Northern Border University

The Vice Presidency of Graduate Study and Scientific Research
Deanship of Scientific Research

Local Committee of Bioethics (HAP-09-A-043)

جامعة الحدود الشمالية

وكالة الجامعة للدارسات العليا والبحث العلمي

عمادة البحث العلمي

اللجنة الدائمة المحلية للأخلاقيات الحيوية والطبية بالجامعة

Local Committee of Bioethics (HAP-09-A-043)
Bioethical Application Form

Email: lcbe@nbu.edu.sa
Phone: 0146615069

Date of application: _____

Please ensure that the Checklist of Ethical Clearance Forms has been reviewed prior to submitting the application.

Human Subjects Protocol

- All responses should be Times New Roman, Bold, and Underlined.
- Submit all materials to the local committee for bioethics at NBU via email lcbe@nbu.edu.sa

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Indicate the type of review you are applying for:

☐ Convened (Full) bioethical committee ***-OR-***

☐ Expedited

* If expedited, complete items 1-4, 6, and 11-24

1. **Protocol title:** _____
2. **Investigator and Contact Person:**
   a. Name of Principal Investigator:_____
   Degree(s)/Title: _____ NBU Employer ID: _____
   Dept/Div:_____ NBU Email Address: _____
   b. Name of Contact Person: _____ Degree(s)/Title: _____
   Phone: _____ E-mail: _____

INVESTIGATOR ASSURANCE STATEMENT & SIGNATURE

By signing as the Principal Investigator, I acknowledge my responsibilities for this Human Subjects Protocol, including:

- Certifying that I and all key personnel comply with reporting requirements of the Northern Border University Conflict of Interest of the local committee for Bioethics;
- Certifying that the information, data, tools and/or specimens collected for the research will be used, disclosed and maintained in accordance with this protocol and Northern Border University policies;
- Following this protocol without modification unless (a) the local committee of bioethics at NBU has approved changes prior to implementation or (b) it is necessary to eliminate an apparent, immediate hazard to a participant(s);
- Verifying that all key personnel listed on the protocol have completed bioethical training and obtained the bioethical certificate and will complete continuing bioethical training as required;
- Verifying that all personnel are licensed/credentialed for the procedures they will be performing, if applicable;
- Applying for continuing review of the protocol at least annually unless directed by the bioethical committee to apply more frequently;
- Conducting the protocol as represented here and in compliance with national committee for bioethics determinations and all applicable national laws and regulations; providing the bioethical committee with all information necessary to review the protocol; refraining from protocol activities until receipt of initial and continuing formal bioethical committee approval.

Signature of Investigator: _____ **Date:** _____

Name, Degree, and department	NBU ID	Role	Governmental ID N.	Conflict of Interest?	Protocol Responsibilities (indicate if this person obtains consent)
Name: Degree: Department:				☐No ☐Yes	
Name: Degree: Department:				☐No ☐Yes	
Name: Degree: Department:				☐No ☐Yes	
Name: Degree: Department:				☐No ☐Yes	
Students if applied:				☐No ☐Yes	
Students if applied:				☐No ☐Yes	

Name and Degree	From Institution with or without own bioethical committee?	Conflict of Interest?*	Protocol Responsibilities and Qualifications (indicate if this person obtains consent)
Name: Degree: Institution: Email:	☐Has own bioethical committee but requests that NBU bioethical committee serve as board of record? ***-OR-*** ☐Does not have own bioethical committee and needs to rely on NBU bioethical committee.	☐No ☐Yes	

3. Funding

Is this protocol funded? ☐Yes ☐No

If No, specify that costs of the protocol will be covered by funds from the NBU department or other source named:_____

If Yes, attach one copy of completed application or request for funding sent to sponsor, and complete a-b.

a. Title of Grant, Contract, or Agreement: _____

b. NBI PI of Grant, Contract, or Agreement: _____

4. Locations Involved

a. Indicate all performance sites that will provide space, services, or facilities for the conduct of this protocol.

- ☐ North Medical Tower
- ☐ Prince Abdulaziz bin Musaaed Hospital
- ☐ Maternity Hospital
- ☐ Mental Health Hospital

☐ Prince Abdullah Bin Musaed Cardiac Centre (PAMCC)
☐ Other (i.e., any performance site not listed above, including those covered by subawards related to this protocol) - Describe:_____

b. Describe the space, service, or facilities available for the conduct of the research in the performance sites listed in Item 4.a (For research on NBU campus, include building names):_____

c. Is this protocol a clinical trial requiring clinical services at one of the performance sites listed in Item a above? ☐Yes ☐No

5. Clinical Trial

Does this protocol meet the following definition of a clinical trial? ☐Yes ☐No

**A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.*

If Yes, you will need to fulfill the following requirements (regardless of funding):

a. This protocol must be registered on Saudi Clinical Trial Registry: SCTR: _____
***Attach a copy** of the SCTR approval.

6. Multi-Site Studies

a. Is this a multi-site study with the NBU investigator as the lead investigator? ☐Yes ☐No

b. Is this a multi-site study with NBU as a coordinating site? ☐Yes ☐No

c. If Yes to a or b, describe the management of information obtained in multi-site research that might be relevant to the protection of participants. Include, at a minimum, how the following items are managed:

- Bioethical approvals from other sites_____
- Unanticipated problems involving risks to participants or others. (For example, if there is an unanticipated problem involving risks to participants or others, which site is responsible for reporting it?)_____

7. Drugs

a. Will any drugs or supplements be *used or studied* in this protocol? ☐Yes ☐No
If yes, attach the Informed Consent Statement form in case of Drug or device experiments
b. Is the drug approved by the SFDA ☐Yes ☐No
c. Are you exceeding the cleared/approved dose that is approved by the SFDA for the drug? ☐Yes ☐ No

8. Devices

a. Will any devices be *studied* in this protocol? ☐Yes ☐No
If yes, attach the Informed Consent Statement form in case of Drug or device experiments

b. Will any *non SFDA-approved* devices be *used or studied* in this protocol? ☐Yes ☐No

9. Special Approvals

a. Does this protocol involve the use of radioisotopes? ☐Yes ☐No

b. Does this protocol include patients with contagious infections (e.g., mumps, measles, chickenpox, TB, meningitis)? ☐Yes ☐No

c. Does this protocol involve obtaining remnant biopsy or surgical? ☐Yes ☐No

d. Does this protocol require obtaining any remnant clinical laboratory specimens, body fluids, or microbiological isolates from the Department of Pathology or any other source? ☐Yes ☐No

e. Does this protocol use stored (existing) specimens from a repository? ☐Yes ☐No

10. Use of Specimens

Does this protocol involve the collection of specimens? ☐Yes ☐No

If Yes, complete 10.a-10.h.

If No, skip to Item 11.

a. How will specimens be obtained, processed, distributed, and stored? _____

b. How will specimens be labeled (e.g., unique identifier, medical record number, ID number, name, date of birth)? _____

c. How will clinical data associated with the specimens be collected and stored? _____

d. What participant-identifying information will be collected and linked to the specimens? _____

e. What steps will be taken to maximize the confidentiality of linked identifiers? For example, procedures could include using a password-protected computer database to link identifiers, with limited personnel knowledgeable of the password, or coded identifiers released without the ability to link to clinical data (also called "stripped" or "anonymized" specimens). _____

f. Is genetic testing planned as part of this protocol? ☐Yes ☐No

If Yes, describe the planned genetic testing here. _____

Attach the Informed consent statement for Genetic study

g. Will specimens be stored for future use? ☐Yes ☐No

If Yes, indicate whether they will be used for the disease under study in this protocol or research on other diseases. _____

h. Will specimens be shared with other investigators in the future? ☐Yes ☐No

If Yes, answer i. and ii.

i. What identifiers, clinical information and demographic information will be shared; or will the specimens be stripped of identifiers (i.e., anonymized)? _____

ii. Outline your procedure for assuring bioethical committee approval for release and use prior to release of specimens. _____

NOTE: Investigators who receive and/or use these specimens must document approval from the appropriate bioethical committees before the specimens may be released.

PROPOSED RESEARCH

11. Purpose - in nontechnical, lay language

a. Summarize the purpose and objectives of this protocol in one short paragraph.

_____

b. Describe how outcomes will be measured for this protocol.

_____

12. Background - in nontechnical, lay language

Summarize in 2-3 paragraphs past experimental and/or clinical findings leading to the design of this protocol. Include any relevant past or current research by the PI. For drug and device studies, summarize the previous results (i.e., Phase I/II or III studies). *Include **in-text citations and references** at the end of this section using AMA style.*

_____

13. Participants (Screening and Selection)

a. How many participants are to be enrolled at? _____

If multi-site study, total number at all sites/institutions (type N/A if not applicable): _____

b. Describe the characteristics of anticipated or planned participants.

Sex (male, female, or both): _____

Nationality: _____

Age: _____

Health status: (e.g., healthy individuals, persons with specific disease): _____

c. From what population(s) will the participants be derived (e.g., access to hospital records)? _____

d. Describe the inclusion/exclusion criteria: _____

e. If participants comprise more than one group or stratification, describe each group (e.g., treatment/intervention, placebo, controls, sham treatment) **and** provide the number of participants anticipated in each group. _____

g. List any persons other than those directly involved in the protocol who will be at risk. If none, enter "None":_____

h. Describe the recruitment process (e.g., medical record review, referrals, letter of invitation, existing patients) that will be used to seek potential participants (e.g., individuals, records, specimens).

_____

i. If you will use recruitment materials (e.g., advertisements, social media posts, email invites) to reach potential participants, **attach** a copy of each item. If not, identify the source from which you will recruit participants. _____

j. Describe the screening process/procedures for potential participants. _____

14. Protocol Procedures, Methods, and Duration - in nontechnical, lay language

a. Describe the procedures for all aspects of your protocol. Tell us what you are doing.

_____

b. What is the probable length of time required for the entire protocol (i.e., recruitment through data analysis to study closure)?

_____

c. What is the total amount of time each participant will be involved?

d. If different phases are involved, what is the duration of each phase in which the participants will be involved? If no phases are involved, enter "None." _____

e. List the procedures, the length of time the procedure takes, the total # of times the procedure is performed, and indicate whether each is performed solely for research or would already be performed for treatment or diagnostic purposes (routine care) for the population.
-Insert additional table rows as needed.
-If procedure is sometimes research and sometimes routine care, include on separate lines with number of times as each.

Procedure	Length of Time Required of Participants	Total # of Times the Procedure is Performed	Research (Res) –OR- Routine Care
			☐Res ☐Routine
			☐Res ☐Routine
			☐Res ☐Routine
			☐Res ☐Routine
			☐Res ☐Routine
			☐Res ☐Routine
			☐Res ☐Routine
			☐Res ☐Routine
			☐Res ☐Routine
			☐Res ☐Routine
			☐Res ☐Routine

f. Will an interview script or questionnaire be used? ☐Yes ☐No
If Yes, attach a copy and include references.

g. Will participants incur any costs as a result of their participation? ☐Yes ☐No
If Yes, describe the reason for and amount of each foreseeable cost. _____

h. Will participants be compensated? ☐Yes ☐No
If Yes, complete i-v.
i. Type: (e.g., cash, check, bank transfer):_____
ii. Amount or Value: _____
iii. Method (e.g., electronically or at visit):_____
iv. Timing of Payments: (e.g., every visit, each month): _____
v. Maximum Amount of Compensation per Participant: _____

15. Benefits
Describe the potential benefits of the research. _____

16. Risks - in nontechnical, lay language
a. List the known risks for participants as a result of participation in the research. This should not include the minimal risk of loss of confidentiality. However, it should include any physical, psychological, social, economic, and/or legal risks. If there is a greater than minimal risk of loss of

confidentiality describe why this is so. Do not list risks associated with the standard-of-care procedures.
NOTE: Risks included here should be included in the consent form or information sheet, as applicable.

_____

b. Estimate the frequency, severity, and reversibility of each risk listed. _____

c. Is this a therapeutic study or intervention? ☐Yes ☐No
If Yes, complete i.-iii.
i. Describe the standard of care in the setting where the research will be conducted: _____
ii. Describe any other alternative treatments or interventions: _____
iii. Describe any withholding of, delay in, or washout period for standard of care or alternative treatment that participants may be currently using: _____

d. Do you foresee that participants might need additional medical or psychological resources as a result of the research procedures/interventions? ☐Yes ☐No
If Yes, describe the provisions that have been made to make these resources available. _____

e. Do the benefits or knowledge to be gained outweigh the risks to participants? ☐Yes ☐No
If No, provide justification for performing the research: _____

17. Precautions/Minimization of Risks

a. Describe precautions that will be taken to avoid risks and the means for monitoring to detect risks.

_____

b. If hazards occur to an individual participant, describe (i) the criteria that will be used to decide whether that participant should be removed from the protocol; (ii) the procedure for removing such participants when necessary to protect their rights and welfare; and (iii) any special procedures, precautions, or follow-up that will be used to ensure the safety of other currently enrolled participants._____

c. If hazards occur that might make the risks of participation outweigh the benefits for all participants, describe (i) the criteria that will be used to stop or end the entire protocol and (ii) any special procedures, precautions, or follow-up that will be used to ensure the safety of currently enrolled participants. _____

18. Informed Consent

a. Do you plan to obtain informed consent for this protocol? ☐Yes ☐No
If Yes, Attach the general Informed consent form.

b. Do you plan to document informed consent (obtain signatures) for this protocol? ☐Yes ☐No

c. How will consent be obtained (for example, online signature)? _____

d. Who will conduct the consent interview? _____

e. Who are the persons who will provide consent, permission, and/or assent? _____

g. What language will the prospective participant and the legally authorized representative understand? _____

h. What language will be used to obtain consent? _____

Data Protection Warranty

22. Procedures to Protect Privacy

Describe how you will protect the privacy interest of the participants. Include how you will make sure others cannot overhear your conversation with potential participants and that individuals will not be publicly identified or embarrassed. _____

23. Procedures to Maintain Confidentiality

a. Describe how you will store research data to maintain confidentiality (both paper records and electronic data), including how access is limited. _____

b. Will any data from this protocol be given to any person, including the subject, or any group, including coordinating centers and sponsors? ☐Yes ☐No

If Yes, complete i-iii.

i. Who will receive the data? _____

ii. What data will be shared? _____

iii. How will the data be identified, coded, etc.? _____

☐ **Declaration:** I attest to protect all the data acquired from this project in accordance with the bylaws of the local committee of bioethics at Northern Border University. And I will not start the research work or submit the related manuscript of the above-mentioned project for publication to any journal before I obtain the Ethical Approval from the local committee of bioethics at Northern Border University.

24. Additional Information

In the space below, provide any additional information that you believe may help the bioethical committee the proposed research, or enter “None.” _____