MOHAMMED BIN RASHID UNIVERSITY OF MEDICINE AND HEALTH SCIENCES

INSTITUTIONAL REVIEW BOARD (MBRU-IRB)

REPORT ON STATUS OF RESEARCH PROJECT

MOHAMMAD BIN RASHID UNIVERSTY OF MEDICINE AND HEALTH SCIENCES

Report On Status of Research Project

Dear Investigator,

This is a tool to report on MBRU-IRB-approved research projects and is to be used for (please choose one):

☐ Annual reporting

☐ End-of-project reporting

☐ Variations to the approved protocol, including extension

This form is to be completed and submitted to the MBRU-IRB on the anniversary of the date of IRB approval, even if the project has not commenced or no work was undertaken. Completion of this report is also required at the conclusion of the project. Failure to submit an annual report may lead to withdrawal of IRB approval of the project.

It is the responsibility of the Principal Investigator to ensure that all information submitted in this report is true and correct.

Additional rows can be added to the tables to accommodate all relevant information. Completed reports should be submitted via e-mail to irb@mbru.ac.ae

1. PROJECT DETAILS:

Project Title	Click or tap here to enter text.		
Application No:		IRB Approval Date:	Click or tap to enter a date.
Reporting From:	Click or tap to enter a date.	To:	Click or tap to enter a date.
Funding:	Is the project funded internally or externally?	☐Yes	☐No
	If yes, please state the amount:	Period of funding:	Click or tap to enter a date.

2. KEY PERSONNEL INVOLVED IN PROJECT:

Name of Personnel	Role in Project	Institution

3. HAS THIS PROJECT BEEN APPROVED BY OTHER RESEARCH ETHICS COMMITTEES OUTSIDE MBRU?

☐ **Yes**	☐ **No**
If **Yes**, please provide the following details:	
Name of approving body	Date of approval
	Click or tap to enter a date.
	Click or tap to enter a date.
	Click or tap to enter a date.
	Click or tap to enter a date.

4. VARIATIONS TO THE APPROVED PROTOCOL

The IRB granted ethics approval for your project on the basis of a submitted protocol. A condition of approval requires that any proposed variations to the protocol may need the approval of the IRB prior to implementation.

Have there been any variations to the protocol in the reporting period which have not been submitted to the IRB? Variations include changes to:	YES	NO	If you answered YES to any of these options, please provide details of the variations and the reasons why approval has not been sought from the IRB, if appropriate.
Investigators	☐	☐	
Study design and research plan	☐	☐	
Participants/records/materials/samples	☐	☐	
Method of recruitment	☐	☐	
Information and consent documents	☐	☐	
Other	☐	☐	

5. PROJECT STATUS (Choose any of the following)

☐ Work in progress. Data collection complete. Analyses is continuing as per IRB approval	Anticipated date of completion: Click or tap to enter a date.
☐ The project is continuing and an extension of IRB approval is required Please explain the reason for extension.	
☐ The project is for student's higher degree and data collection is complete.	
☐ Project not commenced in reporting period.	Anticipated date of commencement: Click or tap to enter a date.
☐ No activity in the reporting period (approval remains current)	Anticipated date of re-commencement: Click or tap to enter a date.
☐ Work never commenced and approval no longer required	
☐ Work commenced and was abandoned and approval no longer required	Date work was abandoned: Click or tap to enter a date.
☐ Work as approved was completed during the reporting period	Date of completion: Click or tap to enter a date.
☐ Were the original, specific aims of the research proposal realized?	

6. PARTICIPANTS

How many participants are/have been involved in the project? If the number of participants differs from the approval protocol, please explain.
How many participants have withdrawn from the project to date?
If known, briefly list the reasons for participants withdrawing.

7. STORAGE OF RECORDS

How are research records and materials being securely stored?
Where are they stored?
Who has access to the records?
If project is completed, how long will they be retained?
If project is abandoned, what has happened to the records and materials that were collected?

8. REPORT OF ACTIVITY

Please provide a concise summary of the current status, progress and outcomes of the research for the reporting period. Include the details of any data collection undertaken, difficulties encountered, and results/interpretations of any analyses conducted during the reporting period.

Provide details of any publication or presentations of outcomes of research undertaken during the reporting period. If no publications were done for the research outcome, please provide (if possible) plans for publication, either in local or international journals, the target journal(s) and possible timeline to publication.

If you agreed to give feedback or findings to participants, provide details what has been provided during the reporting period or when this will occur.

What mechanism have you used to monitor the conduct and progress of the research project?

Report on compliance with conditions of approval prescribed by the IRB.

If project is ongoing, briefly outline the actions planned for the next year.

9. ADVERSE EVENTS AND OTHER INCIDENTS AND COMPLAINTS:

Has there been any adverse events, other foreseen incidents or unexpected outcomes in your project during the reporting period? (eg. side effects of drugs or procedures, participant distress, breaches of participant privacy, failure to obtain other necessary approvals)	☐ **YES**	☐ **NO**

If* YES*, please provide a brief summary of the issues and outcomes.			
Were all events or incidents reported to the IRB?	☐ **YES**	☐ **NO**	☐ **NA**
If the event or incident was not reported to the IRB, attach a report detailing the event.			
Please describe any complaints received in relation to the project.			

What action has been taken in response to the complaint?

10. COMMENTS FOR THE IRB

Is there anything else you want to report to the IRB?

Report completed by:	
Date of report:	Click or tap to enter a date.

Please compile the report along with any supporting documents into a single PDF document.

For official use:

Comments of IRB:
Chairman, MBRU-IRB: **Date:**


MBRU
جامعة محمد بن راشد
للطب و العلوم الصحية
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