University of Jos
Ethical Guidelines for Conducting Research

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PREAMBLE

The University of Jos subscribes to the National Ethics and Operational Guidelines for Research on Human Participants, and the various international guidelines and principles on researches involving both human and non-human participants. As such, the University of Jos Central Research Ethics Committee (UJCREC) was established to develop and sustain a University-wide awareness of and compliance with ethical issues in research, particularly those involving the use of and care for human participants and animal subjects. UJCREC is responsible for ensuring adherence and compliance with the appropriate ethical guidelines for the conduct of such research and for ensuring that all University Faculties, Centres, and Directorates adopt the appropriate ethical procedures for the conduct of research.

UJCREC has the responsibility of ensuring that research participants are treated in accordance with the national and international regulations and best practices on the research enterprise. Therefore, UJCREC will also consider and give guidance and approval for research protocols referred to it from all branches of the University of Jos, and shall hear petitions therefrom.

UJCREC aims at aiding and supporting researchers in maintaining exemplary ethical standards in research, and promoting a wider ethical awareness throughout the University in pursuant to the University of Jos Research Policy.

As discussed further in Section A4.1, UJCREC shall be concerned primarily with the general principles of beneficence and non-maleficence, fidelity and responsibility, integrity, justice, and respect for rights and dignity of human participants and animal subjects in the decision(s) made with regards to ethical approval in research.

Each Faculty shall be encouraged to adopt the principles of the UJCREC as shall be disseminated, and ensure compliance in all cases of research undertaken in such Faculties.

Part A
General Overview of Ethical Research at the University of Jos

A1.0 DUTIES AND RESPONSIBILITIES OF THE UNIVERSITY OF JOS CENTRAL RESEARCH ETHICS COMMITTEE

A1.1 Develop and Implement Guidelines for Ethical Research with Human Participants

i. UJCREC shall:
   a. Develop and disseminate guidelines for and with the three University of Jos Ethical Clusters (Biomedical, Social Science and Humanities, and Earth and Physical Sciences) in relation to the ethical approval of the conduct of research involving human participants.
   b. Ensure that all University of Jos Ethical Clusters, as well as each University Faculty, have in place procedures for the consideration and conduct of ethically sound research involving human participants and/or animal subjects.
   c. Approve terms of reference and internal reporting procedures for the handling of misunderstandings and/or misconduct in the research enterprise.

A1.2 Provide Ethical Approval for Research Involving Human Participants

i. The UJCREC shall play a primary role in the following activities:
    a. Prospective and continuing review of each research protocol involving human participants, including an evaluation of the risk and benefits for the participants/subjects.
    b. Review the adequacy of the Informed Consent process for human participants as documented for each research protocol, particularly as it relates to the description of the risks and benefits inherent in the research procedures.
    c. Receive, evaluate and conduct reviews concerning reports of unanticipated problems, noncompliance, and other information and incidents that might affect the approval of the protocol or the participants' willingness to continue to participate in a research study.

ii. UJCREC shall introduce mechanisms that allow for the rapid review and, where appropriate, the expedited review of research proposals in order not to jeopardise any attempts at gaining external funding, or delay commencement of work on research projects.

iii. UJCREC shall, through the Chairperson, conduct an annual review of its procedures, particularly in reference to current ethical issues, which shall also be under continuous review.

A1.3 Provide Awareness of Ethical Principles and Procedures for Human Participants

i. UJCREC shall develop and sustain a programme of a University-wide awareness of ethical issues arising from all research. In carrying out its duties, it shall have particular regard to the need to protect the:
    a. Rights, health, safety, dignity and privacy of research participants.
    b. Rights, health, safety, dignity and privacy of researchers.
    c. Reputation of the University as a Centre for properly conducted, high quality, and ethically sound research.

ii. UJCREC shall develop and disseminate to all members of the University community guidelines for the administration of beneficence and non-maleficence, fidelity and responsibility, integrity, justice, and respect for rights and dignity with regards to the research enterprise.

iii. UJCREC, in conjunction with the Office of Research and Development (ORD), shall maintain and disseminate to the University research community awareness of the current views on ethical issues by relevant external expert and/or professional bodies on research conducted in the various disciplines.

iv. UJCREC shall ensure that all staff and students are aware of the ethical issues and potential repercussions surrounding their research work and are adequately supported in meeting their ethical obligations to their human participants, scientific community, and society.

v. UJCREC shall ensure that all researchers conducting research on human participants or animal subjects shall possess a relevant certificate of completion of research ethics training.

A1.4 Other Responsibilities

i. UJCREC, in collaboration with ORD, shall put in place provision of appropriate training for members of the UJCREC with specific responsibilities for ethical review.

ii. UJCREC, in collaboration with the ORD and the University Library, shall create a database/repository of all approved researches and protocol reviews carried out in the University.

iii. Having regard to the general principles of natural justice and fairness of the decisions made by the reviewers, UJCREC, in conjunction with the ORD, shall, in exceptional cases and only after the procedures for resolving difficulties have been exhausted at the Ethical Cluster level, hear appeals against decisions made by the Ethical Clusters and make recommendations thereon to the relevant authorities.

A2.0 COMPOSITION AND ADMINISTRATION OF THE UNIVERSITY OF JOS CENTRAL RESEARCH ETHICS COMMITTEE

A2.1 Composition and Tenure of the University of Jos Central Research Ethics Committee

i. The Chairperson of the UJCREC shall be the Director of ORD.
ii. Membership of UJCREC shall be multidisciplinary in nature and gender sensitive.
iii. UJCREC shall comprise of:
    a. The Chairperson of each Ethical Cluster
    b. The Secretary of each Ethical Cluster
    c. One layperson, not being a member of the University community, appointed by the Director of ORD
    d. One biostatistician
iv. Where there is need to review research that involves vulnerable participants, such as children, prisoners, pregnant women, physically and/or psychologically disabled persons, UJCREC shall co-opt one or more individuals knowledgeable and experienced about those participants for the review process on an ad hoc basis. These individuals are not, however, entitled to vote during the UJCREC meetings.
v. The tenure of the members of the UJCREC shall be two (2) years at the first instance, and shall be renewable for another two year term.

A2.2 Ethical Clusters

i. A system of Ethical Clusters is hereby established under UJCREC, with the latter having power of oversight over the former.
ii. The number of Ethical Clusters shall be three, namely;
    a. Biomedical Cluster
    b. Social Sciences and Humanities Cluster
    c. Earth and Physical Sciences Cluster
iii. An Ethical Cluster shall grant ethical approval for every research to be conducted within its area of authority.
iv. The areas over which each Ethical Cluster shall exercise authority are:,
    a. Biomedical Cluster covers the Faculties of Agriculture, College of Health Sciences, Pharmaceutical Sciences, Veterinary Medicine, Natural Sciences, and other research studies that are inherently Biomedical in nature.
    b. Social Sciences and Humanities Cluster covers the Faculties of Arts, Education, Law, Management Sciences, Social Sciences and other research studies that are inherently related to the Social Sciences or Humanities.
    c. Earth and Physical Sciences Cluster covers the Faculties of Agriculture, Engineering, Environmental Sciences, Natural Sciences and other research studies that are inherently related to the Earth and Physical Sciences.
v. An Ethical Cluster shall be constituted as follows:
    a. A Chairperson and Secretary elected from within the cluster by members of the particular Ethical Cluster

b. Every Faculty will appoint two members to the Ethical Clusters. Faculties that are under the jurisdiction of two Ethical Clusters shall appoint one member to each Ethical Cluster, whereas Faculties that are under the jurisdiction of only one Ethical Cluster shall contribute two members to that Ethical Cluster. Such members shall be appointed by the Dean of the Faculty.
c. One layperson, not being a member of the University community, appointed by the Chairperson of UJCREC.

vi. Membership of each Ethical Cluster shall be multidisciplinary in nature and gender-sensitive.
vii. The tenure of the members of each Ethical Cluster shall be two (2) years at the first instance, and shall be renewable for another two year term only.
viii. Each Ethical Cluster shall, with UJCREC's approval, determine the specific procedures for ethical approval of research studies conducted under its jurisdiction (which should include the development of research checklist for each cluster).

A2.3 Responsibilities of UJCREC Members

i. All UJCREC and Ethical Cluster members shall continually disclose the research projects of which they are involved and/or have a conflict of interest.
ii. No UJCREC or Ethical Cluster member shall participate in the initial or continuing review of any project in which the member has a conflicting interest.
iii. Each UJCREC member must maintain confidentiality regarding all meetings, deliberations, applications, information on research participants and related matters that shall come to his/her knowledge during service on UJCREC, even after leaving the UJCREC assignment. In the case of a breach of this trust, the individual will be reported to the Vice-Chancellor through the ORD for appropriate disciplinary action.

A2.4 Administration of UJCREC

i. The UJCREC Secretariat shall be located in the Office of Research and Development and headed by the Secretary of ORD.
ii. The Organizational Chart of UJCREC as shown in Figure 1.
iii. ORD shall, from time to time, recommend to the Vice-Chancellor the amount of remuneration for ethical review by the relevant review board.
iv. The funds generated for ethical review shall be used in the running costs of the UJCREC Secretariat.
v. The UJCREC shall, as it deems necessary, recommend stipend for field/laboratory oversight by UJCREC members or the experts that shall be engaged for such, from time to time. This shall, however not be above the prevailing rate for the said officers as approved by the University.

A3.0 MONITORING AND AUDITING PROCEDURES

i. The UJCREC recognises that the definition and perceived significance of ethical problems may be subject to change and differences of perspectives. In this light, Ethical Clusters must conduct an annual review of their procedures for ethical approval and report to the UJCREC. UJCREC will consider these reports, offering advice and recommendations to the Ethical Clusters as appropriate, and report any procedural changes to the ORD. The Ethical Cluster is responsible to report changes in procedures to their constituents.
ii. Detailed audit of the operation of University's ethics procedures will be part of the annual review process for all Faculties. Any potential concerns or questions shall be reported through the Faculty Representatives to the Ethical Cluster. Advice will be

given by UJCREC on documentation and potential audit trails for ethical approval of research protocols.

A4.0 ETHICAL PRINCIPLES

A4.1 General Ethical Principles

i. The following general ethical principles for conduct of research with human participants are derived from the American Psychological Association (2014) *Ethical Principles of Psychologists and Code of Conduct* (http://www.apa.org/ethics/code/index.aspx).

A4.1.1 Law of Beneficence and Non-maleficence

The first general ethical principle is that of beneficence and non-maleficence. Beneficence means generous or doing good. Maleficence means harm or destruction, so non-maleficence means the absence of doing harm or destruction. To this end:

i. Researchers must avoid harming the participants or subjects involved in their research. This requires careful thought and consideration at the planning stage of a research study.
ii. Researchers must carefully consider how each step in the research procedures might negatively impact participants or subjects physically, psychologically, socially, and/or financially.
iii. Researchers must identify ways that their research can benefit the participants involved in their research. This can include benefits to individual participants in the study, as well as the benefit to the wider community and population in which the participants are situated.

A4.1.2 Law of Fidelity and Responsibility

Fidelity means faithfulness. Responsibility means being accountable to others, including the participants in the research, as well as the scientific community and wider society. To ensure fidelity and responsibility:

i. Researchers must first and foremost uphold professional and ethical standards of conduct.
ii. Researchers must clearly explain to potential participants what participation in a research study entails, as well as the risks and benefits involved in participating in the research.
iii. Researchers must also take responsibility for their behaviour, which includes avoiding conflicts of interest that could lead to exploitation or harm of research participants.

A4.1.3 Law of Integrity

Integrity means being honest and having strong moral principles. To this end:

i. Researchers must promote accuracy, honesty and truthfulness in every aspect of the research process, from acquiring financial support to interaction with participants to the final report of the methods and data.
ii. Researchers must not cheat, steal, engage in fraud, lie, or misrepresent facts. This includes both researchers' responsibility to be truthful to research participants, as well as in the reporting of the results that were derived from participants' involvement in the research.

A4.1.4 Law of Justice

Justice is defined as a concern for justice, peace and genuine respect for people; the quality of being fair and reasonable. To this end:

i. All individuals, regardless of their gender, ethnicity, religion, or psychological disability, deserve a fair chance to be selected as a participant in a research study.
ii. Researchers must ensure that the risks and benefits of a research study should be fairly distributed across participants, as well as communities.

A4.1.5 Law of Respect for Rights and Dignity

Researchers must respect the dignity and worth of all participants, which includes the rights to privacy, confidentiality, and informed consent to participate in the research. An additional aspect of this principle is that of cultural awareness and sensitivity. Researchers must be aware of and respect cultural and individual differences, including those based on age, gender, ethnicity, religion, disability and socioeconomic status. Finally, researchers must be particularly sensitive to respect individuals in vulnerable populations.

A4.2 Ethical Principles for Research Involving Human Participants.

Specific ethical principles taken into account for research projects involving human participants are as follows, derived from the World Health Organization (2011) *Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants*
(http://apps.who.int/iris/bitstream/10665/44783/1/9789241502948_eng.pdf?ua=1&ua=1)

A4.2.1 Scientific Design and Conduct of the Study

Each study must use valid scientific methods. Research that does not use scientifically valid methods exposes research participants or consumers of the research to risks of harm without any potential benefit. Therefore, the ethical review will consider the procedures in the research to ensure they have scientific merit.

A4.2.2 Risks and Potential Benefits

Risks must be minimized by preventing potential harms and minimizing their negative impacts if they should occur, and are reasonable in comparison to the potential benefits of the study. Researchers must consider the potential physical, social, financial and psychological risks. Researchers must also consider that harm may affect the individual, as well as the families and communities.

A4.2.3 Selection of the Study Population and Recruitment of Research Participants

A research protocol must ensure that no group or class of people bears no more than its fair share of the burdens that come with participating in the research study. Likewise, no group or class of people should be deprived of its fair share of the benefits of the research. Benefits may come from directly participating in the research, as well as new knowledge that the research may produce. One implication of this is that the population that bears the risks of participating in the research should also benefit from the knowledge derived from the research. Furthermore, the recruitment strategies in ethical research must be balanced and objectively describe the purpose of the research, the potential risks and benefits of participation, and other relevant details that participants should be aware of before they consent to participate in the research.

A4.2.4 Inducements, Financial Benefits, and Financial Costs.

Reimbursing participants for any costs they incur from participating in the research is ethically acceptable, which can include transportation, child care, and/or lost wages. It can

also be acceptable to compensate participants for their time. However, any form of compensation should not be so large or extensive as to induce potential participants to consent to participate against their better judgment, or compromise their understanding of the potential risks associated with participating.

A4.2.5 Protection of Research Participants' Privacy and Confidentiality.
Researchers must take serious precautions to protect participants' privacy and confidentiality. Violating privacy and confidentiality are not just disrespectful to participants, but can also lead to psychological harm such as embarrassment, as well as other serious effects such as social stigma, rejection by family or community, and/or lost opportunities such as employment or housing.

A4.2.6 Informed Consent Process.
Competent individuals have the right to freely choose to participate in a research study after gaining an adequate understanding of what the research entails. An authorized decision-maker must provide informed consent on behalf of children or adults who lack the ability to understand the risks and benefits. The process of informed consent is based on the ethical value of respect for persons. Therefore, the review will examine the informed consent process for human participants, as well as the information that will be provided to participants before they make an informed decision as to whether to participate in the research. The requirement of informed consent will only be waived in line with international and national standards of ethical research.

A4.2.7 Community Considerations
A research study can impact not only the individuals who participate, but also the communities where the research is located and/or those to whom the results may be linked. Therefore, the ethical principles of non-maleficence and respect require that researchers consider the impact of a research study on communities and minimize any negative effects, as well as promoting positive outcomes of the research in the community. Researchers should engage with communities in the process of planning the research study, and also be sensitive to the community's cultural, traditional, and religious practices.

A4.3 Ethical Principles for Research Involving Animal Subjects

i. For research involving the use of animal subjects, the following shall be considered when reviewing the protocol for ethical approval.
    a. There shall be demonstrable evidence that the study will contribute to knowledge and the study must not be poorly designed.
    b. The minimum number of animal subjects required to obtain valid results should be used.
    c. Pain and distress in animals must be avoided. Animal subjects should not be subjected to unnecessary pain. Experimentally induced pain should be avoided. Necessary pain should be of minimum intensity and duration. Where unforeseen circumstances place the animal in unexpected pain, there must be ways to recognise it.
    d. Researchers and or their assistants shall show evidence that they can recognise the clinical signs associated with pain, and can identify descriptors of a departure from the animal subject normal appearance and behaviour.
    e. Alternative end points to death shall be sought by researchers, especially in terms of moribund animals where no further essential data can be collected.
    f. Euthanasia must be humane.

g. Multiple surgeries on one animal subject shall not be encouraged.
h. Housing, feeding and care for animal subjects must be appropriate.
i. Researchers shall show evidence that veterinary medical care will be provided for the animal subjects.
j. The Animal House personnel caring for and using the animal subjects must possess adequate qualifications and training.

ii. For details of the acceptable environment for research involving animal subjects and plants especially exotic plant species, researchers are advised to consult the Faculties of Veterinary Medicine and Natural Science respectively.

Part B
Procedures for Obtaining Ethical Approval for Research with Human Participants or Animal Subjects

B1.0 BASIS OF ETHICAL APPROVAL FOR RESEARCH WITH HUMAN PARTICIPANTS OR ANIMAL SUBJECTS

i. A decision by the UJCREC to approve a research project should not be taken to imply that an expert assessment of all possible ethical issues or of all possible dangers or risks involved has been conducted; nor does it detract in any way from the ultimate responsibility which researchers themselves must have for all research that they carry out and for its effects on the research participants involved. It is the responsibility of each individual researcher to ensure that their research is properly conducted, truthful and accurate.

ii. A decision by UJCREC and/or its subsidiary Ethical Cluster to approve a research project does not constitute precedence and each application will be judged on its own merits and in the light of present circumstances. For that reason, a decision may be made to approve research of a kind not previously approved. Equally, a decision may be made not to approve research of a kind that was previously approved. In neither case does this imply that the UJCREC decision, nor its decision-making process is flawed, since proper ethical review cannot be reduced to a mechanical or formulaic approach.

iii. Applications for ethical review submitted to the appropriate bodies shall have three possible outcomes: research that meets ethical standards are *Approved*, research that requires minor modifications to meet ethical standards are recommended to *Resubmit after Specific Corrections* as pointed out by the body have been effected, and research with considerable ethical violations are recommended to *Resubmit after Substantial Changes* are made. Applications that are resubmitted after corrections are to receive priority in the approval process.

iv. A decision to change the University's policies or procedures for ethical review of research does not imply that previous policies or procedures were inappropriate and any such changes do not invalidate ethical approval that has already been given. However, researchers are expected to make themselves aware of changes in policies or procedures and to adopt them as necessary.

v. Notwithstanding the scientific validity of research protocols, the UJCREC shall put into considerations the cultural and religious diversities of our communities, and advise researchers as appropriate. This shall also be considered in the review process.

vi. No deviations or changes can be made to the approved research protocol without prior approval by the appropriate ethical review board except where immediate action is necessary to avoid harm to research participants. The review board must be informed promptly of any changes or deviations as well as the justification for doing so.

vii. For multi-disciplinary studies, the UJCREC will determine the appropriateness of multiple ethical considerations and clearances.

viii. Ethical approval shall be granted for a period of twenty-four months, after which the researcher must apply for a renewal of ethical approval. If a research study is planned for longer than a twenty-four month period, the researcher must apply for a longer approval period at the application stage. The Approval Board may grant a longer approval period at their discretion.

ix. Retrospective ethical clearance shall not be given. In the event that a researcher misleadingly applies retrospectively, any such retrospective clearance obtained shall be null and void, and the researcher recommended for additional sanction for misconduct as determined by the University Authority.

B2.0 REQUIREMENT OF ETHICAL APPROVAL AND PROCEDURE FOR PROCUREMENT THEREOF

i. Ethical approval shall be obtained prior to the commencement of any research in the University of Jos involving human participants and/or animal subject(s).

ii. The Principal Researcher/Investigator in any proposed research shall submit a written application to the chairperson of the Ethical Cluster having authority over the Faculty to which the Principal Researcher belongs for ethical approval.

iii. An application for ethical approval shall:

a. Embody the name of the Principal Researcher/Investigator
b. Embody the name(s) of other researcher(s)
c. Show title of research
d. Indicate the qualification of every researcher whose name is included in the proposed research
e. Be signed by a qualified academic staff advisor who is involved in the oversight of the research, where application is made by student(s)
f. Show the general procedures for the research study
g. Articulate the risks and benefits of the research to research participants
h. Describe with clarity arrangement(s) for safeguarding of rights for both human participants and/or animal subjects, particularly privacy and confidentiality
i. Show clearly how participants are to be recruited
j. Clearly describe the Informed Consent procedures and attach Informed Consent documents, if required
k. Articulate the financial and/or nonfinancial cost(s), if any, that may be incurred by research participants, as well as financial and/or non-financial compensation, if any, that may accrue to participants
l. Embody an undertaking to report all sources of support (financial and nonfinancial) for the study
m. Embody disclosure of conflicts of interest in the conduct of the research (conflict of interest in being deemed to exist when professional judgment concerning a primary interest such as the validity of the research may be influenced by a second interest in the form of financial gain, etc.)

Note: Failure to declare a conflict of interest where such exists shall be misconduct. UJCREC shall investigate the conflict, and report to the Vice-Chancellor through the ORD for appropriate sanction by the University Authority.

n. Be accompanied with relevant and approved certificate of completion of training in research involving human participants and/or animal subjects by every researcher participating in the study.

B2.1 Informed Consent Procedures

i. In all cases, researchers submitting protocols for ethical approval shall explain in details the process of obtaining informed consent from potential participants in the research study. The participant must be enlightened on the details of the procedure to be employed in the research, including the risks and benefits, to enable the participant make an informed decision regarding their participation in the study.
ii. The informed consent document shall comprise of a commitment of non-victimization in the event of a potential participant declining consent to participate or withdrawing his/her participation at any point in the course of the research.
iii. Where children are involved in research, extreme care should be taken over ethical procedures, and explicit authorisation for participation of children should always be obtained. The consent of an authorized guardian must also be obtained from the under-aged.
iv. In spite of the intellectual capacity of a minor, everyone below the national approved maturity age of 18 years shall be treated as a minor, especially with regards to the consent process.

B2.2 Privacy and Confidentiality of Research Participants

i. All research proposals shall explain the steps that will be taken to ensure that the privacy and confidentiality of all research participants are protected. When planning to protect the privacy and confidentiality of research participants, the following points should be considered.
    a. Duty of Privacy and Confidentiality
        i. A duty of privacy and confidentiality shall exist between researchers and participants such that confidential information revealed by a participant to a researcher can only be disclosed to others if the party providing the information has given specific authorisation or the researcher is under a legal obligation to disclose it.
        ii. In some cases researchers may be under a professional obligation to disclose information to third parties.
        iii. Whether information is confidential will depend on the circumstances but the key factor shall be whether or not the provider of the information would have considered it as confidential and would expect it to be treated as such. If the answer to both questions is “yes”, then the duty of confidentiality will arise. The duty also arises when the researcher has volunteered to keep confidential the information and/or the identity of the provider.
        iv. As a result of this duty, researchers shall pay attention to any circumstances, such as professional codes of practice, that preclude them from being able to give absolute assurances of confidentiality.
    b. Obligations of Privacy and Confidentiality on Researchers
        i. Researchers may not convey personally identifiable information obtained in the course of research work to others, except with the express permission of the research participant unless *either* alternative arrangements have been agreed by a research participant *or* where the researcher is subject to a legal obligation to disclose that information.

ii. Researchers may not give unrealistic guarantees of confidentiality and anonymity and be aware that legal challenge may prevent them from honouring such a guarantee.
iii. In some circumstances it may be necessary to inform research participants of obligations under law, such as the possibility that the researcher could be required to give evidence or reveal documents. This may make it impossible for certain information to be kept confidential without breaking the law. In other cases, it may be that the researcher's professional obligations would require the disclosure of information (for example, where the welfare of a child is concerned).
iv. The research participant shall be made aware of the possibility of future disclosure in order to be able to decide whether or not to take part in the research. If the researcher has made it clear that information may be passed on as a result of legal or professional obligations and the participant nevertheless agrees to take part, the researcher may pass on that information even if the participant subsequently objects.
v. However, passing on confidential information without the express permission of the participant is not to be undertaken lightly, and legal and professional advice must be sought immediately if this is contemplated by the researcher through the UJCREC and ORD, who shall seek the interpretation/intervention by the University Legal Unit.
vi. Where possible, researchers shall be encouraged to anticipate threats to the confidentiality and anonymity of research data. The identities and research records of those participating in research, therefore, should be kept confidential, whether or not an explicit pledge of confidentiality has been given. Researchers should also consider whether it is either necessary or appropriate to record certain kinds of sensitive information.
vii. Researchers must take appropriate measures to store research data in a secure manner. Researchers should have regard to their obligations to ensure that appropriate methods for preserving the privacy of data are used while also allowing participant access to information where this is requested by a participant.
viii. Researchers must take care to prevent data from being published or released in a form which would permit the actual or potential identification of research participants. In circumstances where it is difficult to protect the anonymity of informants and research participants, they must be informed of this fact before they are asked to take part in the research, or, if the possibility of publication had not arisen at that time, participants must be re-contacted and their agreement obtained prior to the publication.
ix. UJCREC shall be informed of any research proposal that might raise questions about guaranteeing participant confidentiality. If there are significant queries about confidentiality for a specific proposal, they should be brought to the ORD and University Legal Unit for consideration and guidance.
x. UJCREC shall ensure that data is collected and used only for legitimate purposes. For instance, where a researcher is undertaking the research as a contractual obligation, it is the duty of the researcher to also inform his/her sponsor(s) of issues that may arise from the

Privacy and Confidentiality principle that may impede publications/data sharing.

xi. Researchers shall be made aware of the need to limit the University's potential liability in the event of a breach of confidentiality.

B3.0 EXPEDITED REVIEW

B3.1 Qualification for Expedited Review

i. UJCREC may expedite review of research in the following circumstances:
   a. Where research is found to involve no more than minimal risk, meaning that the probability and magnitude of harm is no greater than that encountered in the daily lives of all, or the great majority of persons in the population (under normal circumstances) from which research participants are to be recruited. Minimal risk here shall apply in non-therapeutic research only.
   b. Research does not involve vulnerable populations such as children, prisoners, pregnant women, psychiatric patients, etc.
   c. Minor changes in previously approved research during the period for which approval is authorized.

B3.2 Process for Expedited Review

i. Expedited review may be carried out by the UJCREC or Ethical Cluster Chairperson or his/her designee from among members of UJCREC. In reviewing the research, the reviewer(s) shall exercise all the authorities of UJCREC or Ethical Cluster to approve researches that meet ethical standards on behalf of the Ethical Cluster or UJCREC. However, the reviewer(s) cannot disapprove the research. If the reviewer(s) find problems with the application that would result in disapproval, then it shall undergo a full board review.

ii. The Chairperson of UJCREC or Ethical Cluster shall bring all research reviewed expeditiously to the next meeting of UJCREC for notice and ratification.

B4.0 EXEMPTION

B4.1 Categories of Research Protocol for Exemption

i. Research activities in which the only involvement of human participants will be in one or more of the following categories are exempted from Ethical Committee's oversight.
   a. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:
      i. Research on regular and special education instructional strategies.
      ii. Research on the effectiveness of or comparison among instructional techniques, curricula, or classroom management methods.
   b. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), or observation of public behaviour, unless:
      i. Information obtained is recorded in such a manner that human participants can be identified, directly or through identifiers linked to the participants; and
      ii. Any disclosure of the human participants' responses outside the research could reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, or reputation.

c. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are *publicly available* (note that this refers to availability of data and not the status of the custodian of the information/data) or if the information is recorded by the investigator in such a manner that participants cannot be identified, directly or through identifiers linked to the participants.
d. Studies that are meant to evaluate the outcome of procedures, programmes and services being designed to produce information leading to improvement in delivery of procedures, programmes and services. Such studies usually evaluate measures that are already in use and considered part of standard practice. They may include collection and analysis of data or collection of new data but they do not involve allocation into groups or randomization. New data collected must be completely anonymous, individual participants cannot be identified in the research report, and the data collection will not cause damage or distress.
e. Studies that are designed to evaluate or assess quality of services, programmes and procedures and formulate guidelines leading to their improvement. Such studies may involve the collection and analysis of some data.
f. Clinical audit, where the study is designed and conducted solely to define or judge only current care, without reference to a standard. It may involve the collection and analysis of data but there is no allocation to intervention groups or randomization and the services have been delivered before the audit is initiated. New data collected must be completely anonymous, individual participants cannot be identified in the research report, and the data collection will not cause damage or distress.

B4.2 Procedures for Obtaining an Exemption

i. All exemptions shall be determined by the Ethical Cluster.
ii. Applicants conducting research that require exemption shall submit the proposal that contains enough information for the judgement of exemption to be made, to the Ethical Cluster. The Ethical Cluster Chairperson or his/her designee shall decide whether the research is exempted or not. For the records, this shall be ratified at the next most appropriate meeting of the UJCREC.
iii. Where the Chairperson is uncertain and the uncertainty is unresolved after request for and provision of more information by the applicant, the proposal or summary should be referred to its full Ethical Cluster review board.
iv. All applications for exemption must be brought to the notice of the Ethical Cluster at its regular meeting.

B5.0 AMENDMENT OF RESEARCH/SUPPLEMENTARY SUBMISSIONS

i. UJCREC shall require that applicants apply for permission to amend protocols in any of the following circumstances:
    a. Where there are changes in any part of the research protocol that alters the risk-benefit ratio of the research.
    b. Where there are changes in the named members of the team conducting the research.
    c. Where there are changes in research sites.
    d. Where there are changes in sponsorship, institutional guidelines, institutional structure, UJCREC requirements, national laws or exigencies that impact on the ethical conduct of research.

ii. UJCREC shall require that the researcher submit an application for original research approval where, in its opinion, the proposed amendments are substantial, such as but not limited to, change(s) in inclusion or exclusion criteria, randomization, interventions and outcome measures.
iii. Under no circumstance shall a researcher deviate from approved protocol, except such as is necessary to eliminate immediate hazard to research participants. The researcher shall notify the Chairperson of the Ethical Cluster within a week of such changes.
iv. In such circumstances as described in section (ii) above, the researcher shall stop the research and the Ethical Cluster shall conduct a thorough review of the research before authorizing suspension, continuation or modifications to the research.

B6.0 PENALTIES

i. Failure to follow the University's guidance on ethical review of research may result in disciplinary action as may be determined by the appropriate University Organ on the recommendations of UJCREC.
ii. Failure to follow the University's policy and guidance for the ethical review and approval of research will lead to immediate suspension of the research project.
iii. The Faculty or Ethical Cluster must report the matter to the UJCREC, which shall undertake a formal investigation. The findings of the formal investigation shall be reported to ORD and the Vice-Chancellor.
iv. Any sanctions for ethical violations will be determined by the University Authorities.

Part C
Ethical Considerations for Specialised Types of Research with Human Participants or Animal Subjects

C1.0 RELATIONSHIP WITH THE DATA SAFETY MANAGEMENT BOARD (DSMB)

C1.1 Discovery and Report of Adverse Effects and Incidental Findings

i. A researcher shall report in writing every adverse effect discovered in the course of a study immediately to the UJCREC. Upon discovery of the adverse effect, the research shall be suspended pending a review by the UJCREC and/or invited experts.
ii. Upon receipt of a report of an adverse effect, the UJCREC shall immediately forward a report of same to the DSMB or ORD (as the case may be).
iii. Report of incidental findings, especially of significance to the further pursuit of the research, shall also be reportable to the UJCREC. The UJCREC shall treat such incidental findings as appropriate, where necessary in collaboration with the DSMB.
iv. UJCREC shall from time to time hold joint meetings with the DSMB to review safety of the research enterprise.
v. At such joint meetings, the Director of ORD shall preside, or assign a representative.
vi. Minutes of joint meetings of the UJCREC and DSMB shall be taken by the Secretary of ORD and kept by both parties in their record keeping apparatus.

C1.2 Penalty for Non-Report of Adverse Effects and Incidental Findings

i. Any researcher who fails to report an adverse effect or an incidental finding to the UJCREC shall be deemed to have committed a research misconduct.
ii. Failure to report adverse effect and or an incidental finding to the UJCREC shall be reported by UJCREC to the Vice-Chancellor through the ORD for possible sanctions.

iii. The cost of any investigations and or interventions necessary to mitigate the immediate effects of unreported adverse effects shall be borne by the researcher/sponsor (as the case may be).

C2.0 MATERIAL AND DATA TRANSFERS

C2.1 Material and Data Transfer Agreement (MDTA)

i. Every transfer of research material and data from the Institution to another body shall require a material and data transfer agreement.
ii. Items to be considered for MDTA shall include but not restricted to, biologic specimens, cultural artefacts, classified information in Institutional repositories, industry-sponsored research materials and unpublished thesis and research data.
iii. Researchers who intend to transfer materials and data shall apply for such to the UJCREC, who shall in turn, process same through the ORD.
iv. The Director of ORD or his/her designee, acting on behalf of the Vice-Chancellor, shall be signatory to all MDTA for the University.
v. UJCREC, in conjunction with the various Faculties, shall from time to time design the best form in which the materials shall be transferred, and also determine the quantum of data as appropriate for transfer, in every given case.
vi. Transfer of materials and data without a duly processed MDTA shall be misconduct. This shall be reported to the Vice Chancellor through the ORD for appropriate investigation and sanctions.
vii. UJCREC shall follow up to ascertain receipt of materials and data as transferred, by the appropriate body.

C2.2 Biobank and Residual Samples

i. The term "biobank" when used shall refer to a service whereby biological materials and the data associated with those materials are collected, stored, processed and distributed for the purposes of scientific research and/or medical treatment. Typically, those "biological materials" are human/animal samples — such as tissue, blood, body fluids etc., and the "data" is any information, including medical information pertaining to the donor of that sample.
ii. Population biobanks when used shall refer to biomarkers of population identity and susceptibility, typically from the DNA of large numbers of healthy donors, representative of a country/region/ethnic cohort.
iii. Disease-oriented biobanks shall refer to a focus on biomarkers of exposure, using large numbers of samples, following a healthy exposed cohort/case-control design, studying germ-line DNA or serum markers. The amount of clinical data linked to the sample determines the MDTA value of the sample.
iv. Residual samples refer to tissues taken in the course of clinical care and are leftover (e.g., a diagnostic biopsy or therapeutic removal of tissue). In many cases, the stored tissue will be most valuable for research when it remains linked to information about the person. Where complete anonymization was not done, these samples would not be allowed for use in research unless there is evidence that the donors have been re-contacted and consented.
v. Research on tissue does not usually entail the same risks as research on persons. Residual samples are taken in the course of clinical care; therefore, there are no additional physical burdens involved. It follows that the risks involved in biobank research are tightly connected to the type of research that will be carried out on the sample, as there will be certain studies that are associated with higher risks or

burdens. For this cause, UJCREC shall grant ethical clearance if there is justification of data being coded and donors un-identifiable.

vi. UJCREC shall periodically encourage researchers to be alert to this and adequately obtain informed consent from participants or patients. The potential participants should be made aware of inclusion of their residual tissue as the default position.

vii. Researchers should be encouraged to receive adequate information about whatever research studies they intend to carry out with the samples from the participants, duly obtain advance informed consent, and request to have easy access to additional information should the need arise in the future.

viii. Where some donors object to the use of their residual samples, such samples shall not be recognised in any UJCREC review process. Only samples of duly consented participants shall be admitted for use.

ix. Where only a part of the residual samples would be used for failure to consent on the part of others, those that objected should have an accessible way to object to participation and this should be adequately registered. When the majority approves inclusion of residual tissue, this should not deprive others from their right to make an autonomous decision.

x. When sensitive cells or tissues are used (e.g., gametes), a more extensive consent procedure would be required by UJCREC.

xi. For the vulnerable persons (e.g., psychiatric patients), the competency to understand the presented information needs to be evaluated before tissue can be included. It should be the role of an independent UJCREC to determine the appropriateness or otherwise of the delegated consent procedure.

xii. For certain types of research that are associated with increased burdens or higher risks (e.g., increased psychological or social risks associated with genetic information, or others prone to stigmatization and discrimination), an additional informed consent for use of residual samples shall always be required for UJCREC review of protocol.

xiii. Researches that are controversial and/or require high-impact techniques (e.g., when an immortal cell line is derived or when chimaeras are created) are sensitive and difficult to explain adequately in the general research information, a re-consenting procedure shall always be required for UJCREC review.

xiv. Where the UJCREC desires to apply a waiver for certain categories of residual samples for which an express informed consent was not obtained, the type of tissue and research would be considered in the waiver process.

C3.0 INSURANCE ON RESEARCH ENTERPRISE

i. UJCREC shall encourage researchers to build in insurance cost for clinical trials in their study protocols in case of any adverse effects. This shall be for both the researcher and the human research participants, especially in studies adjudged to be above the perceived minimal risk.

ii. Researchers shall, as much as it possible, provide funds to defray cost of treatment for injuries sustained in the process of participation in the research.

iii. Where the research budget is incapable of catering for treatment for injuries, the researcher shall not be held liable for a properly consented human participant. In situations where litigations arise therefrom, the UJCREC through the ORD shall do all possible to ensure justice for the researcher, where negligence is ruled out.

These Ethical Guidelines were adopted on DATE.