UNAM
UNIVERSITY OF NAMIBIA

RESEARCH ETHICS POLICY, REGULATIONS AND GUIDELINES

RESEARCH ETHICS POLICY,

REGULATIONS AND GUIDELINES

Custodian	Pro Vice Chancellor: Research, Innovation and Development
Responsible Division	Centre for Research and Publications
Contact Officer	Director: Centre for Research and Publications
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Related legislation, policies and regulations	
Legislation and/or other regulatory obligations	**Organizational policies, procedures, guidelines and regulations**
• The University of Namibia Act (Act No. 18 of 1992) • Higher Education Act No. 26 of 2003 • Research Science & Technology Act, 2004 (Act No. 23 of 2004) • Access to Genetic and Biological Resources and Associated Traditional Knowledge Act 2 of 2017	• Delegation of Authority Policy and Framework • UNAM Research Policy • Conflict of interest policy • Policy on Academic Integrity

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1.0 ACRONYMS AND ABBREVIATIONS

Acronym/ Abbreviation	Explanation
Ad Hoc REC	Ad Hoc Research Ethics Committee
AREC	Animals Research Ethics Committee
EEREC	Environment and Engineering Research Ethics Committee
CID	Centre for Innovation and Development
CIOMS	Council for International Organizations of Medical Sciences
CRP	Centre for Research and Publications
HREC	Human Research Ethics Committee
ICH	International Conference on Harmonization of Technical Requirements For Registration of Pharmaceuticals For Human Use
IPR	Intellectual Property Right
IRB	Institutional Review Board
MoU	Memorandum of Understanding
NCRST	National Commission on Research, Science and Technology
NIH	National Institute of Health
PVC: RID	Pro Vice Chancellor for Research, Innovation and Development
REC	Research Ethics Committee
UNAM	University of Namibia
UREC	University of Namibia Research Ethics Committee
URPC	University of Namibia Research and Publications Committee
WHO	World Health Organization

2.0 DEFINITIONS

Terms	Definition
Anonymity	Refers to non-disclosure of information of participants in research studies
Authorship	Lists of persons who have made substantial contributions to a study.
Beneficence and non-maleficence	Beneficence is the obligation to do good. Non-maleficence is the obligation of researchers to do no harm.
Collaborating Partner	Researchers from other institutions cooperating and conducting research under the auspices of UNAM.
Confidentiality	Researchers must ensure that data is not disclosed to third parties during the collection, dissemination and storage of information as this might cause harm, stigma or distress.

Conflict of interest	A situation in which a person has a private or personal interest sufficient to appear to influence the objective exercise of research.
Data Management	Refers to the storing, protection and overall handling of relevant research records (e.g. written procedures, membership lists, lists of occupations, affiliation of members, submitted documents, minutes of meetings and correspondence for a period of 5 years after completion of the studies – excluding longitudinal studies, and make these available upon request.
Ethical Guidelines	Are rules and procedures whose purpose is to improve on prevailing practice and remedy its defects.
Ethics	Refers to moral standards and how these apply to the systems and organizations through which modern societies produce and distribute goods and services, and to the people who work in these organizations.
Ethics and responsibility	Means that researchers are obliged to do what is morally right and be answerable for all aspects and consequences of their research activities.
Fabrication	The invention of data and results, recording or reporting them with the intention of misleading or deceiving the intended audience
Falsification	The manipulation of research materials, equipment, processes or changing results, such that the research is not accurately presented in the research report. This include intentional provision of misleading research information or deliberate false reporting of research results
Financial interest	A situation where a researcher's judgment or performance is unduly influenced by secondary interests such as financial or other professional benefits, which may influence the integrity of the research process and/or the reporting of the research findings
Human participant	A subject on whom an investigator conducts research or who participates in research.
Informed consent	Refers to a process that requires providing relevant information to a participant, ensuring that the participant adequately understands the nature of the study and has agreed or refused to participate without having been subjected to coercion, or undue influence.
Innovation	Process of implementing new or significantly improved products (goods and services) or new marketing methodologies on how the new or existing organizations conduct their business practices to deliver new good and services.
Institutionalized persons	Are persons that are kept in confinement.
Integrity	Refers to values of 'truth' and 'honesty, which are fundamental to all forms of scientific research, creative and scholarly endeavors.

Justice	Refers to a specific principle to ensure the fair distribution of both burdens and benefits of research and is of particular relevance when research involves human participants.
Peer Review	Provision of fair, prompt and rigorous evaluations and respect for confidentiality when reviewing other's work.
Publication Acknowledgement	Researchers must indicate names and roles of those who made significant contributions to the research, including funders, and other persons, even though they do not meet authorship criteria.
Research	Refers to any form of disciplinary inquiry that aims to contribute to a body of knowledge or involves a disciplined inquiry at any level which is designed to demonstrate mastery of research skills and techniques.
Research Affiliates	Refers to a researcher conducting transitory research-related undertakings by using the University of Namibia research facilities through collaborating with researchers in faculty, centers and schools.
Research Associate	Refers to a person from another institution attached to UNAM to conduct research.
Research data management	Covers the planning, collecting, organizing, managing, storage, security, backing up, preserving, and sharing data according to legal, statutory, ethical and funding body requirements.
Research ethics	Refers to the moral standards that govern research. It includes moral standards governing research on Human subjects, Animals, Environment and Engineering, Business research and other specialized areas.
Scientific validity	Use of accepted scientific principles and methods , including statistical techniques, to produce reliable and valid data
Staff member	Any person appointed by UNAM whether full time or part-time.
Technology	Refers to machinery and equipment developed from the application of scientific knowledge.
Research Records	Refers to clear and accurate records of all research in ways that allows verification and replication of their work by others.
Unexpected death	Is any death that occurs prior to the approved experimental endpoint.
Visiting Scholars	Refer to an academic from an institution that visits a host university to teach, lecture, or execute research on a topic for which the scholar is valued.
Vulnerable and marginalized populations	Include the economically disadvantaged, racial and ethnic minorities, the uninsured, low-income, children, the elderly, the homeless, those living with HIV and Aids, and those with other chronic health conditions, including mental illness.

3.0 INTRODUCTION

Ethical considerations are critical in the conduct of research. Research ethics are standards of conduct that distinguish between right and wrong practices in research. UNAM is committed to principles of honesty, objectivity and respect for intellectual property, responsible conduct of research, confidentiality and non-discrimination. UNAM has formulated this Research Ethics Policy in order to establish fundamental principles of research ethics and scientific integrity, which will serve as the foundations for all research activities conducted at UNAM. UNAM supports scientific and ethical practices aligned to internationally acceptable norms that are fundamental to research.

This Research Ethics Policy has been developed from the principle of internationally acceptable ethical guidelines and codes of good practice for the different categories and disciplines of researchers working with animals, humans, the environment, engineering and others. The Policy defines the application of ethical principles and guidelines in the responsible conduct of research in an enabling academic environment.

This Policy also guides the processes for the establishment, operation and review of ethical policy and ethical procedures applied to research conducted by staff members, students, visiting scholars, collaborating research partners, research affiliates and research associates of UNAM.

4.0 POLICY OBJECTIVES

This Policy seeks:

4.1 To direct research agenda that takes into consideration ethical issues with strategic focus on and alignment with local, national, regional and international priorities.

4.2 To provide a broad framework that will guide and direct ethical conduct of research, innovation and related activities.

4.3 To provide a framework to maintain co-operative relationships with respect to ethical issues among the various Campuses, Faculties, Centres, Academics and other Units undertaking research.

4.4 To facilitate the effective promotion of both general and specific research activities based on good ethical code of conduct.

4.5 To ensure adherence to ethical research practices.

4.6 To ensure that the dissemination of research findings is guided by a good ethical code of conduct and practice through publications in peer-reviewed journals, books and other scholarly outlets.

5.0 SCOPE

This Policy applies to:

5.1 All UNAM staff members and students.

5.2 All visiting scholars, collaborating research partners, research affiliates and research associates conducting research at UNAM.

5.3 All externally funded research and research collaborations for which ethical clearance is sought from UREC.

6.0 ACCOUNTABILITY AND RESPONSIBILITY

6.1 The **Pro-Vice Chancellor: Research, Innovation and Development (PVC: RID)** is the custodian of this Ethics Policy and shall be responsible for providing strategic guidance and overseeing the administration, management and adherence to the ethical principles and regulations as stated in this Policy and in line with the UNAM's mission.

6.2 The **Director of Centre for Research and Publications (CRP)** shall be responsible and accountable for implementing the policy and overseeing ethical clearance matters.

6.3 **URECs** shall be established as oversight Committees responsible for promoting and protecting the rights and welfare of research participants, animals and the environment. An Ad hoc Committee shall be constituted to clear all other research projects that do not concern human participants, animals and the environment.

6.4 URECs shall review and provide ethical clearance for all research at UNAM that falls within their areas of jurisdiction and report the outcome to the Director: CRP.

6.5 The **URECs Chairpersons** shall be responsible for facilitating and chairing the URECs committees and ensure that the process of ethical clearance is fair and just.

6.6 The **Campus/Faculty/Centre Research Representatives** shall be responsible for facilitating the approval of research proposals as well as submitting the applications of ethical clearance to the respective URECs.

6.7 Staff and students are responsible for adhering to ethical principles in research projects.

6.8 Researchers are answerable for all ethical activities in research.

7.0 POLICY STATEMENT

7.1 The CRP shall ensure that no research shall be conducted without prior ethical clearance and hence all applications shall be submitted for ethical clearance.

7.2 All UNAM researchers and associates will uphold high ethical standards.

7.3 All UNAM researchers and associates will apply to the relevant URECs for ethical clearance, unless otherwise stipulated in the procedures.

7.4 UNAM researchers and associates may appeal the outcome of an ethical clearance application as per the approved guidelines.

7. 5 The final decision of the UREC with respect to ethical clearance shall be binding.

7.6 No UNAM researcher or associate shall conduct research without prior ethical clearance unless exempted by this policy.

7.7 The CRP shall provide ethical clearance services at a fee to researchers not associated with UNAM.

7.8 The URECs shall maintain excellence in the processing and approval of applications for ethical clearance.

7.9 The CRP shall provide ethics training to UREC members and to other staff involved in research administration on a regular basis.

8.0 SANCTIONS

Staff members and students who breach or violate the content of this Policy or its Regulations and Guidelines shall be subjected to disciplinary action specified in terms of the UNAM Disciplinary Policy and Procedures. Minor violations should be discussed and resolved at Departmental or Faculty level.

All forms of dishonesty as prescribed in UNAM's Policies will be regarded as serious offences. Complaints or awareness of misconduct by researchers or members of URECs will be investigated and managed according to the UNAM Disciplinary Policy and Procedures.

9.0 PROCEDURES

The procedures of this policy are contained in the Regulations, Guidelines and Forms that are part of this policy.

REGULATIONS AND GUIDELINES

A. ETHICAL CONDUCT

A1 Researchers shall ensure informed consent based on the principle of self-determination, honesty, objectivity, and respect for intellectual property, avoiding harm and conferring benefits on research participants.

A2 Researchers shall be required to maintain high standards of integrity and honesty. Academic dishonesty shall include but not limited to the fabrication, and falsification

A3 The investigator shall ensure confidentiality of participants' research data. Participants must be told the limits, legal or otherwise, to the investigators' ability to safeguard confidentiality and the possible consequences of breaches of confidentiality. Participants must also be informed who will have access to their information, especially when their data will be used in future research, and how confidentiality will be safeguarded in this regard.

A4 Investigators should ensure that research participants who may suffer injury as a result of participation are entitled to free medical treatment for such injury and such financial or other assistance as would compensate them equitably for any resultant impairment, disability or handicap. In the case of death as a result of their participation, their dependants are entitled to compensation. Participants must not be asked to waive this right to compensation.

A5 Researchers shall store their research data for a period of five years after completion of the project.

B. COMPOSITION AND FUNCTIONS OF UNAM RESEARCH ETHICS COMMITTEES (URECs)

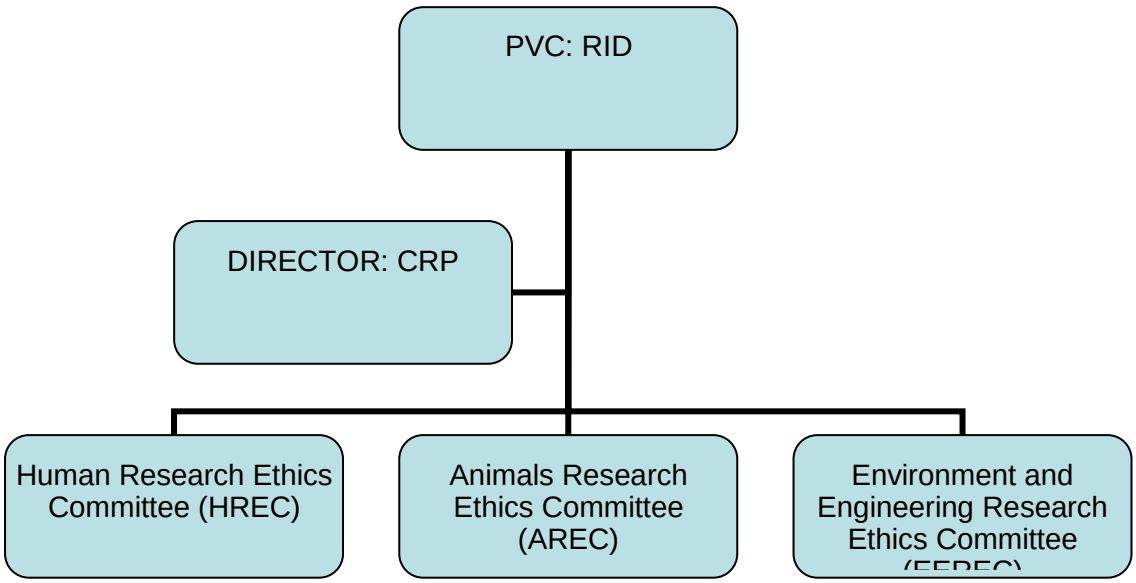
B1. UNAM RESEARCH ETHICS COMMITTEES (URECs)

B1.1 The following URECs will be constituted at UNAM as committees that report to PVC: RID as per Figure 1. The existing Interim UREC shall be replaced by the newly constituted committees as indicated below:

B1.1.1 Human Research Ethics Committee (HREC)

B1.1.2 Animals Research Ethics Committee (AREC)

B1.1.3 Environmental and Engineering Research Ethics Committee (EEREC)



B1.2 Proposals that do not address human, animal, environment and engineering research will be cleared by an Ad Hoc Research Ethics Committee (Ad Hoc REC) constituted by the Director: CRP.

B1.3 The Director: CRP and the Deputy Director: Centre for Postgraduate Studies shall be permanent members of the Ad Hoc REC.

B2. COMPOSITION OF THE URECs:

B2.1 The UREC shall normally consist of FIVE members from multidisciplinary backgrounds relevant to the UREC.

B2.2 The UREC may co-opt up to two (2) other experts and one (1) lay person (who represents the community/society) to participate in the discussions to meet requirements for expert diversity.

B2.3 The Director: CRP shall be an ex officio member of the URECs except the Ad Hoc REC for which he/she shall chair.

B2.4 The URECs shall meet monthly or more frequently to perform their duties.

B2.5 The members of UREC shall be proposed to the CRP by respective APVCs/Deans/ Associate Deans/ Directors and eventually appointed by the PVC: RID.

B2.6 The composition of the UREC must be balanced in gender distribution.

B2.7 The substantive members must be sufficiently grounded in research and have the requisite expertise as evidenced by a PhD degree to be able to make informed decisions.

B2.8 Conflict of interest should be avoided during discussions, but where unavoidable, such interest should be declared.

B2.9 UREC shall consider a system for membership that allows for continuity as well as the development and transfer of expertise.

B2.10 A list of proposed UREC members and their areas of specialization shall be submitted to the PVC: RID for formal appointment.

B3. TERMS OF REFERENCE OF THE URECs

The URECs are expected to perform the following duties:

B3.1 Review the ethical compliance of all research with reference to all the prescribed ethical principles and values of international, national and scientific standards.

B3.2 Ensure the protection of human participants, animals and the environment and that appropriate safeguards are put in place by the researcher.

B3.3 Include members who are familiar with vulnerable populations when processing research that concerns such groups.

B3.4 Ensure that researchers sign a confidentially agreement covering all materials and intellectual property rights submitted for review.

B3.5 Meet monthly or more frequently if necessary.

B3.6 Communicate review decisions to applicants timeously.

B3.7 Monitor and evaluate ethical compliance of approved research projects and take measures against non-compliance.

B3.8 Require undergraduate research supervisors to submit ethical approval checklists of their undergraduate research to Campus/Faculty/Centre Research Committees for monitoring.

B3.9 Submit monthly Reports to the Director: CRP, who shall provide the PVC: RID with quarterly UREC reports.

B3.10 Communicate to the PVC: RID Forum on matters concerning their mandate for notification or action, if needed.

B3.11 Independent advisors/consultants may be invited to the UREC meetings to provide advice.

B3.12 All UREC members, including independent advisors/consultants will sign the applicable confidentiality agreement.

B3.13 Each UREC shall appoint its own Chairperson during its first meeting.

B3.14 In the event that a conflict of interest arises with respect to a member of UREC, such member should withdraw from the meeting. This conflict should be communicated

by such member to the Chairperson of the committee, who in such an instance may co-opt another person to participate in the decision-making.

B3.15 The Term of Service for UREC members shall be four (4) years, renewable once.

B4. MANDATE OF THE URECs:

The mandate of the URECs shall be to:

B4.1 Apply and act in accordance with the UNAM Research Ethics Policy, Regulations and Guidelines in the ethical review process.

B4.2 Review the ethical compliance of all research falling under their thematic areas with reference to all prescribed ethical principles and values in these guidelines.

B4.3 Approve or disapprove research projects submitted for ethical clearance.

B4.4 Provide recommendations to applicants on the ethical compliance of their research.

B4.5 Monitor and evaluate ethical compliance of research and take measures against non-compliance.

B4.6 Report all decisions of ethical review and matters of interest to the Director: CRP for consideration and action if needed. Decisions taken will be communicated to the respective researchers.

C. REVIEW AND APPROVAL OF ETHICAL CLEARANCE APPLICATIONS

In order to approve a research, the respective UREC shall determine whether the following requirements have been met:

C.1 Risks to participants are minimized by using procedures which are consistent with sound research design and which do not necessarily expose participants to risk; and whenever appropriate, by using procedures already being performed on the participants for diagnostic or treatment purposes.

C.2 Risks to participants are reasonable in relation to anticipated benefits.

C.3 Selection of participants is equitable.

C.4 That informed consent will be sought from each prospective participant or the participant's legally authorized representative.

C.5 That informed consent will be appropriately documented.

C.6 Where appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of participants.

C.7 Where appropriate, there are adequate provisions to protect the privacy of participants and maintain the confidentiality of data.

C.8 When some or all of the participants are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons,

or economically/educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of those participant.

C1. TYPES OF ETHICAL REVIEWS

The following ethical review processes are available at UNAM:

C1.1 Full Ethical Review

A Full Ethical Review includes all postgraduate and postdoctoral research involving humans, animals (tissue, bodily fluids); fauna and flora (plant materials); the environment and engineering. This embraces research involving:

C1.1.1 Vulnerable and marginalized populations: children, institutionalized persons, the aged, and persons living with HIV and AIDS.

C1.1.2 Sensitive and controversial issues (cultural, social, legal, sexual preferences, etc.), as determined by the UREC.

C1.1.3 Experimental drugs or devices.

C1.1.4 Invasive procedures, animal studies and studies that may pose risks to the environment.

C1.1.5 Documents required for Full Ethical Review:

- C.1.1.5.1 UREC Application Form (Annex 1);
- C.1.1.5.2 Investigator's Declaration Form (Annex 2);
- C.1.1.5.3 Protocol (Annex 3), if applicable
- C.1.1.5.4 Checklist (Annex 4);
- C.1.1.5.5 A full proposal;
- C.1.1.5.6 A detailed Participant Information Sheet (where applicable) together with the Informed Consent Form (Annex 5);
- C.1.1.5.7 The research instrument (questionnaire; research questions, etc.);
- C.1.1.5.8 Application for Ethics Review of Research Involving Human and Animal Tissue and Bodily Fluids; and Plant Material (Annex 6);
- C.1.1.5.9 All relevant documents such as MOUs, Budgets and others, where applicable.

C1.2 Expedited Review

Expedited reviews must be undertaken by at least three members of the UREC who shall provide a written assessment and approval thereof. The Chairperson, together with two additional members will grant approval for the Expedited Review. The researcher must

specify in a letter why an Expedited Review is necessary. The Expedited Review must be completed within 10 days of receipt of application.

Ethical clearance may be expedited subject to the following:

C1.2.1 The application is a replication of a proposal that was approved by the UREC previously.

C1.2.2 The recommendation of an initial Full Ethical Review allows for an Expedited Review after recommendations were satisfactorily executed.

C1.2.3 All research that does not include humans, animals or the environment may be subjected to Expedited Review.

C1.2.4 The research is part of a wider project for which ethical clearance has been obtained from UREC by the Principal Investigator (PI).

C1.2.5 A previously approved proposal that has been resubmitted for ethical review as a result of changes to the original protocol.

C1.3 Exempted Review

Some research proposals will be exempted from ethical review if such proposals involve secondary data analysis and/or do not involve human or animal participants. In order to qualify for Exempted Review, the research must not pose more than minimal risk.

Minimum risk is the probability of physical, emotional or psychological harm that is normally encountered in the routine interaction with the environment, tissues and human samples, vulnerable people such as students, patients and people with disabilities, elderly people, veterans, children and marginalized communities.

Research that involves analysis of texts such as records in the public domain, literary works (e.g. fiction), speeches and other forms of texts that may be used for linguistic, literary or rhetorical criticism will be exempted from ethical clearance. Researchers whose proposals qualify for Exempted Review shall only need to notify the CRP on the nature of their study. This notwithstanding, investigators must demonstrate that their work will not violate intellectual property rights, will avoid plagiarism and must explain why their proposals should not be subjected to ethical review.

C.1.4 Undergraduate Research Review

All undergraduate research (including Honours degrees and other Level 8 qualifications) should be reviewed for scientific merit and ethical compliance by individual supervisors/lecturers of students at the departmental level, except when the project is part of a bigger project that has already been reviewed. Undergraduates must ensure that they

understand and apply the Research Ethics Guidelines. These reviews will be guided by a uniform UNAM review checklist provided by the CRP and will be monitored by the relevant Research Committees within Campuses, Faculties and Centres. Undergraduate research must not violate intellectual property rights and plagiarism rules. Undergraduate Research Review is only applicable when:

C1.4.1 The research is part of an undergraduate course offered by UNAM.

C1.4.2 The research does not pose more than minimum risk (as defined in section C.1.3).

C1.5 Researchers from Other Institutions who are not UNAM staff or Students

Researchers from other institutions who wish to conduct research at UNAM will need to apply to the Director: Centre for Research and Publications (CRP) for permission to undertake their research. The Director: CRP may grant permission to undertake research at UNAM following the University's decision-making structures. The application for permission to conduct research must be accompanied by the following:

C1.5.1 Letter of application.

C1.5.2 A full proposal.

C1.5.3 A detailed Participant Information Sheet (where applicable), together with the Informed Consent Form.

C1.5.4 The research instruments (questionnaire; research questions, etc.).

C1.5.5 All documents indicating ethical approval from other institutions, research collaborations e.g. MOUs, Sponsorship agreements, Protocol Budgets, Institutional Ethical Clearance, Research Permits, Work Permits as well as all other relevant documentation (where applicable).

C1.5.6 Where ethical approval from other institutions is not available, the researcher must apply for ethical clearance from the appropriate UREC at UNAM.

D. ADMINISTRATIVE FEES ON RESEARCH

The CRP shall levy Administrative Fees on all research not executed by UNAM staff or students. This shall include externally funded research projects and external researchers undertaking research at UNAM. The Administrative Fee shall be calculated at **15%** to **20%** of the total project budget depending on the complexity of the project. Administrative Fees cover expenses for administration, monitoring and evaluation of ethical compliance of projects; UREC training and conference attendance in research ethics matters, getting a layperson/person of interest representation in URECs as well as consultants when needed on URECs. Researchers who write proposals to be funded externally should therefore include a UNAM Administrative Fee as part of their budgets.

E. RESEARCH ETHICS TRAINING OF STAFF MEMBERS

UNAM staff members doing research shall require initial and continued educational opportunities regarding research ethical reviews related to human participants, fauna and flora, engineering and the environment. The educational opportunities shall also target UREC members. Capacity-building for the URECs may include, but is not limited to the following activities:

E1. Establishing and strengthening independent and competent ethical review processes/committees.

E2. Strengthening research capacity.

E3. Developing technologies appropriate to research.

E4. Educating the community from which research participants will be drawn.

F. SUBMITTING AN APPLICATION FOR ETHICAL REVIEW

F1. REQUIRED DOCUMENTATION

The following documents should be prepared and submitted. All the relevant application forms/annexes are available on the UNAM Intranet.

F1.1 The resolution and resolution number of the relevant Campus/Faculty/School/Centre Research Committee as per the UNAM Research Policy.

F1.2 Signed application form (Annex1).

F1.3 Investigators Declaration (Annex 2).

F1.4 Proposal Synopsis (Annex 3).

F1.5 Checklist (Annex 4).

F1.6 Participant Information Leaflet and consent Form (Annex 5).

F1.7 Application for Ethics Review of Research Involving Human Tissue and Bodily Fluids (Annex 6).

F1.8 Questionnaires, diary cards, and/or case report forms intended for research participants (where applicable).

F1.9 Investigator(s)'s updated, signed and dated curriculum vitae (CV).

F1.10 Materials to be used (including advertisements) for the recruitment of potential research participants.

F1.11 Written and other forms of information for potential research participants (clearly identified and dated) in the language(s) understood by the potential research participants. Translations must be verified by a competent person in the vernacular.

F1.12 All other supporting documentation as indicated in Annex 4.

F1.13 A summary of all previous decisions (e.g. those leading to a negative decision or modified proposal) by other URECs or regulatory authorities for the proposed study (whether in the same location or elsewhere) and an indication of modification(s) to the proposal made on that account. The reasons for previous negative decisions must be provided.

F1.14 All relevant prescribed permits and access benefit agreements with communities must accompany the application.

F1.15 Any additional information specific to the project, as may be required by the UREC.

F2. APPLICATION PROCEDURE

All applications for ethical clearance should be submitted according to the following procedure:

F2.1 The Chairperson of the relevant Campus/Faculty/School/Centre Research Committee (as per the Research Policy) shall submit electronic applications for ethical clearance for all projects approved by the Committee to the CRP at least 14 days prior to scheduled UREC meeting dates as specified in the UNAM daily calendar.

F2.2 All applications must be in the English language.

F2.3 Applicants may be expected to clarify issues in person on request of the UREC.

F2.4 Incomplete applications will not be accepted and will be referred back.

F3. THE TURN-AROUND TIME OF APPLICATIONS FOR ETHICAL CLEARANCE

F3.1 Applications for ethical clearance shall have a turnaround time of not more than one month.

F3.2 The UREC members must review submitted documents at least one week (using a checklist) before a scheduled meeting. Individual members of the UREC may request supplementary documentation from applicants and will communicate these to the applicants.

F3.3 All correctly completed application forms received by the CPR prior to the mentioned date will be considered and the outcome will be communicated electronically within a week of the UREC meeting date.

F4. REVIEW PROCESS

All properly submitted applications will be reviewed in a timely fashion and according to an established review procedure. The UREC Meeting requirements are as follows:

F4.1 The different URECs shall meet at least once a month as indicated in the UNAM Calendar.

F4.2 Quorum: In case of a Full Ethics Review, at least three members of the constituted committee will form a quorum.

F4.3 UREC members should receive relevant documentation of the Review Meeting at least seven days in advance.

F4.4 Minutes of proceedings of UREC meetings must be taken and there should be an approval procedure for the minutes.

F4.5 Minutes of meetings will be safely kept according to UNAM procedures.

F4.6 The applicant may be invited to present the proposal or elaborate on specific issues.

F5. DECISION-MAKING

In making decisions on applications, the UREC should take the following into consideration:

F5.1 URECs must have sufficient time to discuss and make decisions on application for ethical clearance of research projects.

F5.2 Decisions should be determined by consensus.

F5.3 Only substantive Members will partake in decision making.

F5.4 The outcome of an ethical review must be communicated to the applicant within one week.

F6. COMMUNICATING A DECISION

The UREC Chairperson shall communicate the decision to the applicant, copied to Director: CRP. This communication shall include the following:

F6.1 The names of the applicants and exact title of the research proposal reviewed.

F6.2 The clear identification of the proposal for research or amendment, date and version number (if applicable) on which the decision is based.

F6.3 A clear statement of the decision reached and any other information as needed.

F6.4 Signature of the Chairperson (or other authorized person).

F6.5.1 Non-approval of an ethical review application will be accompanied by an explanation of the reasons for such non-approval.

F6.5.2 In case of conditional approval of an ethical review, the applicant will be provided with clear suggestions for revision of the project/application as well as the re-application procedure.

F7. APPEAL PROCEDURES

F7.1 The applicant may appeal to the CRP a negative decision pertaining to the application.

F7.2 The CRP will appoint an appeal review committee that may include members of the initial UREC.

F7.3 The applicant shall provide reasons for the appeal in writing to the CRP, and present the case in person at the appeal committee.

F7.4 The outcome of the appeal committee shall be final and binding

F8. FOLLOW-UP PROCEDURES

The CRP should establish a follow-up procedure to track the progress of all studies for which a positive decision has been reached, from the time the decision was taken until the termination of the research. The ongoing lines of communication between the CRP and the applicant should be clearly specified. The follow-up procedure should take the following into consideration:

F8.1 the quorum requirements, the review procedure, and the communication procedure for follow-up reviews, which may vary from the requirements and procedures for the initial decision on an application;

F8.2 the follow-up review intervals should be determined by the nature and the events of research projects, although each protocol should undergo a follow-up review at least once a year;

F8.3 The following events require the follow-up review of a study:

F8.3.1 Any protocol amendment likely to affect the rights, safety, and/or well-being of the research participants or the conduct of the study;

F8.3.2 Serious and unexpected adverse events related to the conduct of the study or study product, and the response of investigators, sponsors, and regulatory agencies;

F8.3.3 Any event or new information that may affect the benefit/risk ratio of the study.

F8.3.4 The decision of a follow-up review should be issued and communicated to the applicant, indicating a modification, suspension, or termination of the UREC's original decision or confirmation that the decision is still valid;

F8.3.5 In the case of the premature suspension/termination of a study, the applicant should notify the UREC of the reasons for suspension/termination; a summary of results obtained in a study prematurely suspended/terminated should be communicated to the UREC;

F8.3.6 The UREC should receive notification from the applicant at the time of the completion of a study.

F8.4. The UREC should receive a copy of the final report of the study.

G. RESEARCH INVOLVING HUMAN PARTICIPANTS

Research on human participants is ethically justified by the prospect of discovering new techniques and materials that benefit society. Such research can be ethically justifiable only if it is undertaken in ways that respect, protect and with due care to the participant of that research and are morally acceptable within the communities in which the research is undertaken. Moreover, because scientifically invalid research is unethical in that it exposes research participants to risks without possible benefits, investigators and sponsors must ensure that proposed studies involving human participants conform to generally acceptable scientific principles, based on adequate knowledge of the pertinent scientific literature.

G1. INFORMED CONSENT

For all research involving human subjects, the investigator must obtain the voluntary informed consent of the prospective participant. In the case of an individual who is not capable of giving informed consent, the permission of a legally authorized representative

should be obtained. The UREC members should consider the following in relation to informed consent:

G1.1 Process;

G1.2 Language;

G1.3 Comprehension;

G1.4 Documentation of information to the participant and consent;

G1.5 Renewing consent;

G1.6 Cultural considerations;

G1.7 Consent to use biological materials (including genetic materials) for research purposes from those participating in clinical trials;

G1.8 Consent to use medical records and biological specimens;

G1.9 Consent to use secondary research or biological specimens;

G1.10 Specification of obligations of sponsors and investigators;

G1.11 Specification of incentives to participate in the study;

G1.12 Assent in the case of children and persons with diminished capabilities.

G2. BENEFITS AND RISKS

For all research involving human participants, the investigator must ensure that potential benefits and risks are reasonably balanced and risks are minimized. Rigorous statistical analysis of proposals is required for all investigations and approval will hinge on proof of statistical review.

G2.1 Interventions or procedures that hold out the prospect of direct diagnostic, therapeutic or preventive benefit for the individual participant must be justified by the expectation that they will be at least as advantageous to the individual participant, in the light of foreseeable risks and benefits, as any available alternative. Risks of such 'beneficial' interventions or procedures must be justified in relation to expected benefits to the individual participant.

G2.2 Risks of interventions that do not hold out the prospect of direct diagnostic, therapeutic or preventive benefit for the individual must be justified in relation to the expected benefit to society (generalizable knowledge). The risks presented by such interventions must be reasonable in relation to the importance of the knowledge to be gained.

G3. RESEARCH INVOLVING POPULATIONS AND COMMUNITIES WITH LIMITED RESOURCES

Before undertaking research in a population or community with limited resources, the sponsor and the researcher must make every effort to ensure that:

G3.1 Groups or communities to be invited as participants in research are selected in such a manner that benefits of the research are equitably distributed with the community.

G3.2 The research is responsive to the health needs and the priorities of the population or community in which it is to be undertaken.

G3.3 Any intervention or product developed, or knowledge generated, will reasonably be made available for the benefits of that population or community.

G3.4 In principal, special justification for inviting vulnerable individuals to serve as research participants is provided, and if such individuals are selected, the means of protecting their rights and welfare are strictly applied.

G4. RESEARCH INVOLVING CHILDREN

Before undertaking research involving children, the investigator must ensure that:

G4.1 A parent or legal representative of each child has given permission;

G4.2 The consent of each child has been obtained to the extent of the child's capabilities;

G4.3 A child's refusal to participate or continue in the research shall be respected.

G5. RESEARCH INVOLVING INDIVIDUALS WITH MENTAL OR BEHAVIOURAL DISORDERS

Before undertaking research involving individuals with mental or behavioral disorders, the investigator must ensure that:

G5.1 Such persons will not be participants of research that might equally well be undertaken on persons whose capacity to give adequately informed consent is not impaired.

G5.2 The purpose of the research is to obtain knowledge relevant to the particular health needs of persons with mental or behavioral disorders.

G5.3 The consent of each participant has been obtained to the extent of that person's capabilities, and a prospective participant's refusal to participate in research shall always be respected, unless in exceptional circumstances.

G5.4 In cases where prospective participants lack the capacity to consent, permission is obtained from a responsible family member or a legally authorized representative in accordance with the applicable law.

G6. RESEARCH INVOLVING WOMEN

Investigators, sponsors or UREC should not exclude women of reproductive age from biomedical research. The potential for becoming pregnant during a study should not, in itself, be used as a reason for precluding or limiting participation. However, a thorough discussion of the risks to the pregnant woman and to her fetus is a prerequisite for the woman's ability to make a rational decision to enroll in a clinical study. In this discussion, if participation in the research might be hazardous to a fetus and if a woman becomes pregnant, the sponsors/investigators should guarantee the prospective participant a pregnancy test and access to effective contraceptive methods if not pregnant, before the research commences. Where such access is not possible, for legal or religious reasons, investigators should not recruit such women who might become pregnant to avoid possible hazardous research.

Pregnant women should be presumed to be eligible for participation in research. Investigators and UREC should ensure that prospective participants who are pregnant are adequately informed about the risks and benefits to themselves, their pregnancies, the fetus and their subsequent offspring, and to their fertility. Research in this population should be performed only if it is relevant.

G7. RESEARCH INVOLVING THE USE OF HUMAN TISSUE AND OTHER HUMAN SAMPLES

The research must indicate any known or potential benefits to the scientific community and/or humans from the study, as well as explain what new information is expected from the research, and its anticipated value. The research must identify what type of human tissue and human samples will be collected, and describe:

G7.1 How the samples will be stored;

G7.2 What universal precautions for handling the human tissue/human samples will be followed;

G7.3 The procedures or safeguards in place for each type of human tissue and human sample, and procedures that will be used in this study to protect persons working with these;

G7.4 How long the samples will be stored;

G7.5 Who will have access to the samples for future use;

G7.6 How samples will be disposed of upon completion of the study;

G7.7 Justification for banking the human tissue;

G7.8 If the research is a multi-centered study;

G7.8.1 The study details, indicating the source/supplier for each type of human tissue or human samples to be used;

G7.8.2 Where will the human tissue /human samples be used (location);

G7.8.3 Has the protocol been submitted to another REC/IRB;

G7.8.4 Indicate the procedures to be completed on each type of human tissue or human samples;

G7.8.5 Whether a written informed consent was obtained for the use of the human tissue or human samples;

G7.8.6 How anonymity of participants and confidentiality of data will be ensured, and describe the procedures to ensure security of data;

G7.8.7 What type of record-keeping will be employed (paper records/electronic records).

G8. CHOICE OF CONTROL IN CLINICAL TRIALS

As a general rule, research participants in the control group of a trial of a diagnostic, therapeutic, or preventive intervention should receive an established effective intervention. In some circumstances it may be ethically acceptable to use an alternative comparator, such as placebo or “no treatment”. In non-therapeutic/quasi-experimental research a control group must also receive the intervention withheld from them during the research project, after completion of the project.

Placebo may be used:

G8.1 When there is no established effective intervention.

G8.2 When withholding an established effective intervention would expose participants to, at most, temporary discomfort or delay in relief of symptoms.

G8.3 When use of an established effective intervention as comparator would not yield scientifically reliable results and use of placebo would not hold any risk of serious or irreversible harm to the participants.

G9. FINANCIAL INTEREST/CONFLICT OF INTEREST

Researchers should disclose all actual, potential or perceived conflicts of interest which may interfere with their objectivity. Researchers should conduct research according to established national and international laws and guidelines. Researchers should demonstrate the potential contribution of the proposed research to either scientific knowledge, students’ skills or to society at large.

G10. COLLABORATIVE RESEARCH, AUTHORSHIP AND INTELLECTUAL PROPERTY RIGHT

Collaborative research projects must be submitted for ethical clearance as stipulated in these guidelines. Sub-themes in collaborative research will undergo separate ethics review. Ethical clearance of collaborative projects may qualify for expedited review as stipulated in these guidelines.

Authorship and intellectual property rights must be clarified between collaborating research institutions and be stipulated in a MoU or Agreement/Contract. This MoU or Agreement/ Contract must be included in the documents needed for ethical clearance.

H. RESEARCH ON ANIMALS, ENVIRONMENT AND ENGINEERING

H1. PROTECTION OF ANIMALS

H1.1 Permission

All researchers who wish to conduct research or perform teaching projects/practical exercises that involve the use of live animals must apply for a permit from the Ministry of Environment and Tourism and produce proof of such a permit to the Ethics Committee of the University *before* research commences. This includes the use of animals in research, teaching, field trials, product testing, diagnosis, the production of biological products and environmental studies.

Projects involving animals may only commence with approval in writing from the Ethics Committee. The validity period of such approvals, including extensions is 36 months. Extensions of this period may be granted by the Ethics Committee. Each request for an extension will be judged on its own merits. The extension request must be submitted to the Ethics Committee in writing.

H1.2 Biosafety

If the project involves the use of recombinant DNA, potential pathogens, radioactive isotopes or other hazardous substances, the project needs clearance from the National Biosafety Council, or the Office of the Environmental Commissioner. Proof of clearance should be provided to the relevant UREC before commencement of the project.

H1.3 Re-use of Animals:

Individual animals may not be used in more than one scientific activity, either in the same or different projects, without the approval of the Ethics Committee. However, appropriate re-use of animals may reduce the total number of animals used in a project, result in better experimental design, reduce distress or avoid pain to other animals. When considering approval for the re-use of animals, the Ethics Committee must take into account:

H1.3.1 the pain or distress and any potential long-term accumulative effects caused by any previous procedures;

H1.3.2 the total time that an animal will be used;

H1.3.3 the pain or distress likely to be caused by the next and subsequent procedures;

H1.3.4 whether an animal has fully recovered from the previous procedure before being used in the next procedure.

H1.4 Release and re-homing of animals:

The Ethics Committee with the aid of a veterinarian or environmental officer can assess the suitability of animals for re-homing or release into the wild. The Ministry of Environment and Tourism should also be contacted in case animals need to be re-homed or released.

H1.5 Unexpected deaths of animals and adverse events:

The Ethics Committee and the Ministry of Environment and Tourism must be notified in writing of any unexpected deaths or adverse events within 72 hours.

H1.6 Monitoring and inspection of animals and animal facilities:

The Animal Ethics Committee or an officer designated by that Committee may inspect any animal facility at any time by prior arrangement with the Principal Investigator. It is recommended that researchers make themselves available to the Committee during the inspections so that they may discuss their work with the Committee. The approval number for a protocol must be displayed prominently on each cage/aviary/area in which animals are held and on the appropriate notice board within the facility containing these animals.

H.2 PROTECTION OF THE ENVIRONMENT

H2.1 Requirements:

The fauna and flora of Namibia must be protected during all research projects. Due care must be displayed when performing research in public and communal environments and the necessary permission must be obtained before research commences in such environments.

H2.2 Field work and the environment:

For studies that involve field work, but no collection of animals, plants or other artefacts, researchers should perform their field work with the greatest care and respect for the environment.

H3. ENGINEERING RESEARCH

Engineering research focuses on practical fields of design, manufacture or construction of machines, engines, equipment, appliances, electro-mechanical devices, nano-devices,

sensors, structures, buildings, infrastructure, transport systems, vehicles, communication systems, electrical power transmission systems, mining operations, mineral processing, materials processing, bio-engineering, artificial intelligence, robotics etc. Information Technology research involves activities such as computing, high-speed computation, micro-processors, cable and fiber communication, wireless communication and distributed networks. In the design and execution of such research projects, due consideration must be given to the protection of persons, animals, plants and the environment.

H4. HUMAN EMBRYONIC STEM CELL RESEARCH

The goals of stem cell research are widely accepted in the biomedical research community and endorsed by diverse scientific societies worldwide. Long-term goals of stem cell research include improvements in human health and the relief of disease, infirmity, and human suffering through advances in knowledge and new clinical tools.

There are, however, scientific, socio-cultural, religious, ethical and legal issues in human stem cell research and the UREC will adopt the guidelines prepared by the International Society for Stem Cell Research in the review, and approval of Human Embryonic Stem Cell research at UNAM.

H5. RESEARCH INVOLVING BIOHAZARDOUS MATERIALS

To ensure safe research activities that involve the use of hazardous materials, UREC approval must be obtained. Research must be conducted safely and in accordance with applicable national laws and UNAM's regulations and best practices.

Biohazardous materials (biological, chemical, radioactive) may include bacteria, viruses, plasmids, cell-lines, recombinant DNA, human (or primate) body fluids (including blood) and all forms of penetrating radiation.

Ethical review and approval must ensure research is carried out in a way that prevents accidents and minimizes exposure to hazardous agents and conditions, prevents degradation of the environment through responsible waste management and active waste reduction, conserve resources and minimizes losses, and achieves regulatory compliance.

I. DATA MANAGEMENT AND STORAGE

I1. The research data management plan which explains how research data will be handled during and after the completion of the research project must be explained and shared with the research participants beforehand.

I2. In cases where a researcher intends to re-use existing data owned by another researcher, the researcher has to comply with the intellectual property rights, copy

right and licensing conditions associated with that data. The researcher is also required to obtain permission to re-use data, clarify the research data's ownership when necessary and always provide appropriate attribution and citation.

I3. The research data must be stored for a period of five years after which is discarded following acceptable environmental standard

J. ACKNOWLEDGEMENTS

The University of Namibia acknowledges that the above guidelines were developed by using ideas and provisions from the following documentation:

J1. Declaration of Helsinki

J2. Belmont Report

J3. National Institute of Health (NIH) Guidelines for the Conduct of Research Involving Human Subjects

J4. World Health Organization (WHO) Operational Guidelines for Ethics Committees that Review Biomedical Research

J5. Council for International Organizations of Medical Sciences (CIOMS) International Ethical Guidelines for Biomedical Research Involving Human Subjects.

J6. ICH Good Clinical Practice Guidelines

K. ANNEXES

The following annexes are included:

K1 Application form (ANNEX 1)

K2 Investigator's Declaration Form (ANNEX 2)

K3 Synopsis Protocol (ANNEX 3)

K4 Applicant's Checklist (ANNEX 4)

K5 Participant Information Leaflet and Consent Form (ANNEX 5)

K6 Application for Ethics Review of Research Involving Human and Animal Tissue and Bodily Fluids; and Plant Material (ANNEX 6)

ANNEXES

ANNEX 1

APPLICATION FORM

UREC NUMBER: (For Official Use)

Original UREC Trails Application Forms must be made available to the Centre for Research and Publications upon request

SECTION 1: DETAILS OF APPLICANT/PRINCIPAL INVESTIGATOR		
Title, First name, Surname:	**Staff/Student number:**	***PROJECT ID NUMBER (Official Use)***
Professional Status:		
University DIVISION:		
University DEPARTMENT:		
Complete Postal Address:		
Telephone No:	**E-mail address:**	
Registration with MOHSS* ☐ Yes ☐ No x	**Registration #:**	
Note: • *or equivalent statutory health council registration no. as appropriate* • *if registration is pending, submit proof of application* • *if a non-medically trained PI is overseeing research which involves medical procedures, the application must include a medical doctor registered with the MOHSS as a co-investigator*		
SECTION 2: TITLE OF STUDY		
Title of Research Project:		
Sponsor's Protocol No. (if applicable):		
Sponsor's Details (if applicable):		
Is this a sub-study (new research question) linked to an existing/main study? ☐ Yes ☐ No		**If yes, HREC #:**

SECTION 3: STUDY FOR DEGREE PURPOSES	☐ Yes ☐ No	**Undergraduate** ☐	**Postgraduate** ☐
Name of Degree:		**Supervisor:**	
Division:			
Department:		**E-mail:**	

SECTION 4: DETAILS OF COLLABORATING INVESTIGATORS		
Name and Title	**Position and role**	**Division AND Department**
1.		
2.		
3.		
4.		

SECTION 5: DETAILS OF SUB-INVESTIGATORS		
Name and Title	**Position and role**	**Division AND Department**
1.		
2.		
3.		

SECTION 6: WHERE WILL THE STUDY BE CONDUCTED?	
1. Windhoek Central Hospital	
2. Oshakati Hospital	
3. ……. Hospital	
4. Faculty of Medicine and Health Sciences	
5. Other: please list	

SECTION 7: HUMAN SUBJECTS RESEARCH PROTECTION	
1. Does the research involve human subjects who are alive?	☐Yes
Dead (includes identifiable tissues specimens)?	☐Yes
Medical records only?	☐ Yes ☐
Students, staff or alumni of the University of Namibia	☐Yes ☐
2. Will any medicine be tested during the investigation?	☐Yes ☐
2.1 If Yes to question 2, is the medicine approved by the Medicines Control Council?	☐ Yes ☐
2.2 If Yes to question 2.1, is the medicine registered for the dose which will be used in this specific project?	☐ Yes ☐ No
2.3 If Yes to question 2.1, is the medicine registered for the indication(s) which will be used in this specific project?	☐ Yes ☐ No
2.4 If No to question 2.1, is the medicine approved by the Medicines Control Council for your use in this specific project?	☐ Yes ☐ No
2.5 If No to question 2.2 and/or 2.3, is the medicine approved by the Medicines Control Council for your use in this specific project?	☐ Yes ☐ No
3. Will any radioactive material be administered to the patient during the	☐Yes ☐
4. Is any biohazardous material (*) involved in the project? (*) *"Biohazardous material" refers to recombinant DNA molecules, viruses, fungi, parasites, bacteria and all other potentially biohazardous material or products that are dangerous to both the*	☐Yes ☐ No

experimental patient and the researcher.	

SECTION 8: RESEARCH WITH CHILDREN	
1. Does your research involve children? *(A child is defined as a person younger than*	☐Yes
If No, please continue to section 9	
If Yes, please specify the age range of potential child	

1.1 Indicate whether the child research is *Therapeutic* or *Non-therapeutic* *(Please check [✓] the appropriate box below and provide a brief justification)*	
1.1.1 **Therapeutic research** = Interventions that hold out the prospect of direct health-related benefit for the child participant; OR	
1.1.2 **Non-therapeutic research =** Interventions that do not hold out the prospect of direct health-related benefit for the child participant but results may be produced that significantly contribute to generalisable knowledge about the child participant's condition.	
1.1.3 Brief justification:	

1.2 Indicate which risk category is applicable to your research involving children (Please check [✓] the appropriate box below and provide a brief justification)	
1.2.1 "The research poses no more than minimal risk to the child (that is, the risk commensurate with daily life or routine medical or psychological examinations – referred to as 'negligible risk' in some guidelines).	
1.2.2 The research poses more than minimal risk but holds out the prospect of direct benefit for the child participant.	
1.2.3 The research poses a minor increase over minimal risk, with no prospect of direct benefit to the child participant, but will likely yield generalisable knowledge about the condition under study.	
1.2.4 The research does not meet the conditions for the risk categories above but presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children.	
1.2.5 Brief justification:	

1.3 This research is essential research for children and presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children.	☐ Yes ☐ No

SECTION 9: STUDY TYPE			
1. Industry Sponsored Clinical Trial		**2. Self Initiated Clinical Trial**	
3. Retrospective Record Review		**4. Laboratory-Based Research**	
5. Qualitative Research		**6. Prospective Descriptive Study**	
7. Other		**Please state type if 'Other':**	

SECTION 10: HOW IS THIS RESEARCH FUNDED? *(State approximate total budget)*			
1. Industry	**N$**	**2. NIH/US government funded research , etc.**	**N$**

3. Other international grant funded research (e.g. Wellcome Trust)	**N$**	**4. National grant funded research (e.g. NCRST, etc.)**	**N$**
5. Harry Crossley funded research	**N$**	**6. Research funded solely from UNAM URPC budget**	**N$**
7. Self funded research	**N$**	**8. Non-sponsored student research for degree purposes at the University of Namibia**	

SECTION 11: DISCLOSURES

1. Have you acquainted yourself with the code of conduct regarding the ethics of research at this Institution and do you undertake to fully comply with it at all times?	☐Yes ☐ No
2. Has this study been, or is it likely to be, submitted to any other Research Ethics Committee?	☐ Yes ☐ No
2.1 If yes, please name the Committee(s) and provide outcome, i.e. approved/rejected. *(If approved, attach approval letter)*	
3. Has the Principal investigator or any of the co-investigators previously been/or are presently being investigated for alleged research misconduct?	☐ Yes ☐No
3.1 If yes, please provide details and dates	
4. Are any of your intended research participants in other research studies and/or trials?	☐ Yes ☐ No
4.1 If yes, please provide details	
5. Are you presently a Principal Investigator (PI) in other research and/or clinical trial activities?	☐ Yes ☐ No
5.1 If yes, please provide details and % of your time allocated to each	
6. Have you completed a Payment instruction form: Health/Human or Payment instruction form: Clinical trial AND attached proof of payment to this application (Health/Human research)?	☐ Yes ☐No
7. Does this protocol comply with the Helsinki Declaration of 2013? *(See http://www.wma.net/en/30publications/10policies/b3/)*	☐ Yes ☐ No
7.1 If no, please explain with full justification	
8. Does the protocol provide insurance for research-related adverse events?	☐ Yes ☐ No
8.1 If yes, please describe:	

8.2 If no, please justify:	
8.3 Is there provision for insurance?	☐ Yes ☐ No
8.4 If no, please justify:	
9. Does the project involve the use of diagnostic test results (e.g. those obtained by imaging or by laboratory testing)?	☐ Yes ☐ No
9.1 If yes, has the applicant consulted a professional from a relevant diagnostic discipline (e.g. radiology or pathology, as applicable)?	☐ Yes ☐ No
9.2 Please provide the name, position, and discipline of person consulted:	

SECTION 12: SIGNING OF APPLICATION		
Applicant	**Supervisor** *(only for student research)*	**Head of Division**
…… Print name …… Signature …… Date	…… Print name …… Signature …… Date	…… Print name …… Signature …… Date

ANNEX 2

INVESTIGATOR'S DECLARATION

UREC NUMBER: (Official Use)

The Principal Investigator, Supervisor, as well as all Sub-and Co-Investigators must each sign a separate declaration

SECTION 1: INVESTIGATOR'S DETAILS AND ROLE IN THIS RESEARCH (For Official Use)				
Title: First Name, Surname:		**Staff/Student #**		**CRP Project #**
Professional Status:				
Faculty/Department/Division:				
Telephone No:		**E-mail:**		
Role (mark with x)	☐ **Principal Investigator**	☐ **Co-Investigator**	☐ **Sub-Investigator**	**Supervisor**

SECTION 2: PROJECT TITLE

SECTION 3: CONFLICT OF INTEREST (OBLIGATORY) PLEASE INDICATE

I, (Title, Full name) …….. declare that:

- I have no financial or non-financial interests, which may inappropriately influence me in the conduct of this research study; OR
- I do have the following financial or other competing interests with respect to this project, which may present a potential conflict of interest (attach a separate detailed statement).

Signature…… Date……...

SECTION 4: DECLARATION (OBLIGATORY)

I, (Title, Full Name) ……. declare that:

- **I have read through the submitted version of the research protocol and all supporting documents and I am satisfied with their contents.**
- I am **suitably qualified and experienced** to perform and/or supervise the above research study.
- I agree to conduct or supervise the described study personally in accordance with the relevant protocol and will only change the protocol after approval by the **UREC,** except when urgently necessary to protect the safety, rights, or welfare of subjects. In such case, I am aware that I should notify the UREC without delay.
- I agree to timeously report to the UREC **serious adverse events** that may occur in the course of the investigation.
- I agree to maintain **adequate and accurate records** and to make those records available for inspection by the appropriate authorized agents when necessary.
- agree to comply with all other requirements regarding the obligations of clinical investigators and all other pertinent

requirements in the Declaration of Helsinki (2013), as well as Namibian and ICH GCP Guidelines and the Ethical Guidelines of MOHSS, as well as applicable regulations pertaining to health research.

- I agree to comply with all regulatory and monitoring requirements of the UREC.
- I agree that I am conversant with the above guidelines.
- I will ensure that every patient (or other involved persons), shall at all times be **treated in a dignified manner and with respect.**
- I will submit all required reports within the stipulated timeframes.

Signature……. Date……

ANNEX 3

PROTOCOL SYNOPSIS

(Not longer than 2 typed pages)

Name:
Staff/Student Number:
Title:

1. **Introduction, Motivation and Literature (1 paragraph)**

2. **Research Questions (1 paragraph)**

3. **Study Objectives/Aims (4 lines)**

4. **Research Methodology (clear, concise and to the point. 5 lines)**

5. **Ethical Considerations (State clearly and how these fit the research context. 4 lines)**

ANNEX 4

CHECKLIST

(To be typed by the applicant and checked by Centre for Research and Publications)

UREC NUMBER: (For Official Use)

PROJECT TITLE:

SECTION 1: CHECKLIST - COMPLETION OF APPLICATION FORM		
Have you completed all the sections in the application form? Please answer yes, no or not applicable in the "applicant column".	**Applicant**	**Admin Office**
	Y / N / NA	**Y / N / NA**
Section 1: Details of Applicant/Principal Investigator		
UNAM staff number		
Faculty		
Department		
Registration with Appropriate Ministry (MOHSS, etc.)		
Registration number (where applicable)		
Section 2: Title of Study		
Is this a sub-study linked to an existing main study?		
Section 3: Study for degree purposes		
Study for degree purposes		
Name of degree		
Supervisor indicated in case of study purposes?		
Section 4: Details of collaborating investigators		
Section 5: Details of sub-investigators		
Section 6: Where will the study be conducted?		
Section 7: Human subjects research protection		
Section 8: Research with children		
Section 9: Study type		
Section 10: Is the research funded?		
Is the approximate total budget stated?		
Have you paid the HREC review fee? (Where applicable)		
Section 11: Disclosure(s) submitted?		
Did you complete ALL questions?		
Have you completed a Payment instruction form: Health/Human or Payment instruction form: Clinical studies AND attached proof of payment to this		

application (Health/Human research)?		
Section 12: Signing of Application		
Applicant Signature		
Supervisor Signature (only for student research)		
HOD Signature		
SECTION 2: CHECKLIST - COMPULSORY DOCUMENTS ATTACHED		
Have you attached the following compulsory documents? Please answer yes, no or not applicable in the "applicant column".	**Applicant** **Y / N / NA**	**Admin Office** **Y / N / NA**
1. Application form		
2. Checklist		
3. Study protocol		
3.1 Page numbers on protocol		
4. Protocol synopsis or summary (not exceeding 2 pages)		
5. Participant Information and Consent Form (ICF)		
6. Investigator CVs and Investigator Declarations attached?		
6.1 Principal Investigator *(insert name)*:		
• **CV attached?** • **Declaration attached?** • **Declaration signed?** • **Conflict of interest signed?**		
6.2 Supervisor (*insert name):* ***[only for student research]***		
• **CV attached?** • **Declaration attached?** • **Declaration signed?** • **Conflict of interest signed?**		
6.3 Sub/Co-Investigator 1 *(insert name):*		
• **CV attached?** • **Declaration attached?** • **Declaration signed?** • **Conflict of interest signed?**		
6.4 Sub/Co-Investigator 2 *(insert name):*		
• **CV attached?** • **Declaration attached?** • **Declaration signed?** • **Conflict of interest signed?**		

6.5 Sub/Co-Investigator 3 ***(insert name):***		
• **CV attached?** • **Declaration attached?** • **Declaration signed?** • **Conflict of interest signed?**		
6.6 Sub/Co-Investigator 4 ***(insert name):***		
• **CV attached?** • **Declaration attached?** • **Declaration signed?** • **Conflict of interest signed?**		
7. Budget		
8. Questionnaires		
9. Other measuring tools/instruments		
10. Recruitment material / Advertisement(s)		
11. MOHSS or other letters of approval to conduct research		
12. Material Transfer Agreement		
13. Proof of payment for UREC review fee (External applications only)		

Section 3: CHECKLIST - INFORMED CONSENT FOR RESEARCH

To be completed by Applicant

Element	**Applicant**
	Y / N / NA
1. That consent is being sought from the participant to participate in research.	
2. Statement of the purpose of the research and where it will be conducted.	
3. The expected duration of the participant's involvement in the research.	
4. The total number of participants that will be involved at this site.	
5. A description of all the processes and procedures to which the participant will be subjected to, emphasizing any experimental procedures that are innovative that have not yet been used in medical practice.	
6. The principal investigator's name and contact details.	
7. Explanation of participant's responsibilities during the research.	
8. Detailed explanation of any randomization process (where applicable).	
9. Circumstances that may result in the project being terminated or the participant being withdrawn.	
10. A description of foreseeable risks and discomforts.	
11. A description of benefits to the participant or others both during and after the research. If there are no expected benefits, the participants must specifically be made aware of this, and this must be reflected on the Informed Consent Form (ICF)	

12. Disclosure of alternative procedures and course of treatments available if applicable	
13. Description of extent to which confidentiality will be maintained and protected.	
14. Statement that sponsors of the study, study monitors or auditors or UREC members may need to inspect research records.	
15. Statement that the Research Ethics Committee has approved the research.	
16. Contact details of the committee (UREC)	
17. Explanation of how research-related injury will be managed and details of insurance if applicable.	
18. Explanation as to whom to contact in the event of research-related injury.	
19. Statement that participation in the study is entirely voluntary.	
20. Participants are free to withdraw at any point without explanation or any negative consequences. Their routine health care will not be adversely affected.	
21. Participants must be informed of their rights to be told any new relevant information that arises during the course of the trial and the ICF should be revised where appropriate to incorporate this information. Revisions must be submitted to the UREC.	
22. The study will be conducted according to the International Declaration of Helsinki and other applicable international ethical codes for research on human participants.	
23. Any expense to which the participant may be liable.	
24. Explanation regarding payment for participation or out of pocket expenses.	
25. Identity of the funder, where applicable and any potential conflict of interests.	
26. Simple, clear language has been used (Maximum Grade 8 reading level) and all medical and technical terms have been explained.	

Section 4. PROTOCOL CHECKLIST *To be completed by Applicant*	
Element	Applicant **Y / N / NA**
1. Does the study have relevance and scientific or clinical value and applicability to the proposed research population?	
2. Does the protocol include an adequate literature review?	
3. Is the selection of subjects equitable and appropriate; adequate consideration and protection of vulnerable research populations.	
4. Is the design and methodology appropriate to answer the research question?	
5. Is the methodology clearly described, in sufficient detail?	
6. Is the statistical analysis plan, including sample size calculations, clearly outlined and justified?	
7. Are the inclusion and exclusion criteria clearly defined and appropriate?	
8. Have risks been minimized and is there an acceptable balance between potential risks and benefits?	
9. Does the PI have the necessary qualifications, expertise, facilities, and time and support staff, to carry out the proposed research?	

10. Has a section on 'Ethical Considerations' been included in the protocol?	
11. Has the informed consent process been clearly explained in the protocol?	
12. Are issues relating to protection of privacy and confidentiality of data adequately addressed, especially if the study involves a retrospective review of clinical records?	
13. Has a waiver of informed consent been requested if the study involves a retrospective review of clinical records?	
14. Does the study involve collection of DNA/RNA and, if so, has consent been adequately sought for this?	

ANNEX 5

PARTICIPANT INFORMATION LEAFLET AND CONSENT FORM

TITLE OF THE RESEARCH PROJECT:

REFERENCE NUMBER:

PRINCIPAL INVESTIGATOR

ADDRESS

CONTACT NUMBER

You are being invited to take part in a research project. Please take some time to read the information presented here, which will explain the details of this project. Please ask the study staff or doctor any questions about any part of this project that you do not fully understand. It is very important that you are fully satisfied that you clearly understand what this research entails and how you could be involved. Also, your participation is **entirely voluntary** and you are free to decline to participate. If you say no, this will not affect you negatively in any way whatsoever. You will also be free to withdraw from the study at any point, even if initially you do agree to take part.

This study has been approved by the Research Ethics Committee at The University of Namibia and will be conducted according to the ethical guidelines and principles of the international Declaration of Helsinki, South African Guidelines for Good Clinical Practice and Namibian National Research Ethics Guidelines.

What is this research study all about?

a) *Where will the study be conducted; are there other sites; total number of participants to be recruited at your site and altogether.*

b) *Explain in participant friendly language what your project aims to do and why you are doing it?*

c) *Explain all procedures.*

d) *Explain any randomization process that may occur.*

e) *Explain any randomization process that may occur.*

f) *Explain the use of any medication, if applicable.*

1. Why have you been invited to participate?

a) *Explain this question clearly.*

2. What will your responsibilities be?

a) *Explain this question clearly.*
b) *Explain how long the participant will be expected to participate in the study (i.e. 2 hours, 4 days, etc.)*

3. Will you benefit from taking part in this research?

a) *Explain all benefits objectively. If there are no personal benefits then indicate who is likely to benefit from this research, e.g. future patients.*

4. Are there in risks involved in your taking part in this research?

a) *Identify any risks objectively.*

5. If you do not agree to take part, what alternatives do you have?

a) Clearly indicate in broad terms what alternative treatment is available and where it can be accessed, if applicable.

6. Who will have access to your medical records?

a) Explain that the information collected will be treated as confidential and protected. If it is used in a publication or thesis, the identity of the participant will remain anonymous. Clearly indicate who will have access to the information.

7. What will happen in the unlikely event of some form of injury is incurred as a direct result of your taking part in this research study?

a) Clarify issues related to insurance cover if applicable. If any pharmaceutical agents are involved will compensation be according to ABPI guidelines? (Association of British Pharmaceutical Industry compensation guidelines for research-related injury which is regarded as the international gold standard). If yes, please include the details here. If no, then explain what compensation will be available and under what conditions.

8. Will you be paid to take part in this study and are there any costs involved?

9. Is there anything else that you should know or do?

a) You should inform your family practitioner or usual doctor that you are taking part in a research study. (Include if applicable).

b) You should also inform your medical insurance company that you are participating in a research study. (Include if applicable).

c) You can contact Dr ……..…….….. at tel …… if you have any further queries or encounter any problems.

d) You can contact the Health Research Ethics Committee **at +264 061 2063061** *if you have any concerns or complaints that have not been adequately addressed by your study doctor.*

e) You will receive a copy of this information and consent form for your own records.

10. Declaration by participant

By signing below, I ……..……. agree to take part in a research study entitled *(insert title of study)*.

I declare that:

a) I have read or had read to me this information and consent form and it is written in a language with which I am fluent and comfortable.

b) I have had a chance to ask questions and all my questions have been adequately answered.

c) I understand that taking part in this study is **voluntary** and I have not been pressurized to take part.

d) I may choose to leave the study at any time and will not be penalized or prejudiced in any way.

e) I may be asked to leave the study before it has finished, if the study doctor or researcher feels it is in my best interests, or if I do not follow the study plan, as agreed to.

Signed at (*place*) .....……. on (*date*) ……..…….. 2005.

…… ……

Signature of participant Signature of witness

11. Declaration by investigator

I *(name)* declare that:

- I explained the information in this document to ……..
- I encouraged him/her to ask questions and took adequate time to answer them.
- I am satisfied that he/she adequately understands all aspects of the research, as discussed above.
- I did/did not use an interpreter. (*If an interpreter is used then the interpreter must sign the declaration below.*

Signed at (*place*) .....……. on (*date*) ……..…….. 20…..

…… ……

Signature of investigator Signature of witness

12. Declaration by interpreter

I *(name)* declare that:

a) I assisted the investigator (*name*) ……. to explain the information in this document to (*name of participant*) ……..…….. using the language medium of (Oshiwambo, Oshiherero, Afrikaans, etc.)

ANNEX 6

APPLICATION FOR ETHICS REVIEW OF RESEARCH INVOLVING HUMAN AND ANIMAL TISSUE AND BODILY FLUIDS AND PLANT MATERIALS

UREC NUMBER: (For Official Use)

Original Human Tissue and Bodily Fluids Forms must be made available to the Centre for Research and Publications upon request

SECTION 1: GENERAL INFORMATION

1. Principal Investigator:	E-mail:
Department:	
2. Co-Investigator:	E-mail:
Department:	
3. Supervisor:	E-mail:
Department:	
4. Student Investigator:	E-mail:
Department:	

5. <u>Project Level</u>

Faculty Research ☐

Post-Doctoral Research ☐

Thesis Research: PhD ☐ MA ☐ MSc ☐

Other: (Specify)

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6. Funding Status

Is this project funded? Yes ☐ ☐ No

If Yes: Sponsor's Name: ----------

Funding period: ----------

If No: Is funding sought? Yes ☐ ☐ No

7. Is this research a multi-center study?

Yes ☐ ☐ No

If **YES**, which Institutions are involved (Name(s) and country must be provided).

---

8. Has this Research Protocol been submitted to another REC/IRB?

Yes ☐ ☐ No

If **YES**, provide the REC/IRB date of ethics review and the decision.

REC/IRB Name ----------

REC/IRB Decision Details ----------

Date of decision taken:----------

9. Will you be using or processing biological materials such as blood, tissue, cells or bodily fluids in the proposed research?

Yes ☐ ☐ No

If **NO**, skip question 9.

If **YES**, what will you be using or processing? (Check all that apply).

☐ Blood

☐ Tissue

☐ Urine

☐ Saliva

☐ Cell lines

☐ Other Biological material. Specify type: ----------

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10. For each type tissue, fluids or materials checked, indicate the procedures to be completed on each.

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11. Study Details: Indicate the Source/Supplier for each type of tissue, fluid or materials to be used.

☐ Health Care Facility Type ----------

☐ Commercial Supplier Type ----------

☐ Donation Type ----------

☐ Other: Please specify Source ----------

12. Where will the tissue, fluid or materials be used?

☐ On Campus Specify Location ----------

☐ Off Campus Specify Location ----------

13. If the tissue, fluid or materials are to be used on more than one day, indicate how it will be stored, security, facility, etc.

---

14. What is the plan for the final disposition of each type of tissue, fluid or materials upon completion of the study?

Note: unused/excess tissue may present a threat to the privacy of donors. Justification is required for banking the tissue.

☐ Kept for future use by Principal Investigator. If yes, was Informed Consent granted by participants?

Explain the details of reasons for future use.

☐ Transferred to another researcher(s) (Provide researcher's name(s) & Institution.

☐ Disposal (Specify method and by whom).

☐ Other (Explain in detail).

15. Potential benefits from the study

Identify and describe any known or potential benefits to the community (scientific) and public from the study. Explain what new information is expected from the conduct of this project and its anticipated value.

---

16. Potential risks to handlers/researchers

a) Will any universal precautions for handling tissue, fluids or materials be followed? **Explain in detail.**

Yes ☐
No ☐

---

b) For each type of tissue, fluid, materials and procedures to be used in this study, provide a description of any known or anticipated risks to the persons working with the tissues and/or procedures.

---

c) Describe the procedures or safeguards in place for each type of tissue, fluids, materials and procedures used in this study to protect persons working with these substances.

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17. Informed Consent process

a) Was written informed consent originally obtained for use of the tissue, fluids, materials in the research?

Yes ☐ No ☐

18. Anonymity of participants and confidentiality of data

a) Is the sample donor identifiable or is the sample anonymized (i.e. No possibility of trace back to the donor)?

Donor identifiable ☐
Sample anonymized ☐

b) Describe the procedures to ensure security of data, etc.

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c) Describe the duration and location of secure data storage, and the method to be used for final disposition of the data.

☐ **Paper Records**

☐ Confidential shredding after ---------- years

☐ Data will be retained indefinitely, in a secure location. Specify the location

---

☐ **Not applicable**

☐ **Other** (Provide details on type, retention period and final disposition, if applicable.

☐ **Electronic Records**

☐ Erasing electronic data after ---------- years.

☐ Data will be retained indefinitely in a secured location. Specify location

---

☐ Not Applicable

Specify location: ----------

19. Did you agree with the community on access and benefit sharing if relevant to the research?

Yes ☐

No ☐

20. If yes, attach the agreement

21. Investigator's agreement

This application for Ethics review of Research with Tissue, Fluids, and materials describes all the procedures for which human tissue/fluids are necessary. I agree that all procedures will be carried out according to the description in this application, and by or under the direct supervision of trained and competent staff members. Any modification to the existing procedures or human tissue/fluids use must be submitted in writing to the Centre for Research and Publications for prior ethics review and clearance.

_____ _____

Principal Investigator's Signature Date

FOR OFFICIAL USE ONLY:

_____ _____

Signature **Date**