

BIUST Document Control Cover Sheet

1.0 Document Information

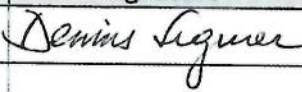


Document Title : HUMAN RESEARCH ETHICS POLICY

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2.0 Document History

Version	Date Released	Released to	Purpose
V 1.1	24-08-2017	Ad-Hoc Committee On Scientific Research	Internal Review
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3.0 Document Sign Off:

Name	Position/ Role	Signature	Date
DENNIS SIGNER	Ag. DVC Research, Development & Innovation		21/6/2018
Dr. Letswe Tshel	SENATE Chair/Vice Chancellor		26/10/2018
benani tshel	Chairperson of COUNCIL		30/10/2018



BOTSWANA INTERNATIONAL UNIVERSITY
OF SCIENCE & TECHNOLOGY

Policy Title:	HUMAN RESEARCH ETHICS POLICY
Policy Number & URL:	ORDI 08.01.17
Policy Category:	Research Policy
Responsible Division/Faculty/Directorate:	Research and Development
Policy Owner:	Deputy Vice Chancellor Research, Development & Innovation
Policy Manager:	Director: Research and Development
Policy Approved by:	COUNCIL
Policy Approval Date:	22-06-2018
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Related Policies, Guidelines & Regulations:	<ul style="list-style-type: none">▶ Code of Conduct for Research and Innovation

1. Background

Research ethics govern the standards of conduct for scientific researchers. It is important to adhere to ethical principles in order to protect the dignity, rights and welfare of research participants.

Research with human subjects can be defined as 'any social science, biomedical, behavioural, or epidemiological activity that entails systematic collection or analysis of data with the intent to generate new knowledge, in which human beings are exposed to manipulation, intervention, observation, or other interaction with investigators either directly or through alteration of their environment; or become individually identifiable through investigator's collection, preparation, or use of biological material or medical or other records.

2. Purpose

The purpose of the Human Research Ethics Policy is to ensure that all University research and relevant teaching activities involving human participants conform to ethical standards. Such standards are distinct from legal requirements, though ideally the law should reflect what is ethically right. Ethical standards are evolving, not fixed; they are grounded in our best current understanding of the fundamental rights, responsibilities, and interrelationships of human beings.

This Policy is administered primarily by the University Human Research Ethics Committee (HREC) and all research involving human subjects will be reviewed by the Human Research Ethics Committee to ensure that the appropriate ethical standards are being upheld. This function may be delegated, under supervision to a sub-committee in a Faculty or Academic Department but the delegated authority carries the responsibility for compliance with this Policy by staff and students within the faculty, department or research centre. The HREC must be familiar with the different methodologies and ethical considerations that apply to each type of proposed research they review.

Individual researchers are generally in the best position to assess the ethical implications of their proposed activity. Nevertheless, to ensure consistency and impartiality in considering the interests of potential participants, as well as to provide protection for the researcher, research involving human participants must be approved by the HREC in accordance with this Policy before being conducted.

3. Scope

This Policy applies to:

- 3.1 All staff and students of the University and its associated entities, as well as any persons or organizations not affiliated to the University, who conduct research involving human subjects, whether on University premises or off-site, using the university's infrastructure

and/or data or the university's staff, students as participants, or anyone who conducts research under the auspices of or in collaboration with the university and/or its staff and students.

Such research includes but is not limited to:

- i. Clinical trials
- ii. Epidemiological research
- iii. Social science research
- iv. Research on medical records or other personal information
- v. Research on stored human samples
- vi. Health systems research

3.2 Teaching-related activities such as research projects, assignments or tasks that involve the use of human subjects.

4. Policy Goal

To establish a common understanding of the right and acceptable practices in the field of Human Research Ethics in BIUST.

5. Policy Objectives

The objectives of the Policy are to:

- 5.1 Promote the use of the Policy of Human Research Ethics to allow students, academic and research staff to avoid abuses on human subjects during their research;
- 5.2 Provide principles, guidelines and good practices of respecting Human Research Ethics in the university;
- 5.3 Establish responsibilities and accountabilities for Human Research Ethics respect within the University's governance and managerial structures;
- 5.4 Provide a framework for the monitoring and evaluation of Human Research Ethics practices within the University.

Assure the quality, integrity and standing of BIUST in the field of research involving human subjects.

6. Policy Principles

6.1. General Moral principles

The following four internationally recognized moral principles of ethics as bases for research are advocated:

- i. autonomy (research should respect the autonomy, rights and dignity of research participants)
- ii. beneficence (research should make a positive contribution towards the welfare of people)
- iii. non-maleficence (research should not cause harm to the research participant(s) in particular or to people in general)
- iv. Justice (the benefits and risks of research should be fairly distributed among people)

These principles are not ranked in any order of preference. In disputes a balance between the four principles should be pursued.

6.2. Respect and care for persons

This principle involves recognizing and respecting the inherent autonomy and dignity of each individual.

- i. *Informed consent free of coercion.* Individuals have the fundamental right to decide whether they wish to participate in research. If they decide to participate, they have the right to withdraw their participation. At the time of informing potential participants about the research it should be made clear at what point in the research process it is no longer possible to withdraw participation, for example, once data analysis has started. The participants need not provide reasons, either for not participating or for discontinuing their participation. In short, an individual's participation in research must at all times be obtained through voluntary and informed consent, free of any hint of coercion.
- ii. *Minimization of harm to participants, groups or communities.* It is unacceptable to expose participants or third parties to unnecessary harm. Harm includes such things as pain, stress, fatigue, emotional distress, undue embarrassment, cultural dissonance and exploitation. Any level of harm to participants must be balanced against the potential benefit, to the participants and/or to society, and the importance of the knowledge to be gained from the research.
- iii. *Limitation of deception.* Where a project involves a measure of deception, any departure from the standard of fully informed consent must be acceptable when measured against potential benefits and the importance of the knowledge to be gained. Wherever possible, projects involving a measure of deception should incorporate an appropriate 'de-briefing' of the participants after the project has been completed.

- iv. *Special care of potentially vulnerable participants.* Special care must be taken of people who may be vulnerable due to lack of power, knowledge or competence in research contexts and processes, for example, young children, people with mental health issues, people with learning disabilities, the socially disadvantaged, and prisoners.
- v. *Respect for property rights, including intellectual property.* Researchers should respect the property of others. This extends to their legal rights to land, goods, and intellectual property (including confidential information, copyright, trademarks, patents, and design rights) as well as the spiritual treasures or culturally sensitive data of a particular group.
- vi. *Minimization of harm to researcher.* It is important to ensure the safety of the researcher, and those assisting them, as well as the participants. Care should be taken to ensure that the researcher is protected from risk of physical harm, from risk of possible litigation, and from any emotional stress or distress that might result from inadequate preparation for unsolicited disclosures by participants.
- vii. *Minimization of harm to the University.* The University is committed to the concept of academic freedom in research. At the same time, researchers are required to assess and appropriately manage the risks involved in research in order to protect the reputation of the University.
- viii. *Sensitive to significant social and/or cultural practices.* Researchers have a responsibility to be sensitive to significant social and/or cultural practices of the communities to which individual participants may belong.

6.3. Managing of dual and multiple roles/relationships and conflicts of interest

- i. Researchers should ensure that the roles they occupy and relationships they have with the people who are invited to take part in their research do not compromise the participant's ability to freely consent or decline to take part in that research. Reassurance from the researcher about the independence of research participation from these other roles and relationships may not sufficiently address the concerns of potential participants.
- ii. Perceptions of possible adverse consequences to either accepting or declining participation are particularly likely when a pre-existing role or relationship leads the research participant to be dependent on the researcher in some way (e.g., when the participant is a student for whom the researcher is a teacher with an assessment role).
- iii. Researchers should be aware that their personal or professional interests (e.g., financial) may conflict – or lead others to perceive a conflict – with their ability to conduct research in an objective and professional manner.
- iv. Researchers should design their research and relevant teaching activities so that they are not in a position where their activities as a researcher (or teacher, in the

case of teaching applications) could (i) conflict with other professional or personal interests they may have, and (ii) have them recruiting participants with whom they have pre-existing personal or professional relationships in which the participant could view themselves as being dependent on the researcher in any way (material, emotional, financial etc.).

- v. Even where no perception of dependence is likely to exist, researchers should avoid wherever practicable recruiting participants with whom they have an existing relationship.

6.4. Research and Teaching Activities Which Require Ethical Approval

- i. No research or teaching activity involving human participants, human tissue or otherwise affecting people's privacy, rights and freedoms may proceed without approval by the HREC. It is the responsibility of the organizers, principal researchers and research supervisors to ensure that HREC approval has been obtained where required, and to ensure compliance with the conditions of the approval. Research students are expected to make their own applications for ethical approval after consultation with their academic supervisors.
- ii. Approval is required for research and teaching activities which involve access to personal identifying information not already publicly available. Where access to personal information located outside the University has been granted by an agency holding the information, an application for ethical approval is still necessary.
- iii. Approval is required for research and other activities involving questionnaires and surveys conducted within and outside the University, including those where the participants are anonymous.
- iv. The principles and procedures presented here apply specifically to research and teaching activities with adult human participants and human tissue. In general, the same principles apply where children or other dependent people are the participants. However, their participation demands additional ethical considerations, as does research with older people and members of non-dominant groups or cultures. Researchers who involve children or other special groups in their work should seek the advice of the HREC in relation to these additional considerations and procedures.

6.5. Research and Teaching Activities Which Do Not Require Ethical Approval

At the start of any research that involves human participants, it is always important for researchers to consider whether ethical approval is required. The following should be read in that light. Ethical approval is not required for:

- i. Exploratory research consisting solely of preliminary interaction or discussion where the exact research aims have not yet been formulated. If a researcher later

wishes to use data collected at an exploratory stage, retrospective HREC approval and the consent of participants should be obtained to use the data.

- ii. Research in which the investigator is the sole participant of their own research, and where no physically or emotionally hazardous procedure is involved. If the investigator is a participant in their own research it is expected that there is no reference to any other participants or third parties. If other participants or third parties are referred to in the research, ethical approval must be obtained.
- iii. Some interviews which merely seek non-sensitive factual information (e.g. requests for statistical information or information about services from public agencies).
- iv. Research involving existing publicly available documents or information (e.g. analysis of public archival records).
- v. Informal discussions with colleagues, family and friends, as a contribution to a class discussion or project, where no formal publication of the data is intended. Any later publication would require retrospective approval and the use of an informed consent process.

6.6. Appeals

- i. Where an applicant is dissatisfied with the decision of a convener of a committee with delegated authority from the HREC, the applicant may appeal to the HREC.
- ii. An appeal to the HREC may also be lodged by any other person, including research participants, researchers, supervisors, or members of the public.
- iii. If the HREC becomes aware through an appeal that there is the likelihood of harm occurring to participants, the HREC may suspend approval of an application while an appeal is considered. During the period of suspension, no research involving human participants, as set out in the ethics application, may be conducted. The grounds for the suspension must be communicated in writing to the applicant and the complainant.
- iv. Complainants will be kept informed about the progress of their complaint and will be informed in writing about the outcome.

6.7. Sanctions

Where University employees fail to obtain ethical approval when such approval is required or where they act contrary to the decision of a body authorized to consider applications for ethical approval, the matter may amount to misconduct and be dealt with under the Terms and Conditions of Service for staff. Where a student has engaged in an unethical activity, the matter should be dealt with under the misconduct provisions of the University's Student Code of Conduct.

7. Policy Applicability

The policy covers all research entities and all parties involved in research for or with BIUST.

8. Policy Implementation Framework

The Deputy Vice Chancellor Research, Development and Innovation is the custodian of this policy. This Policy will be reviewed at planned intervals as per the BIUST Policy on Policies.