cross-disciplinary).

5.2.4 On submitting an application, researchers will be asked to indicate the level of risk they associate with the study. On receiving the submission, the RU-HREC or [X]-REC Chair, depending on the level of risk indicated by the researcher, will assign at least two peer reviewers through the relevant software (ERAS) system, at least one of whom must be a committee member. In addition to a substantive review of the ethics issues associated with the study, reviewers will be asked to confirm the level of "risk" as outlined below. Where peer reviewers differ with a researcher's assignment of low risk level, the dispute must be discussed at the relevant REC committee. The ethics protocol may be up-scaled to the RU-HREC (if the researcher indicated low risk) for further processing.

5.2.5 Reviewers will be required in all cases of 'medium' and 'high' risk to address the committee in writing and/or person, on various matters contained in the reviewed applications. The review process is outlined in Section 5.4.

5.3. Criteria for assigning reviewers

For ethics reviews to be thorough, rigorous and supportive, careful selection of reviewers is necessary. For an adjudged low risk study, at least one reviewer should, and at medium or high risk levels, preferably both reviewers should:

- preferably hold a PhD in the relevant or cognate discipline;
- be research active;
- have submitted ethics protocols themselves;
- completed the review induction training;
- have no conflict of interests in relation to the study under review.

For capacity development, a less experienced reviewer may be paired with a reviewer with the above requirements for ethics protocols at low or, at times, medium risk. To aid in the ongoing learning required in ethics review, each reviewer will be provided with the other reviewer's comments once both reviews are completed.

Reviewers should have no vested interest in the study being reviewed; they should not be a supervisor or co-supervisor, or research team member, or a family member of the applicants. Where the Chair of any of the [X]-RECs is the applicant applying for ethics clearance, the Deputy Chair of [X]-REC will oversee the process. Where the Chair of RU-HREC is the applicant, the Deputy Chair should manage the review and discussion of the Chair's application. The Chair will recuse themselves from any committee discussions.

Reviewers can be selected from Faculty members and do not necessarily have to be a member of the relevant committees. The Chair of the RU-HREC and [X]-REC Chairs will appoint eligible reviewers, in consultation with Heads of Department (HoDs), on the basis of their meeting the above criteria, and their fields of expertise. It is expected that HoDs will consider the work that reviewers and committee members take on in terms of workload allocations. Where a department offers significant support to any REC (reviewing or being members of committees), the HoD may liaise with the Research Office regarding workload relief. In addition, significant contribution to ethics review should be taken into consideration in personal promotions and in the allocation of research funding through the Rhodes University Research Committee.

5.4. "Risk" categories

All research carries potential risks and potential benefits. The weighing up of risks and benefits are part and parcel of ethics decision-making. Rhodes takes a nuanced (as opposed to hard and fast) approach to risk, acknowledging that the risk and benefits associated with participation in research are produced in context. "Risk" status of a research project, thus, refers to a confluence of: the positions or characteristics of proposed human participants; the research purpose and topic; and the actions carried out in the course of research. Rhodes University recognises that "risk" is fluid (i.e. may change over time), and multi-faceted (i.e. risk in one area of human functioning may not translate into risk in others).

In understanding the various "risk" categories of research, attention must be paid to the question of vulnerability. The importance of protecting the welfare of certain classes of participants must be balanced against the danger of homogenising these groups and failing to acknowledge their (situated) agency and complexity. In line with the NHREC (Department of Health, 2015), Rhodes University views vulnerability not as an absolute condition but rather as occurring on a sliding scale and deeply intertwined with contextual or temporal circumstances. Vulnerability is seen as a socially located praxis rather than an inherently personal characteristic, and not as something that defines particular individuals at all times and places. Thus, the term "person with vulnerabilities' or "a person made vulnerable" is preferable to "vulnerable person".

As indicated by the DoH (2015), "additional protective measures should not be automatic just because vulnerable groups will be recruited; rather, the decision should be based on the particular circumstances of the proposal" (p. 27). This should be taken into consideration in determining the risk level of a study. Rhodes University uses the following "risk" categories for the purposes of ethics review. These categories are meant for guidance and are not definitive. In deciding on a risk category, researchers and reviewers should simultaneously take into consideration participant vulnerabilities, researcher vulnerabilities, topic, location, and data collection techniques.

Risk category 1: No ethics clearance required

Definition: No contact with human participants

Examples: Use of previously-collected data that received ethics clearance; use of anonymized human datasets; document analysis of documents firmly in public domain; literature review; studies based on theoretical or secondary analysis alone; use of human biological material (e.g. human cells lines from a commercial source(s) or established cell lines, where the results or the sourcing of such materials definitely do not lead to social risks); use of open access digital texts that are in the public domain. Should any researcher be in doubt about whether their research fits into this category, they should consult with the relevant ethics committee chair.

Risk category 2: Low risk

Definition: The risk of harm is no greater than those imposed by daily life under stable social conditions, or in undertaking routine educational, psychological, health or social interventions or tests.

Examples: Market research; non-sensitive questions about people's everyday lives, and opinions; review of non-sensitive privileged information (e.g. documentation not publicly available); research on usual classroom or educational activities, routine psycho-social interventions (e.g. empowerment programmes). [Note: usual classroom, educational or psycho-social activities may include minors; where minors are not expected to do anything more than participate in usual activities associated with these activities, the study may be assigned low risk status]

Risk category 3: Medium risk

Definition: Where risk to participants, researchers and/or institutions is greater than those imposed by daily life under stable social conditions, but where appropriate steps can be taken to mitigate or reduce overall risk; the risk of harm is reasonable in relation to anticipated benefits or knowledge gained.

Examples: Research concerning topics that have the potential to evoke negative feelings; research involving groups with vulnerabilities; research conducted in a locality that may contain potential risks to the participants and/or researchers.

Risk category 4: High risk

Definition: Where there is significant and likely risk of harm to researcher, participant(s) and institutions which may lead to serious adverse consequences if not managed in a responsible manner; remedial interventions might be possible should harm occur, including by external professional intervention. The absence of remedial measures does not automatically disqualify the study where the risk of harm is reasonable in relation to anticipated benefits or knowledge gained.

Examples: Research on highly sensitive topics such as experiences of violence, rape, illegal activities; research involving groups with significant vulnerabilities or multiple vulnerabilities; research conducted in a locality that definitely contains risks to the participants and/or researchers; research involving deception of the participants; research involving illegal activities; research activities in which the participants may place themselves at risk of harm if they participate; research activities in which the researcher may place themselves at risk of harm; where the researcher may place themselves at risk of breaking the law.

5.5. Review process

Risk category 1 studies need not receive ethics clearance (although postgraduate student research proposals still need to be subjected to quality assurance through the relevant Higher Degrees Committee or other Faculty approved mechanisms). Studies designated in the risk categories 'low', 'medium' and 'high' need to be subjected to ethics clearance procedures. On submission the applicant will indicate the risk category into which they feel the study falls.

Peer reviewers will be appointed as outlined in Section 5.3. All efforts to ensure that reviewers have the required expertise in the field must be made.

Peer reviewers are encouraged to provide constructive feedback that not only points to problems with the ethics protocol but, where possible, suggests possible ways of solving these or moving forward. In addition to confirming a risk category and providing substantive input, they must recommend one of the following decisions:

A. Ethics clearance;
B. Ethics clearance pending gatekeeper approval;
C. Ethics clearance with minor modifications; no peer re-review required;
D. Major modifications; resubmission and re-review required;
E. Unsuccessful; serious ethics concerns requiring interaction between the applicant and RU-HREC (see Section 5.8).

The peer reviews and recommendations will serve at different committees depending on the category of research:

Category of research	**Committee**
Risk category low : RU researchers in faculties with [X]-RECs	Relevant [X]-REC

Risk category medium (all faculties)	RU-HREC
High risk category (all faculties)	RU-HREC

5.6. The Decision process

All decisions regarding ethics clearance are made by RU-HREC. RU-HREC is supported in this process by [X]-RECs where applicable. [X]-RECs will consider low risk applications and send recommendations through to RU-HREC. Applicant Researchers may be invited to meetings of any of the ethics committees if this is deemed to facilitate the clearance process.

The final recommended decision of RU-HREC or [X]REC will be by consensus or, where this is not possible, majority vote of the committee. Where the recommended decision is (A) Ethics clearance as is, or (B) Ethics clearance with minor modifications, the RU-HREC or [X]REC Chair may review the recommendations and send an ethics clearance letter, or a decision letter outlining the changes required. If minor modifications are required, the researcher will be invited to effect these changes on the online system (ERAS). The researcher may upload a covering letter on the ERAS system outlining how the changes have been effected, or substantive reasons for disagreeing with certain recommendations (where these apply). The REC Chair may review these changes and issue an ethics clearance letter if satisfied. The Chair may also elicit the opinion of one or more other members of RU-HREC or [X]REC if uncertain that the changes have been effected satisfactorily.

In cases where the decision is (D) Major Modifications (requiring resubmission and re-review), the Chair of RU-HREC must send a decision letter outlining the concerns and inviting the researcher to re-submit the ethics protocol for re-review. In addition to making changes in the ethics protocol, they may upload a covering letter on the online system in which they indicate how they responded to reviewer concerns, including changes made and substantive reasons for disagreeing with certain recommendations (where these apply). The Chair may decide, on the basis of the covering letter, to ask the original reviewers to review the resubmission, or to appoint new reviewers. New reviewers will be appointed only in exceptional circumstances when the Chair believes that additional input will strengthen the feedback or where the researcher's responses show disagreement with the original reviewers' comments. New reviewers will have access to the previous decision, comments by the previous reviewers, and the response of the researcher.

In the case of a decision of (E) Serious Ethics Concerns, the Chair of RU-HREC must send a decision letter outlining the concerns and inviting the researcher to respond in writing and/or in person to the concerns raised. The procedure to be followed is outlined in Section 5.8 (iv). Given the supportive stance that Rhodes University takes to ethics in research, these cases should be rare. The desired outcome is eventual ethics clearance, but denial of ethics clearance, if no compromise can be reached, is also an option.

Appendix 2 provides a summary of the routes taken for ethics applications emanating from different people and faculties.

On rare occasions, with valid reasons, **expedited** review may be effected through the following mechanisms:

1. Low risk projects may be reviewed and decided by the appropriate REC Chair in consultation with the Deputy Chair;
2. For medium and high risk, peer reviews must be conducted. However, if peer review recommendations align, ethics clearance can be decided upon in an ad-hoc meeting of the RU-HREC or through RU-HREC Chair circular.

Resolving disputes regarding these decisions is dealt with in 5.8.

5.7. Retrospective applications

On rare occasions, researchers may wish to apply retrospectively for ethics clearance. These applications will only be considered if the activity being researched **was not initially set up as a research project**. Examples of such data include: student assignments from past years; case notes taken by healthcare workers and therapists; administrative data collected by government or other agencies. These participants' data were collected for other intentions and their informed consent to have the material used for research purposes may, depending on the data, need to be sought. The procedures outlined

above apply to retrospective applications as well. Researchers wishing to use data collected in the course of their teaching at Rhodes University should consult Rhodes University Teaching and Learning Policy as well as the RU-HREC guidelines.

5.8. Settling disputes or conflicts of interest

Disputes may arise when: (i) the applicant is unable to agree to modifications suggested by the committee; (ii) a minority of the relevant REC members register dissent from a recommended decision concerning an ethics protocol, (iii) a conflict of interest is confirmed or suspected (e.g. reviewer also collaborates with the researcher); and/or (iv) reviewers outline serious ethics concerns that require follow-up by RU-HREC.

These will be dealt with as follows:

i. **Applicant unable to agree with alterations suggested by reviewers**: When asked to revise a submission, researchers will be able to provide, in a covering letter on the online system (ERAS), substantive reasons for not agreeing with some or all of the recommendations. This letter should be shared with the committee, and the committee's response recorded. Where agreement is reached between the committee and the applicant, this will be recorded on the ERAS system. If the committee and applicant are unable to reach a compromise, then the Chair of the RU-HREC must appoint, in consultation with the committee, an arbitrator whose recommendations will be shared with the RU-HREC. This person must be a senior academic in the field, either internal or external to Rhodes University.

ii. **Minority of committee members register dissent:** If after exhausting avenues for reaching common ground, a minority of committee members still disagrees, they may ask for their dissent to be minuted. This should only occur if they feel that their objections are sufficiently substantive to require further discussion. In this instance, if the minority members are from the relevant [X]-REC, then the matter must be referred for discussion to the RU-HREC. If the members are from the RU-HREC the matter is referred to RUREF for the facilitation of a resolution. Internal and external expertise may be sought by RUREF to assist in resolving the dispute.

iii. **Conflicts of interest:** Reviewers and members of the relevant REC shall disclose, withdraw from voting, and recuse themselves in any case of actual or potential conflict of interest. This might be in a conflict of interest in relation to affiliation, collaboration, project sponsoring or any financial reward accruing to the proposed project. The Chair may ask a reviewer or member to recuse themselves in cases of potential conflicts of interest, such as where the member is the supervisor of the researcher seeking ethical clearance. Should a reviewer or member not declare, or not be aware of, a conflict of interest, all reviews or input from this person shall be flagged on such a conflict of interest coming to light. In cases where the Chair has a conflict of interest, a Deputy Chair is to be appointed by the committee for the specific application and the Chairperson must recuse themselves.

iv. **Reviewers outline serious ethics concerns that require follow-up by RU-HREC**: Reviewers have the option of recommending "application unsuccessful" if they feel that there are sufficiently serious concerns that cannot be remedied through revision of the ethics protocol. In such cases, these concerns should be communicated to the researcher by the Chair of RU-HREC. The researcher will be given an opportunity to respond to these serious concerns. Two responses are possible: (i) the researcher withdraws the application; (ii) the researcher provides substantive reasons for disagreeing with the recommendation. In the latter case, the Chair of RU-HREC will appoint, in consultation with the committee, an arbitrator (a senior academic in the field, external or internal to the University) who will recommend a decision to RU-HREC. The recommendation should be either: (i) the ethics review process can continue subject to the consideration of various elements – to be laid out in detail; or (ii) the application is sufficiently flawed to warrant rejection of the application. The RU-HREC will review the arbitrator's recommendation and communicate a final decision to the applicant. In the former case, the application may proceed if the researcher is willing to make the substantive changes indicated by the arbitrator as agreed to by the committee. If the researcher is unwilling to make the changes, RU-HREC must reject the application. In the latter instance, the Chair of RUREF should engage with the researcher and other researchers associated with the research to facilitate further discussion and input on ethics. Applicants may also use the appeal process laid out below if they fundamentally disagree with the final decision.

5.9. Objections and appeals to ethics clearance decisions

Objections against an ethics clearance decision may take two forms: (i) an objection by a colleague internal to Rhodes University, or external party (e.g. funders), to a complete application; (2) an objection by a researcher who disagrees with the decision of the RU-HREC.

In the first case, the objector must lodge the objection, with valid written reasons relating to the ethics premises of the research, with the Chair of the RU-HREC Committee. The Chair is then obliged to respond to the substantive concerns

raised. Vexatious objections, without substantive reasons, may be turned away. Depending on the nature of the objection, the preferred avenue is to attempt to resolve the issues raised in consultation with the relevant parties (objector, the researcher, RU-HREC). The input of a senior academic in the field, either internal or external, may be required to assist the RU-HREC in resolving the issue. Where the objection cannot be resolved in this fashion, the DVC:R&I should attempt to resolve the dispute. Where this is unsuccessful, the objector may appeal to the NHREC.

In the second case, a researcher who wishes to appeal an ethics clearance decision, they will write to the RU-HREC Chair with a clear rationale for the appeal. Responses will depend on the risk level of the study. In risk levels 'low' and 'medium', the Chair should invite the researcher and (where applicable) the supervisor, to discuss the appeal with the RU-HREC in person or in writing; RU-HREC may then revise the decision, retain the decision, or seek further advice from RUREF, and/or internal or external experts. At risk level 'high' the RU-HREC Chair should appoint senior academic reviewers either internally or externally to review the application, the previous reviews, and the researcher's response, and make a recommendation to RU-HREC regarding how to resolve the issue.

5.10. After ethics clearance

Once RU-HREC has approved an application, the researcher must conduct the research in accordance with what is documented in the application. If more than minor modifications to the methodology/protocol become necessary, the researcher must record this on the online system detailing – with rationale – the changes required. The Ethics Coordinator must alert either the [X]-REC Chair or the RU-HREC Chair, depending on risk level, to the changes. The Chairperson may at their discretion refer the matter for the opinion of the relevant (sub) committee, or to approve it on their own authority. Where changes are substantial, the Chair, in consultation with the committee, may advise the researcher to submit a new ethics clearance application.

5.11. Dealing with adverse events

Adverse events include: negative consequences and/or outcomes of the research not covered in the ethics protocol or not remediated during the course of conducting the study; researchers conducting the research outside the parameters laid out in the ethics clearance; preventable injury to a study participant that has occurred as a result of reckless behaviour by a member of the research team carrying out a particular research study.

If any adverse events occur, these must be reported to the Chairperson of RU-HREC as soon as possible, but definitely within one month of the incident occurring. Adverse event reports can be submitted by internal or external parties. The report must contain the following particulars: nature, time and date, location of the adverse event(s), people involved and responses from relevant parties, any remedial actions that have been taken. A person reporting adverse events may request that they remain anonymous (with good reason) in the course of the investigation, although their identity must be known to the Chairperson.

All research activities in the context of the project where adverse events have been reported must stop until an investigation into the adverse events has been concluded. Given the negative impact that this may have on the research, the investigation must be concluded speedily. Within 24 hours of the receipt of the adverse events report, the Chairperson of RU-HREC must commence an investigation into the merits of the report. The first step is for the (possibly anonymised) complainant's report to be circulated to the members of the RU-HREC for perusal, along with reference to the initial ethics protocol and reviews. Simultaneously, the affected parties (where suitable) may be given a chance to respond to the report. After the documents have been studied by all members of the committee and affected parties, a meeting must be scheduled expeditiously, preferably within one week. The strictest level of confidence must be maintained during the meeting and deliberations. Deliberations in the meeting must examine the merits of the adverse events report. The affected parties must be given a chance to present their case to the committee. If necessary, the advice of internal or external experts should be sought, and further investigations performed, including following up with affected parties. In its deliberations, RU-HREC must consider the adverse events reports and other information in relation not only to this Policy but to all other relevant policies at Rhodes University, including (but not limited to) the staff and student disciplinary policies.

Once the investigation is completed, the Chair of RU-HREC shall compile a draft investigation report based on the information accumulated during the investigation. This report must be finalised with input from the RU-HREC committee members and where applicable, the [X]-REC subcommittee members. The report is then to be emailed to the DVC: R&I. The text of the investigation report must clearly outline the process that RU-HREC followed in reaching its conclusion(s), the information and/or evidence considered, the final recommendations arrived at, including any recommended remedial action to be taken by Rhodes University and/or the researcher(s) involved. The DVC: R&I may return the report to RU-HREC for further

investigation or clarification. The DVC: R&I or their appointee must communicate the outcome of the investigation to all affected parties. At this point the complainant's identity will be disclosed (had they previously asked to be anonymous). The text of the communication must also indicate that the affected parties have 7 days to appeal the findings of the investigation report, and the remedial and/or disciplinary action to be taken. The report and all communication must be securely stored for five years for any future audits and/or other purposes.

Affected parties can appeal the findings of an investigation report within 7 days of the receipt of the communication from the DVC: R&I. The DVC or their designate must within 7 days of the receipt of the appeal appoint a panel of no less than 3 and no more than 5 suitably qualified members of the Rhodes University community as members of the appeals panel (these individuals will be designated as appointees). This panel must convene within 7 days of the appointment by the DVC. They must re-examine all the materials that formed the basis for the original report by RU-HREC. A report by the panel must be finalised and submitted to the DVC: R&I within 1 month. The DVC should communicate with all affected parties within 1 week of the submission of the panel's report. The decision will be seen as binding. Any further recourse must take place outside of Rhodes University, e.g. in a court of law.

5.12. Internal Quality Assurance

Senate may decide to conduct a quality assurance check of the functioning of the RECs at any particular point, but minimally once every three years. The aim of the exercise is to ensure that the processes and practices of the RU-HREC and Faculty RECs are suitably standardised and of the required standard, and that the regulations stipulated by this Policy are being followed. Internal Quality Assurance will be carried out by an independent Quality Assurance Committee recruited by the Research Committee and approved by Senate. This committee will comprise the Quality Assurance Chairperson, one research ethics specialist and one other member as deemed appropriate. If needed, the committee will provide supportive guidance to RU-HREC and/or [X]-REC on how to address any identified concerns. Internal Quality Assurance findings will also be shared with the NHREC as and when appropriate. This process is separate to the external audits conducted by NHREC.

5.13. Publication ethics

Publication ethics refers to how research is represented in formal publication routes, including journal articles, books and book chapters, technical reports and conference proceedings. This includes the need for research ethics clearance, transparent and honest data reporting, original work, single submission for consideration by publisher, proper citation practices, consent to reproduce published material, ethics of authorship, and avoidance of conflicts of interest.

Concerns with publication ethics are generally dealt with by the relevant journal or publisher. However, the DVC: R&I may receive complaints or reports of breaches of publication ethics. In this case, the DVC: R&I may, where relevant, approach the Chair of RU-HREC for advice on the matter. The process should include liaison with, and input from, the relevant publisher. Advice may also be sought from the international Committee of Publication Ethics (COPE). [https://publicationethics.org/]

6. ROLES AND RESPONSIBILITIES

(Roles and responsibilities of Key personal/Divisions/Faculties/Departments)

ROLE	RESPONSIBILITY
Researchers	Primary responsibility for ensuring that the policy and protocols on human research ethics are adhered to rests with the RU researchers involved in any study conducted at, or in conjunction with, Rhodes University. All researchers carry responsibility for conducting the research in accordance with ethics standards. The supervisor is responsible for guiding student researchers.
Ethics Coordinator	The Ethics Coordinator occupies a full-time, permanent post. They report administratively to the Director of Research. They support the Chairs and committees of RUREF, RU-HREC, RU-AREC and [X]RECs. They are responsible for: a. Co-ordinating, administering and developing the administrative aspects of the ethical application and review processes; b. Providing support, education and training in relation to research ethics; c. Assisting RU researchers in their research application process; d. Providing administrative and operational support in the research ethics application process, including prompt processing of research ethics submissions to the relevant REC,

	through all stages of review, clearance, and monitoring. e. Maintaining the Rhodes University Ethics website and online submission platform; f. Supporting the work of the Chairs, Faculty Representatives and ethics committee members. g. Assist with coordinating the Rhodes University strategic approach that contributes to the University's research strategy, including the RECs' roles in the intellectual health, growth and reputation of ethical research
Committees and subcommittees	The following committees are involved in research ethics as Rhodes University: RUREF; RU-HREC (NHREC accredited); RU-AREC (NHREC accredited); [X]RECs. RUREF is the strategic committee through which ethical research is supported at Rhodes University. It meets formally four times a year (with ad hoc meetings being called as necessary). Without interfering with the ethics clearance decisions made by RU-AREC, RU-HREC, or Faculty RECs, it provides the following supportive functions: a. drafting ethics policies and guidelines; b. receiving reports from the Ethics Coordinator about their functions as outlined above; c. assisting with the budgeting for and facilitating research ethics training and support; d. reviewing reports from faculties and research units about their needs in relation to research ethics training and/or mentoring; e. receiving annual reports from RU-HREC and RU-AREC to inform strategic directions regarding ethics; f. facilitating, where suitable, resolution to disputes (as indicated in Sections 5.8 to 5.11) [Note: the role is facilitation and not abitration; RUREF may not overturn ethics clearance decisions] g. advocating where necessary to the Institutional Planning Committee and the Research Committee about the resourcing needs of research ethics processes. RUREF consists of the following members: • The Chairs of RU-AREC, RU-HREC; • The Ethics Coordinator; • The Director of the Centre for Postgraduate studies; • One representative of Postgraduate Liaison Sub-Committee • A faculty representative from each faculty (these may be the Chair of the [X]-REC or another representative). The Human Resources Director, Registrar and DVC: R&I may sit in on meetings when there are relevant matters on the agenda. Other members of the RU community may be invited, or may request, to attend meetings. As a forum, the Chair of RUREF will rotate amongst members on an annual basis. RUREF's minutes will serve at the Research Committee. RUREF should, where necessary, flag particular issues as Class A matters for onward reporting to Senate. RUREF is supported administratively by the Registrar's Office. The RU-HREC, RU-AREC, F[X]-RECs, and Ethics Coordinator's administrative office, supported by the Research Office, are responsible for: a. assisting with drafting ethics policies and guidelines; b. constructive review of research ethics protocols as outlined above; c. ethics clearance of research projects; d. collating and maintaining a list of peer reviewers and REC members within Rhodes University in consultation with Faculties and Heads of Departments; e. ensuring the availability of peer reviewers with adequate knowledge of and training in

	research ethics; f. liaising with researchers during the course of the study, when required, for guidance; g. investigating, withdrawing ethics clearance and recommending further appropriate actions to RECs and/or other relevant Rhodes University bodies (e.g. disciplinary committees), in the event of allegations of unethical conduct (as outlined above). RU-HREC and RU-AREC are responsible for liaising with and reporting to NHREC as necessary. RU-HREC consists of: • The Chair and Deputy Chair appointed by the DVC: R&I after a nomination and voting procedure outlined below; • The Chair and/or Deputy Chair of the [X]-RECs and at least one further delegate from [X]-REC where these exist (delegates may vary by meeting); • Elected members of faculties without a [X]-REC; • Two Senate representatives • One representative of the Community Engagement Division • One external representative of a community based organisation or non-governmental organisation • The Ethics Coordinator. One third of the committee members will constitute a quorum. [X]-RECs consist of: • A trained member of each department in the faculty; • A trained member of institutes, centres or units of substantive size; • Additional trained members as necessary. [X]-REC will appoint a Chair and one or two Deputy Chairs. One half of committee members will constitute a quorum. RU-HREC will compile an annual report for tabling at the Research Committee, for onward forwarding to Senate. It will outline the following: • Number of ethics clearance applications received and processed (for noting); • Any appeals and their resolution, anonymous (for noting); • Any adverse events and their resolution, anonymous (for noting); • Liaison with NHREC (for noting). As RU-HREC and RU-AREC are independent committees, the Research Committee and Senate may not intervene in any of the matters for noting. The smooth functioning of the research ethics system and support and training in research ethics do, however, fall within the ambit of the Research Committee and Senate.
Peer reviewers	Peer reviewers should be trained, but do not necessarily have to be a member of the relevant REC. Research ethics protocol reviewers are responsible for: a. conducting a close reading of the ethics protocol (application); b. estimating a risk level for the study; c. providing detailed and constructive feedback on the proposed ethics decisions outlined in the ethics protocol; d. recommending a decision; e. availing themselves to deliberate the decision in person or in writing; and f. abiding by confidentiality principles in relation to their reviews.
Other bodies	The Faculty Higher Degrees Committees, where these exist, are responsible for quality assurance of student research proposals (this function falls outside of the scope of this policy) and for liaising as and when necessary with the Faculty Ethics Committees and/or RU-HREC. Faculties are responsible for appointing a Faculty Research Ethics Committee where such is agreed

	to by Faculty, and ensuring the departments provide adequate, disciplinary suitable ethics training to staff and students. Departments, institutes, centres, or any unit within which, or through which, research involving human participants is conducted, are responsible for: a. providing disciplinary ethics training and guidance to researchers, students and research supervisors; and b. supporting researchers within the unit in thinking through ethics decisions in relation to a particular study. The Registrar and Human Resources Director are responsible for keeping a register of research conducted on RU property, but cannot overturn REC decisions.
Constitution of the committees and subcommittees	The Deans (or Deputy Dean of Research) of Faculties, with administrative support of the Faculty Office, are responsible for constituting Faculty Ethics Committees. The Dean should: (i) provide an outline of the roles and responsibilities of members to HoDs; (ii) call for nominations from departments. HoDs will provide the names and brief reasons for nominating the person(s). The members of the Faculty Ethics Committee will be appointed formally by letter signed by the Dean and DVC: R&I for a period of three years. Re-nomination is possible. The members of the committee will nominate a Chair. The [X]-REC Chair may not be the same person as the Chair of the Higher Degrees Committee; however, the members of the [X]-REC may overlap with the Higher Degrees Committee. The committees must meet separately as they play different, albeit complementary, roles. The DVC's Office will provide, through the Ethics Coordinator, an outline of the roles and responsibilities of RU-HREC members to the Community Engagement Division, Senate, and Faculties without a [X]-REC to guide them in their nomination of members. Each of these entities has the obligation to ensure that their nominees have the necessary background and experience to contribute constructively to RU-HREC and are willing to undergo training. The Directors/HoDs will provide the Ethics Coordinator with the names of the nominated person(s) with brief reasons for their nomination. The members of RU-HREC will be appointed formally (i.e. by letter signed by the DVC: R&I) for a period of three years. Re-nomination for one further term is possible. Given the high level of responsibility assigned to the Chair and Deputy Chair of RU-HREC, a formal process for their appointment will be instituted. Nominations and brief motivations by any trained ethics reviewer or committee member of any of the RECs or RUREF will be called for by the DVC: R&I through the Ethics Coordinator. The DVC: R&I will (drawing on this policy): (i) provide an outline of the roles and responsibilities of the Chair/Deputy Chair in relation to the RU-HREC committee; (ii) call for nominations, with these nominations being accompanied by a brief motivation; (iii) implement a formal voting procedure. Voting will be open to any trained ethics reviewer or committee member of any of the RECs or RUREF. The successful candidate will be vetted by the DVC: R&I and appointed for a (renewable) period of three-years through formal letter. The Chair or Deputy Chair may not be the Chair or Deputy Chair of [X]-REC or RUREF.

7. CONTACTS

Area of Concern	Division/Faculty/Department	Telephone	Email
Ethics Coordinator	Research Office - Mr Siyanda Manqele (Rhodes Ethics Coordinator 2018 -)		ethics-committee@ru.ac.za/s.manqele@ru.ac.za

8. POLICY REVIEW PROCEDURE

(Actions and processes by which the policy will be reviewed)

Faculties reviewed the revised policy in December 2020 and submitted written comments. All comments were taken into account by a working group consisting of a representative of each Faculty, and the RU-HREC Chair. Faculty and Senate approval was sought in May 2021. The policy must be reviewed in 2026.
Communication of the review process

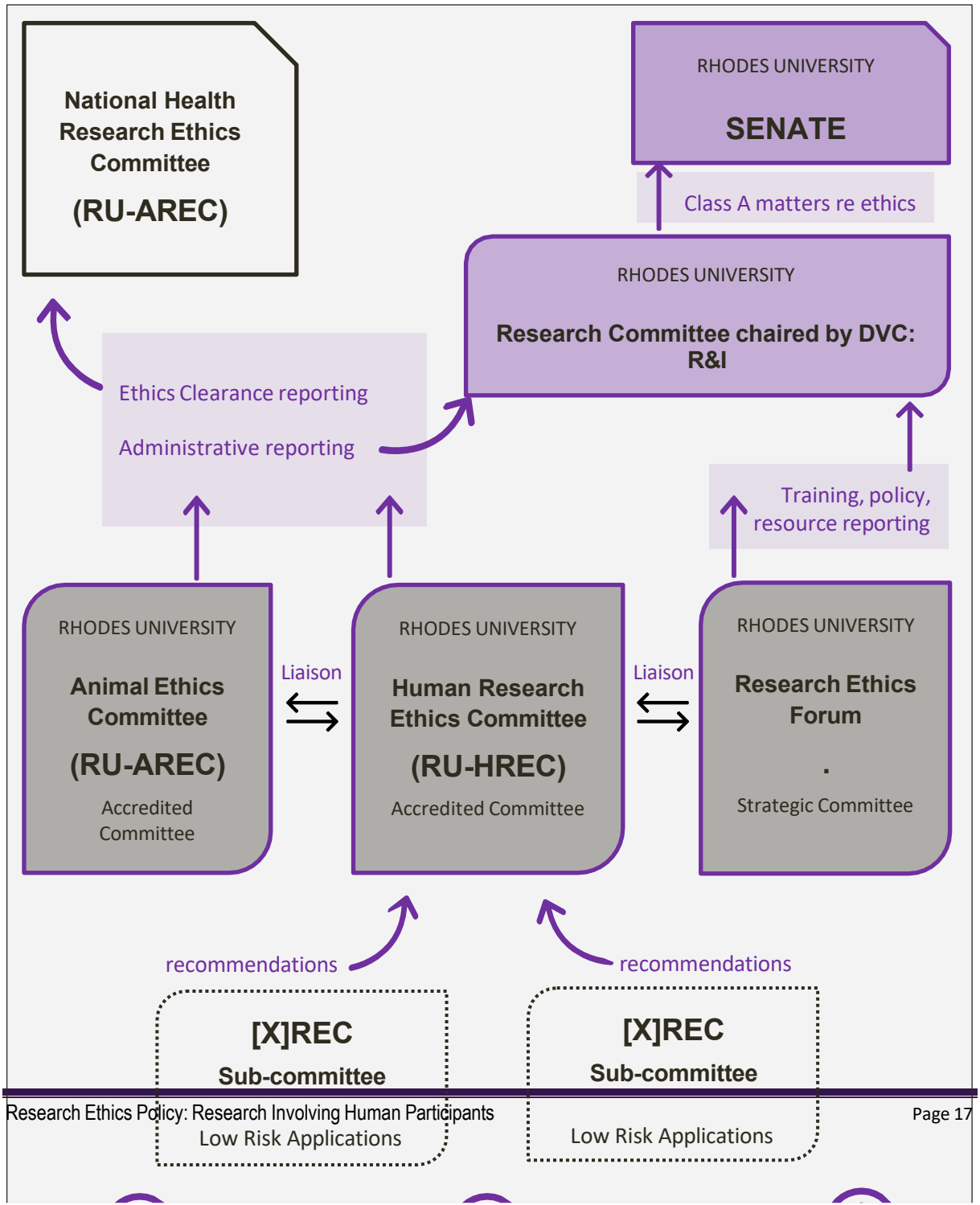
9. POLICY CONTEXT: RELEVANT DOCUMENTS CITED/CONSULTED/ADOPTED

1	Department of Health (2015). Ethics in Health Research: Principles, processes and structures (2nd ed.) Pretoria: Department of Health, Republic of South Africa.
2	NHREC Audit Letter to Rhodes University, 2018 & Audit Report to Rhodes University, 2017
3	NHREC Registration Certificate ((RU-HREC) valid until 30 November 2023

LIST OF APPENDICES

Appendix 1

Organogram of Rhodes University ethics structure



Appendix 2

Ethics clearance application pathways

[Note: only student research proposals are vetted by Higher Degrees Committees, where these exist]