جامعة محمد بن راشد
للطب و العلوم الصحية

MOHAMMED BIN RASHID UNIVERSITY
OF MEDICINE AND HEALTH SCIENCES

MOHAMMED BIN RASHID UNIVERSITY OF MEDICINE AND HEALTH SCIENCES

INSTITUTIONAL REVIEW BOARD (MBRU-IRB)

EXPEDITED/FULL REVIEW FORM

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EXPEDITED/FULL REVIEW FORM

Dear Investigator,

This form is intended for use if you are seeking MBRU-Institutional Review Board (MBRU-IRB) for either Expedited or Full review. Kindly, proceed with filling out the full application. Make sure to include all necessary requested information and supporting documentations. In the event that your application is incomplete, the application will be returned to the Principal Investigator for completion without MBRU-IRB review, which could stall or delay your process of obtaining the needed MBRU-IRB approvals.

Please, keep in mind that in order to approve any research involving human subjects, the MBRU-IRB must determine that the research design adopted is scientifically sound. **YOU CANNOT** proceed with your research project without MBRU-IRB's written and a stamped approval by the MBRU-IRB office and chairperson. **YOU CANNOT** proceed with recruitment, consent, data collection, or any other stage of your research until you are approved, and you have received that approval from MBRU-IRB.

Your research SHOULD AND MUST ADHERE to the basic ethical principles clearly outlined and described by the Belmont Report that revolves around respect for persons, beneficence, and justice. The research should ensure the voluntary participation of human participants, clearly outline the informed consent process, and it should emphasize the fair and non-discriminatory recruitment of human participants (especially if recruitment entails vulnerable populations). It should clearly outline how the risks associated with the research are reasonable and justify that by the expected benefits. It should have a clear and adequate monitoring plan to ensure the safety of participants as well as indicate how additional protection will be safe guarded, when vulnerable subject populations are included.

Please, also, note in the case of any additional changes to any part of the approved research material (like for instance, increase in sample size, changes in recruitment methods, modification to the survey questions/instrument, revision of consent forms/oral scripts, etc.), an amendment for approval must be submitted and approved by the MBRU-IRB, prior to any changes that need to be made. Your research, moreover, depending on the requested changes/amendments, may or may not be eligible for approval (even if it qualified originally). Do not hesitate to contact the MBRU MBRU-IRB office for instructions on how to submit an amendment or modification to previously approved research project.

Submitting an Application

In addition, to the completion of this application, please ✓ the following (listed below) are also appended to the application:

- ☐ The Research Proposal
- ☐ The Informed consent (s)
- ☐ Participant Information Sheet (if any)
- ☐ Peer review (If any)
- ☐ Funding Award letter (if any)
- ☐ Recruitment material (if any is being used)
- ☐ The Data Collection form (s) or Questionnaire
- ☐ Copies of the CITI or NIH Certification or equivalent for the PI and each of the co-investigators on the research project, valid for two years and for the duration of the project
- ☐ Conflict of Interest Form
- ☐ Other material you perceive that may be needed

CITI Certification

MBRU requires that all researchers involved in conducting human research to complete the appropriate CITI or NIH training program for Human Subjects Research. All researchers including research assistants as well as the data collectors involved in the project (whether at MBRU or elsewhere, should attach a copy of the CITI or NIH certification or equivalent to this application. Failure to attach copies of these certificates will render the application incomplete; hence, the application will be returned to the PI without being reviewed. The CITI modules can be accessed at: **https://www.citiprogram.org/index.cfm?pageID=22** and the NIH modules can be accessed at: **https://phrp.nihtraining.com/users/login.php**).

Completed application must be emailed to the MBRU Institutional Review Board at irb@mbru.ac.ae.

1. TYPE OF THE RESEARCH PROJECT

Faculty Research Project: ☐ Yes ☐ No

Post Graduate Research Project: ☐ Yes ☐ No

Undergraduate Research Project: ☐ Yes ☐ No

Other (Specify): _____

2. TITLE OF THE PROJECT

3. PRINCIPAL INVESTIGATOR

Name			Degree
Title		Department	College
Submission Date	Phone #	Emergency Phone #	E-mail

4. STUDY COORDINATOR

Name		Degree
Title	Department	College
Submission Date	Phone #	E-mail

5. KEY STUDY PERSONNEL – include all people responsible for the design and conduct of the study at MBRU (for collaborators at other institutions go to "6")

Name	Dept. or Affiliation	Role in Study	CITI course completed
			☐ YES ☐ NO
			☐ YES ☐ NO
			☐ YES ☐ NO
			☐ YES ☐ NO
			☐ YES ☐ NO

			☐ YES ☐ NO
			☐ YES ☐ NO
			☐ YES ☐ NO

6. COLLABORATORS AT OTHER INSTITUTIONS

Name	Affiliation	Role in Study

7. FUNDING

Is this research funded? ☐ Yes ☐ No

Proposed Annual Budget (AED): _____

Specify the Source of Funding/Sponsor Name:

_____

Starting Date of Study: _____

Expected Date of Study Completion: _____

Site where the study will be conducted: ☐ MBRU ☐ Outside MBRU (specify):

8. REQUESTED REVIEW ☐ Expedited ☐ Full

(If requesting exemption from MBRU-IRB review, do not fill this form; instead submit the Exemption Application Form)

If you are applying for Expedited Review, please indicate the category of research that best describes it by checking one or more of the categories listed below*:

☐ (1) Collection of blood samples by finger stick, heel stick, ear stick or venipuncture. For adults, normally not drawing blood exceeding 450 ml during an 8 week period, and not more than twice a week. For children and those less than 50 kg, not more than 50 ml or 3 ml/kg whichever is less during an 8 week period and collection may not occur more frequently than 2 times per week.

☐ (2) Prospective collection of biological specimens for research purposes by noninvasive means, e.g.: non-disfiguring hair and nail clipping, excreta and external secretion, placenta at delivery, amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; mucosal and skin cells collected by buccal scraping or swab, skin swab or mouth washings, etc.

☐ (3) Collection of data through noninvasive means (i.e. not involving general anesthesia or sedation) routinely employed in clinical practice **excluding x-rays and microwaves**, e.g.: ECG, EEG, MRI, ultrasound, echocardiography, electrocardiography, electroencephalography, ultrasound, Doppler blood flow, thermography, body composition assessment, moderate exercise by healthy volunteers, muscular strength testing, weighing testing, sensory acuity.

☐ (4) Research involving materials already collected (data documents, records and pathological or diagnostic specimens) or will be collected solely for non-research purposes (such as medical treatment or diagnosis).

☐ (5) Collection of data from voice, video, digital or image recordings made for research purposes.

☐ (6) Research on individual or groups characteristics or behavior such as perception, cognition, motivation, identity, language, communication, cultural beliefs or practices and social behavior, test development where the investigator does not manipulate that subject's behavior and no stress to the subject may occur, or research using survey, interview, oral history, or quality assurance methodologies (some research in this category can be exempt).

** Expedited Review Categories for Research Involving Human Subjects are defined in the US Code of Federal Regulations for the Protection of Human Subjects (45CFR46). You can refer to the following website for guidance:*

http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm

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9. WHICH OF THE FOLLOWING STUDY DESIGNS DOES YOUR RESEARCH BEST DESCRIBE?

- ☐ Cross Sectional Study (Survey)
- ☐ Case control Study
- ☐ Cohort (Longitudinal) Study
- ☐ Placebo controlled trial
- ☐ Randomized study
- ☐ Blinded study (Describe)
- ☐ Investigational drug or device (non-approved for use): attach investigator's brochure

10. RESEARCH ABSTRACT.

The abstract should not exceed 500 words. It should be written in Lay Public, Non-Technical, simple language. It should include details on the below:

- ✓ Scientific context
- ✓ Hypothesis/aims

- ✓ Experimental design, subject selection/recruitment, procedures involving human subjects
- ✓ Justify involvement of human subjects
- ✓ Describe risks and benefits, and risk/benefit ratio
- ✓ Discuss privacy and confidentiality issues

Kindly, note that your abstract should be as simple but as comprehensive as possible so that is easily understood by people whose specialty is non-scientific and non-medical.

11. INFORMED CONSENT

A. Specify all languages to be used for the informed consent form:

☐ Arabic ☐ English ☐ Other: specify _____

B. Describe the setting in which an informed consent will be obtained

C. Provide the names of those who will obtain informed consent from the subjects

Name	Qualifications	CITI/NIH course completed
		☐ YES ☐ NO
		☐ YES ☐ NO

		☐ YES ☐ NO
		☐ YES ☐ NO

D. Does the person obtaining consent have any relationship with the patient (e.g. personal physician)?

☐ Yes ☐ No

If yes, describe the relationship and indicate ways of protecting against undue influence or coercion.

E. Will you request a waiver of written informed consent or omission of any requirements (e.g. non-disclosure of information to subject)? Check "MBRU-IRB Policies and Procedures" criteria to see whether it is possible depending on the nature of your research).

☐ Yes ☐ No

If yes, justify the need for waiver or non-disclosure.

F. If oral consent is to be obtained, provide the MBRU-IRB with the script that will be used and describe means to document oral consent. Check "MBRU-IRB Policies and Procedures" criteria to see whether it is possible depending on the nature of your research).

12. SUBJECT SELECTION AND RECRUITMENT

A. Number of subjects to be recruited:

Whole study: Total:_____ at MBRU only: _____

Total:_____ at MBRU only: _____

B. Identification and recruitment of subjects: details the procedures of subjects' identification and recruitment, the location/setting and the time frame (e.g. provide script for personal or phone contact).

C. Are advertisements being used to solicit participants? ☐ Yes ☐ No

If yes, provide a copy of the advertisement and choose from among the most applicable category from below:

☐ Letter ☐ Flyers ☐ Mass E-mail ☐ Internet ☐ Newspaper

☐ Newspaper ☐ Posters ☐ MBRU publication
☐ Departmental Bulletin Boards ☐ Telephone
☐ Other (Please Describe): _____

D. Describe the subject population.

E. Will your study consist of recruitment of vulnerable population groups?

i) Indicate which, if any, of the following vulnerable groups will be included as research subjects?

- ☐ Children/minors
- ☐ Cognitively impaired
- ☐ Comatose/Traumatized
- ☐ Elderly
- ☐ Terminally ill participants
- ☐ Others, specify:
- ☐ Pregnant women/fetal tissue/placenta
- ☐ Prisoners
- ☐ Subordinates/employees at institution
- ☐ Students
- ☐ Emergency unit patients

ii) Describe why it is necessary to include these groups in your research.

F. Kindly, list the specific recruitment criteria for inclusion/exclusion of potential subjects.

G. Justify the exclusion if any- of any group based on age, sex, ethnicity, and social or economic factors.

H. Please provide the summary that will be used indicating the participant's right to withdraw from the study and the process for it. Also, indicate what will happen to collected any data already collected if the participant wishes to withdraw from the research.

13. SPECIMEN COLLECTION (IF ANY)

A. Blood drawing (if any): describe amount per drawing, frequency, and total amount.

B. Other tissues (if any); describe

C. If genetic tests are to be done describe in informed consent form.

D. Distinguish between procedures that are part of normal clinical practice from those being conducted specifically for research purposes.

14. DATA CONFIDENTIALITY AND STORAGE

A. Kindly, indicate how will the research data be stored during data collection and following study completion

- On the MBRU Servers with password protection: ☐ Yes ☐ No
- On an Encrypted laptop: ☐ Yes ☐ No
- In a locked filing cabinet: ☐ Yes ☐ No
- In an External company: ☐ Yes ☐ No
- In a Public sector organization: ☐ Yes ☐ No
- Others (Please, specific):

  _____

15. RISKS

A. Risks: Describe any potential risks associated with your research. Risk includes physical, psychological, social (potential stigmatization e.g. HIV), legal (research on illicit behavior) or financial (cost of study).

Describe the frequency and magnitude (minimal[1], severe, potentially fatal, etc...) of the risks

B. Are there other methods to run the research that might minimize these risks? Describe and justify not using them.

B. Will ionizing radiation be used as part of this study?

☐ Yes ☐ No

[1] Minimal risk is defined as the probability and magnitude of harm or discomfort not exceeding those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

If yes, please describe

D. Describe your plan for data safety monitoring and for reporting adverse effects to the MBRU-IRB.

E. If this is a therapeutic trial, list the therapeutic alternatives.

F. If this involves use of placebo, the risk related to these must be mentioned in the protocol and informed consent form. Check the applicable justification for use of placebo:

☐ No alternative standard therapy

☐ Alternative standard therapy exists but risks of placebo are minimal (discuss)

☐ Alternative therapy exists, risks of placebo are > than minimal, but plans for intervention exist (Describe plans for intervention should adverse effects occur)

16. BENEFITS

A. Describe the anticipated benefits to the research subjects. If no direct benefits are expected – please indicate and include this statement in the consent form (Monetary compensation is not considered a benefit and it should be set at minimum accepted value).

B. Describe benefits to society or to science/medicine as a whole

17. RISK/BENEFIT RATIO

Assess the relative weights of the study's risks and benefits. Whenever possible, indicate whether any provisions will be followed to ensure medical or professional intervention in the case of adverse effects to the subject (e.g. an unblinded co-investigator in a high-risk Phase I study). Discuss why the risks to subjects are reasonable compared to the anticipated benefits to subjects vis-à-vis with the importance of the knowledge that could be reasonably generated or gained as a result of the research

18. COMPENSATION OR COSTS TO SUBJECTS

A. There are very limited circumstances when research participants may be responsible (either directly or via their insurance) to cover some of the research-related expenses. If the study participant or their insurer(s) will be billed for any portion of the research study, please indicate the additional expenses that will be incurred (e.g. extended hospitalization, extra laboratory tests, travel…) as well provide a justification of why this should be perceived appropriate and acceptable.

B. Describe what types of compensation will be offered for the research participants. The MBRU-IRB will not approve a study where there is only a lump sum payment at the end of the study because this can be considered coercive.

C. For research with more than minimal risk, describe any medical treatment, insurance and/or compensation available to the subject if he/she is injured as a result of participating in the study.

19. PERSONAL/FINANCIAL INTEREST

All personnel involved in this study must complete the Conflict of Interest Form to disclose any personal or financial interests in the research and the extent of such interest in the sponsor of the study if applicable, including whether any of the members of the research team have involvement with either the funder(s) or organization(s) where the research will be taking place.

20. CONFLICT OF INTEREST (Adds extra rows if necessary)

All personnel involved in this study must complete the Conflict of Interest Form and enclose it with this application.

Name of Personnel	Is there any potential conflict of interest with this study?	
	Yes (Please provide information on nature of conflict of interest)	No
	☐	☐
	☐	☐
	☐	☐
	☐	☐
	☐	☐
	☐	☐

21. BIBLIOGRAPHY AND REFERENCES:

List up to five relevant and most up-to-date publications that, in your opinion, would be helpful for the MBRU-IRB during the review of your research.

PRINCIPAL INVESTIGATOR'S ASSURANCE STATEMENT

1. I certify that the information provided in this application is complete and accurate;

2. I understand that as principal investigator, I bear the ultimate responsibility for the conduct of the herein proposed research. I will maintain the ethical performance of the research, ensure the protection of the rights, safety and welfare of the human participants, and strictly adhere to the research protocol. I will, also, guarantee that any amendments or modifications made to the research project will be relayed to the MBRU-IRB, and the project will be suspended until the necessary approval has been granted by MBRU-IRB;
3. I will submit any modifications made to the protocol and/or the informed consent form and/or any other documents for MBRU-IRB approval, prior to applying those modifications into the research, as indicated above; and

4. I agree to abide by the policies and procedures of the MBRU-IRB regarding the protection of human subjects including, but not limited to:
   - Ensuring that all personnel involved in the research have completed the human subjects training online course, and respective certificates are attached to this application,
   - Ensuring that the research will only be conducted by qualified personnel,
   - Obtaining informed consent from participants or their legally appointed representatives or guardians, using the informed consent form stamped by the MBRU-IRB approval as well as I will provide a copy of the signed form to the research participant,
   - Reporting adverse events or other unexpected problems and risks involving human subjects to the MBRU-IRB promptly,
   - Promptly adhering to the MBRU-IRB decision to stop or discontinue the research, if prompted to do so,
   - Obtaining the necessary approval to continue with the research after the end of the approval period by submitting a renewal request BEFORE the research expires. I

understand that if I fail to apply for renewal, the study will automatically expire and all activity must be terminated, until MBRU-IRB approval is granted again,

- Maintaining accurate and complete research records including all informed consent documents, for at least 3 years from the date of study completion
- Fully informing the MBRU-IRB of all sites used for research subjects' recruitment, and being responsible for obtaining and maintaining MBRU-IRB approvals and letters of cooperation from investigators and study collaborators from outside MBRU, and

I hereby certify that the information provided in this application is complete and accurate.

Principal Investigator's Signature | Date

Department Chair's Name and Signature | Date

APPROVALS

Name	**Signature**	**Date**
Chairperson/or Designee of the MBRU-IRB		

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THIS APPLICATION FORM SHOULD BE SENT BY THE PRINCIPAL INVESITGATOR (PI) NAMED ABOVE.

THE MBRU-IRB WILL ASSUME THAT BY DOING THIS THE PI IS FULLY AWARE AND RESPONSIBLE OF THE APPLICATION, ITS CONTENT AND HAS REVIEWED IT FOR ACCURACY OF DETAIL. MOREOVER, THE PI ASSUMES FULL RESPONSIBLILTY OF THE RESEARCH THAT WILL BE CONDUCTED