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| **Administrative Information** | |
| **Title of Research Proposal:** (Please include version number and any codes if present) | |
| **Study sponsor (if applicable):** | |
| **Principal Investigator (PI):**  **Name:**  **Title/Position:**  **Affiliation & Department:** | |
| **Mobile No:** | **Email:** |

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| **Purpose of the project** | | | | | | | | | |
| Graduate project | | | Post-graduate project | | | * Research project | Other: | | |
| **Type of Project and activities involved** (please check all applicable options) | | | | | | | | | |
| Retrospective chart review  Human participant recruitment  Interviews / Questionnaire  Audio or video recording  Diagnostic tests  Blood sampling  Tissue sampling | | | | | Other samples:  Radiologic investigation  Other diagnostic tests:  Approved therapeutic intervention  Un-approved therapeutic intervention  Animal studies  Basic science in vitro studies | | | | |
| **Is there any possibility that the study may involve any of the following vulnerable groups?** | | | | | | | | No | Yes |
| If yes, please complete the following section. | | | | | | | | | |
| Participants < 18 years  Pregnant ladies  Prisoners  Participants with mental impairment | | | | | Participants with physical impairment  Socio-economically disadvantaged  un-conscious subjects  Others: | | | | |
| **Is the study a single or a multi-center study?** | | | | | | | | | |
| Single center | | Multicenter **If multi-center please list participating centers:** | | | | | | | |
| **Has the study been previously reviewed by another ethics committee or IRB?** | | | | | | | | | |
| No | Yes and approved | | | Yes and disapproved (please state reason): | | | | | |

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| **Name of co- investigators** (no limit to number of co-investigators)   |  |  |  |  |  | | --- | --- | --- | --- | --- | | **Co-Investigators** | **Title/Position** | **Affiliation/**  **Department** | **Study role** | **Signature** | |  |  |  |  |  | |  |  |  |  |  | |  |  |  |  |  | |  |  |  |  |  | |  |  |  |  |  | |  |  |  |  |  | | | | | | |
| **Roles in research:** | | | | | |
| 1. Protocol Development 2. Record Review and Data Collection 3. Data Analysis (one person only) 4. Perform Informed Consent Process 5. Decide on Subject Eligibility | | | 1. CRF Entries / Corrections 2. Lab Report Review 3. Lab Specimen Processing 4. ECG Review 5. Study-Specific Physical Exams and Medical History 6. Other (please specify) | | |
| **Anticipated starting Date:** | **Expected duration:** | | | | **Total Fund Available (SR):** |
| **Principal Investigator’s Assurance:**  All co-investigators to accept responsibility for the scientific and technical conduct of the proposed research and submission of progress reports if this application is approved. My research project cannot begin until I have received the IRB approval letter. No changes in this study will be implemented until an amendment form has been submitted and approved by the IRB. If the IRB approves this study via expedited or full procedure, I will submit for continuing review as stipulated in the approval letter. If the study or data analysis will exceed the approval period, I will submit a Submission Form for Continuing Review of IRB Approved Studies in a timely manner (well in advance of the renewal date). I will provide a copy of the signed consent form to the subject or patient, if applicable understand that study activities may not continue past an approval period. I will retain all signed informed consent documents and study-related records for a minimum of three (3) years (or longer as stipulated by funding agencies) from the date, the study is concluded. I will report in writing any serious adverse events to the IRB within 24 hours and all other adverse events and unanticipated problems within 5 working days. I will provide participants with any significant new information obtained during the course of the study and submit reports of new information to the IRB as a Study Amendment. If my study has been approved at the Expedited or Full Review levels, I will report to the IRB when this study has closed (no further data collection or analysis). This report will be provided no later than 30 days after the end of the study via the IRB Closing Report Form. | | | | | |
| **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Name of Principal Investigator** | | **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Signature** | | **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Date ( DD/MM/YYYY)** | |
| **Approval by HOD/Supervisor** | | | | | |
| **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Name of the HOD/ Supervisor** | | **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Signature** | | **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Date ( DD/MM/YYYY)** | |

**Important submission instructions:**

1. Both hard and electronic copies are required for submission but the review process can start once electronic document submission has been completed.
2. For electronic form submission, please fill forms, sign, scan, and send the scanned copies. Original signed hard copies are also submitted.
3. Please send completed documents to  [irb.uqudent@uqu.edu.sa](mailto:irb.uqudent@uqu.edu.sa) .

Please make sure your protocol has a version number.

1. Please make sure you sign the front page of your research protocol.
2. Please make sure that each investigator has signed and dated every page on his/her CV.
3. Please make sure your data collection forms do not include any identifiable participant information.
4. The covering letter is required for research projects initiated outside UQUDENT and should be directed from the sponsor of the project to the DEAN of UQUDENT briefly explaining the purpose of the proposal and inviting UQUDENT for participation.
5. A covering letter is not needed for proposals initiated by UQUDENT staff, only signature of the department head or student supervisor for( graduate or under graduate) research.
6. Please make sure all documents are complete before submission; an IRB number is given only for complete submissions. In addition, a submission date is counted only after document completion.
7. Any inquiries about the submission process or documents can be sent to [irb.uqudent@uqu.edu.sa](mailto:irb.uqudent@uqu.edu.sa) .