جامعة نزوى
University of Nizwa

UoN HUMAN RESEARCH ETHICS POLICY

Research Involving Human Participants

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Chancellor of the University

UoN Human Research Ethics Policy

Proposed by:

Vice-Chancellor for Graduate Studies Research and External Relations Office (VCGSRER)

Approved by:

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I. INTRODUCTION

University of Nizwa (UoN) is committed to maintaining the highest ethical standards in research involving human participants or ethical issues which pose an environmental risk or cause any sort of political or social tensions. All such research proposals are subject to review by the Human Research Ethics Committee (HREC) prior to the commencement of the research activities.

The Human Research Ethics Committee reports to the Vice-Chancellor for Graduate Studies Research and External Relations Office (VCGSRER). The Committee's function is to review research proposals to ensure that all researchers at UoN adhere to the highest ethical principles & Omani cultural values while conducting research involving human participants. Researchers should always consider their research from the perspectives of the participants and any other people who may possibly be affected by it. Proposals submitted by staff and students should include: the necessary details on the method of participant recruitment; the informed consent process; the steps taken to maintain the privacy of participants; a confidentially statement, data collection; data storage; and an analysis procedure to ensure appropriate review of the ethical components pertaining to the study.

II. OBJECTIVE

The aims of this policy are to:

1. Provide the general framework for ethical considerations of research involving human participants
2. Develop a systematic approach to the ethical approval of all research applications that involve human participants
3. Ensure a high level of ethical standards in all researches involving humans at UoN.

III. PURPOSE

The purpose of this policy is to encourage quality research with the highest possible standards of integrity and ensure that ethical principles are followed throughout the research process. This policy will ensure that all research activities within the University uphold the values of the institution of academic excellence in teaching and learning, and research and innovation. The policy is developed to provide guidance on research ethics for all staff and students and reduce risks to the university, departments and individual researchers. Further, it is aimed at protecting the dignity, rights, safety and well-being of human participants.

IV. SCOPE

This policy applies to all staff, undergraduate and graduate students, visiting researchers and post-doctorates, at University of Nizwa, on a full-time or part-time basis, and are involved in the conduct of human-participant research, human tissues, material or remains or personal information as well as researches that may raise ethical issues such as the possibility of posing environmental risks or causing political or social tensions. Animal research ethics is regulated by the Animal Research Ethics Policy and is not covered in this Policy.

V. DEFINITIONS

In applying the provisions of this policy, the following words and phrases shall have the meaning assigned to each of them unless the context requires otherwise.They are listed based on their alphabetical order.

Term	Definition
Confidentiality	The protection of personal information that has been disclosed with the expectation that it will not be revealed to others without permission.
Human participant	A human being from whom data is collected through biological sampling, interview, measurements, database consultation, etc. for the purpose of research.
Informed consent	A voluntary agreement to participate in research, with a complete understanding of the research and its risks.
Post-doctoral research fellow	A person holding a PhD degree and involved in a research project as a full-time or part-time researcher.
Principal Investigator (PI)	The researcher responsible for leading the Research Project.
Project Team	All the investigators and personnel assigned to the Research Project.
Researcher	Permanent staff of UoN, staff visiting the UoN from other local/international institutions, and undergraduate and graduate students at the University.
Vulnerable person	A human being who has diminished competence or is susceptible to being wounded or hurt, physically or emotionally.

VI. RELATED POLICIES AND DOCUMENTS

- UoN Research Policy and Regulations
- UoN Animal Research Ethics policy
- UoN Operational Guidelines for Human Research Ethics Committee (HREC).

VII. POLICY STATEMENTS AND GENERAL PROVISIONS

Ethical principles regulating Research activities:

1. UoN is committed to maintaining the highest ethical research principles. All researchers and students based at the University are required to adhere to all the ethical principles stated in this policy.

2. All research involving human participants must undergo a rigorous ethical review by the HREC. Research that does not involve human participants but may raise ethical issues such as religious/political/social tensions shall also be subject to ethical approval.

3. Ethical principles that should be observed prior to conducting any research involving human participants include the following:

    i. Participation of a human subject in any type of research (including undergraduate and graduate projects) must be voluntary.
    ii. No imbursement, inducement or compulsion to participants is allowed. Participants should never be offered any financial inducement to donate samples. However, payments to participants in research studies are sometimes made to cover costs incurred by the participants, and do not contribute to an individual participating against better judgement. Such payments should be disclosed to the Human Research Ethics Committee.
    iii. Researchers have an obligation to protect the participants from any potential harm that may arise during research activities.
    iv. Physical/mental risk or harm to participants must be minimized.
    v. Benefits of the research should outweigh potential risks or harm.
    vi. Participant's decision must be treated with respect and allowed to exercise autonomy.
    vii. Researchers must respect the rights, interests and dignity of participants.
    viii. A written informed consent should be obtained from participants.
    ix. If the participants are below 18 years old, a written informed consent of parents/guardians must be obtained.
    x. Consent should be given freely without any type of enforcement or coercion.

4. Research activities to be conducted outside UoN should be approved by the relevant institution/s, prior to commencement of the research.

5. Researchers must provide the participants with adequate and appropriate information about the research project prior to taking the informed consent.

6. The confidentiality of information taken from the participants must be maintained.

7. Personal information of the participants must be kept securely and protected from any unauthorized access.

8. Researchers may not sell samples of human biological material that they have collected as part of their research.

9. All research activities should comply with all the relevant laws, guidelines and cultural values of the societies where the study might be conducted.

10. Any major divergence from the approved project should be reported to the HREC.

11. Any conflict of interest should be declared.

12. Researchers should ensure that the data published is complete, accurate and unambiguous.

13. The nature of financial support must be appropriately acknowledged as well as the contributions of all researchers who have contributed.

14. Research in social science, psychology or medicine may lead to learning about illegal activities. Researchers have a legal obligation to report such unlawful activities. Researchers must ensure that participants are fully informed of the conditions in which confidentiality may be breached.

Non-compliance with the Human Research Ethics Policy:

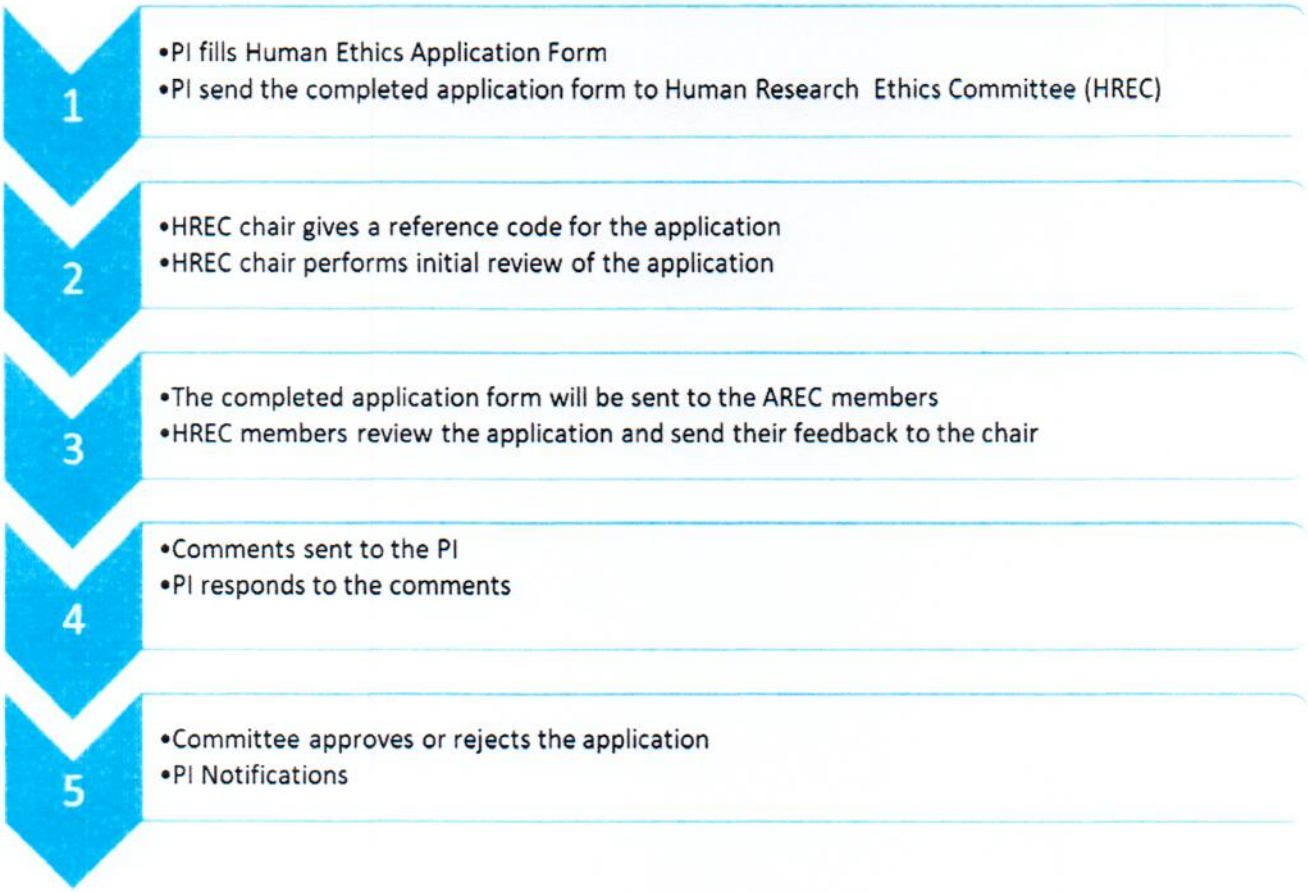
Non-compliance with the Human Research Ethics Policy, whether deliberate or negligent, will be considered as research misconduct. This may include but is not limited to:

a) conduct of research without any appropriate permission
b) deception in relation to the research proposals
c) unethical behavior in the conduct of research such as not maintaining the confidentiality of information gained as part of the research
d) fabrication, falsification or corruption of research data
e) plagiarism
f) inappropriate attribution of authorship
g) fraud or misuse of research funds or research equipment.

Any instance of ethical misconduct must be reported to the Deanship of Research (DoR) or VCGSRER

VIII. PROCEDURE/PROCESS

The procedure for obtaining ethical approval for the research to be conducted is as follows:



IX. ROLES AND RESPONSIBILITIES

The Human Research Ethics Committee (HREC) shall ensure that researches at UoN involving human participants conduct their research in accordance with the ethical principles, cultural values, as well as international guidelines and declarations:

-The primary role of the Committee is to review research proposals involving human participants to ensure conformance with the ethical practices at the University.

-The committee members should act independently, free from bias and undue influence from the researcher and from any personal or financial interests.

-The chairman of the HREC should request all the members to declare any conflict of interest they may have in relation to an application prior to the HREC meeting.

-Any involvement of HREC members as investigators or co-investigators is considered as conflict of interest and they should be requested to withdraw from the meeting.

The HREC committee members are responsible for:

a. Ethics review and approval of projects involving human participants
b. Evaluation of any updates or issues that may arise after commencement of the research activities

c. Writing, review and update of Standard Operating Procedures (SOPs)
d. Response to any other requirements assigned by the Office of the VCGSRER.

X. APPENDICES

Appendix I: Human Ethics Committee Application Form (UoN/GSRER-POL-004/FORM-001/V1/2020)

XI. HISTORICAL RECORDS

- This Policy was drafted by the Office of VCGSRER
- It was edited by Dr. Mohamed Ismail, Pro-VCAA
- It was approved by the UEB in Meeting 1/S2020, dated 18th February, 2020.

Human Research Ethical Approval Application Form

استمارة الموافقة الأخلاقية للبحوث على الإنسان

1.INVESTIGATORS DETAILS تفاصيل الباحثين	**DATE** التاريخ:
Research title عنوان البحث	
There is an obligation on the Principal Investigator to bring to the attention of the Human Research Ethics Committee any issues with ethical implications not clearly covered by this application form. يجب على الباحث الرئيس الإشارة إلى أي قضايا أخرى ربما تتعلق بالأخلاقيات وان لم تذكر في هذا الطلب	
Principal investigator: الباحث الرئيس	
Staff ID: الرقم الوظيفي	
Department/College القسم \الكلية	
Email: البريد الإلكتروني	
Phone: رقم الهاتف	
Co-principal Investigator الباحث الرئيس المناوب	
Title and Name: الاسم و اللقب	
Staff ID/ Student ID: الرقم الوظيفي/الجامعي	
Department/School: القسم\ المدرسة	
Email: البريد الإلكتروني	
Phone: رقم الهاتف	
Co-investigator 1 الباحث المشارك الأول 1	
Title and Name: الاسم و اللقب	
Staff ID/ Student ID: الرقم الوظيفي/الجامعي	
Department/School:	

Email: البريد الإلكتروني	
Phone: رقم الهاتف	
Co-investigator 2 الباحث المشارك الثاني 2	
Title and Name: الاسم واللقب	
Staff ID/ Student ID: الرقم الوظيفي/الجامعي	
Department/School: القسم \الكلية	
Email: البريد الإلكتروني	
Phone: رقم الهاتف	

You can add more co -investigators if needed. بإمكانك أضافه أشخاص آخرين من الفريق البحثي

Type of research			
Undergraduate طالب بكالوريوس أو دبلوم	**Graduate** طالب الدراسات العليا	**Staff member** موظف	**Others** آخرون

Provide information to demonstrate that the researchers involved in the project have the necessary training, expertise and experience to carry out their role in the research.

الرجاء ذكر تأهيل وخبرة وتدريب الباحثين لأجراء هذه النوعية من البحوث

2. PROJECT DETAILS تفاصيل المشروع البحثي

2.1 PROJECT SUMMARY (Maximum 200 words). ملخص المشروع (لا يزيد عن 200كلمة)

2.2 Research background (Maximum 150 words). خلفيات المشروع (لا يزيد عن 150 كلمة)

2.3 Research objectives (Maximum 150 words) أهداف المشروع (لا يزيد عن 150 كلمة)

Please summarise the objectives of the research, الرجاء تلخيص أهداف البحث

2.4 Research methodology including the location and duration (Research start/end date) if the location/ population is other than UoN campus/population, provide details of the approval/permission to gain access to that location/population.

طريقه التنفيذ وتشمل مكان الدراسة والفترة الزمنية. إذا كان موقع الدراسة خارج حرم جامعه نزوى، يجب موافاة اللجنة بتفاصيل الموافقات الرسمية لعمل الدراسة من مكان أو أماكن الدراسة.

3.1 PARTICIPANTS (target group of the study) معلومات عن الفئه المستهدفة في الدراسة

		YES	NO	N/A
	Healthy people (18 years and above) أشخاص طبيعيون في سن 18 سنة فما فوق			
Do participants fall into any of the following special groups? هل أفراد الدراسة ينتمون لأي من المجموعات الخاصة الآتية؟	Minors (under 18 years of age) أشخاص قاصرون تحت 18سنه			
	Handicapped People أشخاص معوقون			
	Patients مرضى			
	People in custody/prisoners أشخاص معتقلون او سجناء			
	People engaged in illegal activities أشخاص متورطون في أنشطة غير قانونية			

Others.... please specify	خلاف ما تقدم... الرجاء التحديد			

3.2 SAMPLE DETAILS عينة من التفاصيل

Approximate number	العدد التقريبي
From where will the participants be recruited? من أين سيتم الحصول على أفراد الدراسة (المشاركين)	
Inclusion Criteria معايير إشمال أفراد الدراسة من نفس الفئه ولكن غير مناسبين لدراسة	
Exclusion Criteria معايير استبعاد أفراد الدراسة (الأشخاص غير المناسبين للدراسة)	

Will participants be remunerated, and if so in what form?

هل سيتلقى أفراد الدراسة مكافئات ...؟إذا كانت الإجابة بنعم ما هي أشكال هذه المكافئات

4. RISKS TO PARTICIPANTS مخاطر الدراسة على الأفراد

Please describe any risks to participants that may arise due to the research. Such risks could include physical stress, emotional distress, perceived coercion. What measure will you take to minimize this risk

أذكر أية مخاطر على الأفراد المشاركين في الدراسة. المخاطر قد تكون عضوية أو نفسية أو الإجبار والإكراه. ما هي الإجراءات التي تم اتخاذها للحد من هذه المخاطر؟

5. INFORMED CONSENT (Form should be in English and Arabic) الموافقة بعد التبصير

Please tick the boxes below. Please attach the informed consent, if any, and information sheet

الرجاء وضع (√) في المكان المناسب أدناه. الرجاء إرفاق "الموافقة بعد التبصير" إذا وجدت وصفحة المعلومات.

	YES نعم	NO لا	N/A لا تنطبق
Will you obtain a written informed consent from the participants? هل سوف تقوم بأخذ الموافقة، بعد التبصير، كتابياً من أفراد الدراسة؟			
Will you give the participants an information sheet about the project and explain the main experimental procedures to participants in advance? هل سوف تقوم بإعطاء أفراد الدراسة معلومات مكتوبة عن الدراسة وتشرح خطوات التجارب البحثية قبل إشراكهم في الدراسة؟			
Will you inform the participants that their participation is voluntary and may be withdrawn at any point? هل سوف تقوم بإعلام أفراد الدراسة أن مشاركتهم طوعية وبأماكنهم سحب موافقتهم في أي وقت يشاؤون؟			
If the research is observational, will you ask for their consent to being observed? إذا كانت الدراسة عباره عن مشاهدة فقط، هل ستأخذ موافقتهم؟			
With questionnaires, will you give participants the option of omitting questions they do not want to answer? هل ستعطي أفراد الدراسة الحرية في عدم الإجابة عن بعض الأسئلة في الاستبانة؟			
Will you tell participants that their data will be treated with full confidentiality and that, if published, it will not be identifiable as theirs? هل ستعلم أفراد الدراسة أن المعلومات المستخرجة من الدراسة سوف تعامل بسرية كاملة وفي حاله النشر العلمي لن تذكر أي معلومات تؤدي إلى التعرف عليهم؟			
Will the data be anonymous? هل المعلومات المستخرجة من الدراسة سوف تكون غير معرفه بالاسم؟			
If the consent form is not required, indicate the reason for that. اذكر السبب إذا كنت تعتقد انه ليس هنالك حاجه لأخذ الموافقة بعد التبصير من الأفراد.			

6. CONFIDEENTIALITY السرية

Please outline your approach to ensuring the confidentiality of data.

كيف سوف تحافظ على سرية المعلومات المستخرجة من الدراسة وتخزينها؟

7. FUNDING AND CONFLICT OF INTEREST التمويل وتضارب المصالح

7.1 Is the Project Funded? If Yes, please state the sources of all the funds to be used for this project.

هل هذا المشروع تم تمويله او سوف يتم تمويله؟ إذا كانت الإجابة بنعم، أذكر مصادر التمويل.

7.2 Is this project part of a multi-center research project? If YES, please provide a copy of the ethical approvals from the study centers.

هل هذا المشروع جزء من مشروع أكبر تشارك فيه مراكز متعددة؟ إذا كانت الإجابة بنعم، ارفق نسخة من المصادقة الأخلاقية من كل من المراكز المشاركة

7.3 Conflict of Interest: Will you or any of the researchers receive any sort of remuneration or reward from non- University Sources for work done in this research. If YES, please provide necessary information.

تضارب المصالح: هل أنت أو أحد الباحثين تلقى أو سوف يتلقى مكافآت أو جوائز من خارج إطار المؤسسة؟ إذا كانت الإجابة بنعم، أذكر التفاصيل.

7.4 Declare any conflict of interest associated with this research.

أعلن أية تضاربات في المصالح تتعلق بهذه الدراسة.

8. COLLABORATIONS (OTHER THAN CO-INVESTIGATORS)

التعاون (لا يشمل الباحثين في الدراسة المذكورين أعلاه)

Name of collaborator اسم المتعاون	Name of the Organization اسم المؤسسة	Address/email عنوان المؤسسة والبريد الإلكتروني

9. APPLICATION FORM CHECKLIST قائمه بالمستندات الخاصة بهذا الطلب

My application includes the following documentation: هذا الطلب يحوي المستندات التالية	INCLUDED مرفقه (yes/no) نعم أو لا	NOT APPLICABLE لا ينطبق (NA)
Participant Information sheet صفحة معلومات الدارسة للأفراد		
Participant Informed Consent form الموافقة بعد التبصير		
Questionnaire/Survey الاستبيان		
Ethical Approval from external organizations موافقه أخلاقية خارجيه تخص الدراسة		
Official Ethical Approval, if any. الموافقات الرسمية إن وجدت		

10. SIGNATURES التوقيعات

LIST ALL CO-INVESTIGATORS WITH SIGNATURES أورد قائمة بجميع الباحثين مع توقيعاتهم

Principal Investigator الباحث الرئيس Date: التاريخ:

Co-Principal Investigator الباحث الرئيس المناوب Date: التاريخ:

Co-investigators الباحثون المشاركون في الدراسة Date: التاريخ:

11. STATEMENT OF ETHICAL APPROVAL (for Human Research Ethics Committee)

نص الموافقة الأخلاقية (هذا الجزء خاص بلجنة أخلاقيات البحوث على الأنسان)

Date of meeting: _____ _____

Comments: _____

Chair of Human Research Ethics Committee

This project has been considered by the Ethics Committee and ethical approval is granted

Chairman Committee Comments: _____ Date _____