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)

EXEMPT REVIEW FORM

MBRU

جامعة محمد بن راشد للطب و العلوم الصحية

MOHAMMED BIN RASHID UNIVERSITY OF MEDICINE AND HEALTH SCIENCES

MOHAMMED BIN RASHID UNIVERSTY OF MEDICINE AND HEALTH SCIENCES

EXEMPT REVIEW FORM

Dear Investigator,

This form is intended for use ONLY if you are seeking MBRU-Institutional Review Board (MBRU-IRB) Exemption. You are entitled to request MBRU-IRB Exemption if your research study falls within one of the listed six categories*:

Please Tick one or more of the categories below that best describes your research project:

☐ (1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, ***such as***:
(i) research on regular and special education instructional strategies, or
(ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

☐ (2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, ***unless:***
(i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and
(ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

☐ (3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under the above paragraph of this section, ***if:***
(i) the human subjects are elected or appointed public officials or candidates for public office; or

(ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

☐ (4) Research involving data already collected, documents, records, pathological specimens, or diagnostic specimens, ***provided*** that these different existent sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects [Existent sources mean that the research materials are already archived when the research is being proposed; for example, blood samples are already taken from patients or subjects for other clinical or research purposes.

☐ (5) Research and demonstration projects that are carried out by or subject to the approval of departments aimed to study, evaluate, or otherwise examine the:
(i) public benefit of service programs;
(ii) procedures for obtaining benefits or services under those programs;
(iii) possible changes in or alternatives to those programs or procedures; or
(iv) possible changes in methods or levels of payment for benefits or services under those programs.

☐ (6) Taste and food quality evaluation and consumer acceptance studies, ***if***:
(i) wholesome foods without additives are consumed, or
(ii) food is consumed that contains a food ingredient at or below the level and for a use found to be safe,
(iii) food containing agricultural chemicals or environmental contaminants is at or below the levels found to be safe, by the national regulatory agencies of Food and Drug Administration, and/or for Environmental Protection, and/or for the Food Safety and Inspection for Agriculture Protection.

**Exempt 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

Kindly note, that even if you are applying for Research Exemption, **YOU CANNOT** proceed with your research project without MBRU-IRB's written and a stamped approval for Exempt Status by the MBRU-IRB office and chairperson. **YOU CANNOT** proceed with recruitment, consent, data collection, or any other stage of your research until your Exempt determination status has been approved, and you have received that approval of exemption from MBRU-IRB. Submission of the requested materials for exemption review (listed in the coming sections) is **NOT** sufficient – you must wait for approval before you proceed with your research.

It should be noted that research projects, which are eligible for Exempt Status, ARE NOT EXEMPT from the ethical principles that guide the responsible conduct of research involving human participants. Exempt projects 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.

Please, also, note in the case of any additional changes to any part of the approved research materials (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 Exemption (even if it qualified originally for Exempt status). Do not hesitate to contact the MBRU-IRB office for instructions on how to submit an amendment or modification to previously exempt approved research project.

Further, your application will only be reviewed when it is complete. To be considered for MBRU-IRB Exemption approval, a complete MBRU-IRB application should consist (at minimum) of the different documents outlined below. Failure to amend the application with the below requested documents means your application is incomplete and the MBRU-IRB will return it to the Principal Investigator for further completion prior to any review.

The documents needed are (please √**) :**

- ☐ A complete MBRU-IRB Exemption application
- ☐ The Research proposal (see instructions in Appendix I)
- ☐ The Informed consent(s) (if applicable)
- ☐ The 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

CITI/NIH 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 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 (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. TITLE OF THE PROJECT

2. PRINCIPAL INVESTIGATOR

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

3. COLLABORATORS/CO-INVESTIGATORS (Adds extra rows if necessary)

Name	Affiliation	Role in Study

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

All the above-mentioned personnel must complete the Conflict of Interest Form and enclose it with this application for all studies.

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

	☐	☐
	☐	☐

DATE OF SUBMISSION TO MBRU-IRB: _____

STARTING DATE OF THE STUDY: _____

EXPECTED END DATE OF THE STUDY:

_____

The following should be:

- The determination of whether a given research meets the MBRU-IRB requirements for Exempt Status relies solely on the written information completed as well as provided in the application.

- A research study that has been determined by the MBRU-IRB to be Exempt does not require continuing progress reviews or a final study report.

Principal Investigator Assurance: I agree to abide by all MBRU Policies and Procedures on Ethics as well as all relevant UAE laws in this study.

Principal Investigator's Signature Date

Department Chair's Name and Signature Date

APPROVALS

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

APPENDIX I

Please submit a research proposal not exceeding two pages. You can use the headings below as a guide.

1. Research/study question or hypothesis

2. Recruitment of research participants thorough description of the informed consent process, the informed consent, or the script of consent information when oral consent is obtained instead should be detailed. You are allowed to use verbal scripts, online scripts, emails, etc. However, these documents should be submitted. In addition, the process of informing study participants along with their ability to discontinue participation at any point of the study and/or to skip of their involuntary participation or sensitive questions, etc., when needed, should also be clearly described in the proposal.

3. Protection of participants' privacy and data confidentiality (In the case when an exempt study has identifiers, the participants need to be reassured regarding the means to guarantee the protection of their privacy, confidentiality, etc.).

4. Research method/procedure protocol that will be followed to conduct the study (in the case of open-ended interviews for instance, you can give a list of topic questions and explain the direction you want to pursue. It can also be helpful to highlight any perceived sensitive information or topics that will be avoided).

5. Plan of data analysis and disposition of data collected (including any audio or video recordings).

6. Plan of dissemination of research findings.

THIS APPLICATION FORM SHOULD BE SENT BY THE PRINCIPAL INVESTIGATOR (PI) . THE MBRU-IRB WILL ASSUME THAT BY DOING THIS THE PI IS FULLY AWARE AND RESPONSIBLE FOR THE APPLICATION AND HAS REVIEWED IT FOR ACCURACY OF DETAIL. MOREOVER, THE PI ASSUMES FULL RESPONSIBLILTY FOR THE RESEARCH THAT WILL BE CONDUCTED.