**Research Committee – Panel on Research Ethics**

**Sub-Panel on Biomedical Science & Engineering Research Ethics (Human Participants)**

Research Ethics Application Form

**Instructions to applicants**

1. Please complete the Application Form, and do not modify its format.
2. Please submit the completed Application Form via email to [rskto.ethics@um.edu.mo](mailto:rskto.ethics@um.edu.mo).
3. The Research Protocol Form, Informed Consent document in appropriate language, and any written information to research participants must be uniquely identified, and submitted along with the application form.
4. For information on research ethics and methodology, please refer to <https://www.um.edu.mo/research/ethic.html>.

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| **Application Dossier** | **Requirement** |
| Completed Application Form | Mandatory |
| Research Protocol |
| Signature from Supervisor / Course Director | Mandatory for student projects |
| Participant Informed Consent document | Mandatory |
| Principal Investigator and/or Co-Investigator’s biography | Subject to the need of the research design |
| Written information for participant, such as recruitment advertisement/flyer, information sheet, permission letter from other parties for accessing data/information, etc. |
| Questionnaires | Subject to the need of the research design |

*These documents must be in languages understandable for the target participants.*

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| --- | --- | --- | --- | --- |
| **Basic Information** | | | | |
| Principal Investigator: | |  | | |
| Faculty/Unit/Affiliation: | |  | | |
| Academic Rank/Title: | |  | | |
| Protocol Title: | |  | | |
| Email: | |  | | |
| Telephone No.: | |  | | |
| **For Research Ethics Sub-Panel Use Only** | | | | |
| Application Reference Number: | | |  | |
| Application received: | | | */ / (dd / mm / yyyy)* | |
| Sub-panel decision date: | | | */ / (dd / mm / yyyy)* | |
| Notify applicant of Sub-panel decision: | | | */ / (dd / mm / yyyy)* | |
| If Sub-panel disapproves, reason is: | | |  | |
| **Chair/ delegate:** |  | | **Decision:** |  |
| **Signature:** |  | | **Date:** |  |

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| **PART I: OUTLINE OF APPLICATION** |  |

1. **Co-Investigator (Co-I) and other participants**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Last name | First name | Title | Faculty & Department. | Affiliation | Relevant qualifications |
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1. **Study Site(s)**

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| --- | --- | --- | --- |
|  | Is this a local or international trial? |  |  |
|  | Study sites in Macau |  |
|  | Applying site |  |
|  | Collaborating site(s) |  |

1. **Parallel Ethics Review for Cross-cluster Study**

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|  | Has the protocol been reviewed by another ethics review committee?  *(If yes, please provide the review and/or approval documents)* |  |

1. **Milestones**

|  |  |  |
| --- | --- | --- |
|  | Project/study start date: | /      *(mm / yyyy)* |
|  | Project/study end date: | /       *(mm / yyyy)* |

1. **Brief Summary of Study** *(< 500 words, use language that can be understandable)*

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1. **Major Ethical Issues** *(< 500 words, use language that can be understandable)*

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**PART II: STUDY DETAILS**

1. **Scientific Basis**

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| --- | --- |
|  | Background, current evidence and key references: |
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|  | Aim(s) of study: |
|  |
|  | Hypotheses (*e.g. Compared to x control, y intervention leads to a greater rate of z outcome*) |
|  |

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| --- | --- | --- | --- |
|  | | **Outcome measure(s)** | **Time-point** |
|  | Primary outcome(s) |  |  |
|  |  |
|  | Secondary outcome(s) |  |  |
|  |  |

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| --- | --- |
|  | In what way will the research contribute to knowledge or healthcare development? |
|  |

1. **Study Participants**

|  |  |
| --- | --- |
|  | Inclusionary criteria: |
|  |
|  | Exclusionary criteria: |
|  |
|  | Sample-size and rationale for calculation: |
| Sample size =        Based on the following rationale: |
|  | Number of participants to be recruited locally in relation to this application: |
| N =        in applying site. |
|  | How will participants be identified and recruited? |
|  |

1. **Risk Assessment**

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|  | Will study incur extra clinical intervention(s) to participants? |  |
|  | Will study impose additional risk to participants? |  |
|  | Will study raise sensitive / important privacy concerns? |  |
|  | Will the study involve the following vulnerable participants?   1. *Fetuses in Uteri/non-viable fetuses/abortus* 2. *Infants (age 0 to <1)* 3. *Children (age 1 to <13)* 4. *Adolescents (age 13 to <18)* 5. *Pregnant / lactating women* 6. *Persons related unequally to investigators, e.g. student, employee* 7. *Special population, e.g. prisoners, mentally / cognitively impaired* 8. *Others (please specify)* |  |
|  | Are there any special precautions to protect the interest of vulnerable subjects? |  |

1. **Study Design and Methodology**

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| --- | --- | --- |
|  | Study design (please choose from below)   1. *Prospective* 2. *Retrospective* 3. *Case-control study* 4. *Case report/series* 5. *Cohort study (comparing different cohorts)* 6. *Cross-sectional* 7. *Diagnostic test (correlation) study* 8. *Non-randomized controlled trial* 9. *Randomized controlled trial* 10. *Questionnaire survey* 11. *Others (please specify)* |  |
|  | Methods of assignment: |  |
|  | Control: |  |

|  |  |
| --- | --- |
|  | Disease group *(choose the most appropriate one)* |
|  |
|  | Key conditions under study *(e.g. asthma, etc.)* |
|  |
|  | Study article |

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| --- | --- | --- |
|  | Will an application of clinical trial certificate be made? |  |
|  | Has a *Phase I* study been done? |  |
|  | Number of extra visits / admissions on top of usual care: |  |
|  | Will any of the study interventions / procedures be performed by persons other than the Investigators, and if so by whom and where? |  |
|  | Will biological samples or data be stored for future use? (*If yes, please give details and explain how consent will be obtained)* |  |

1. **Methods of Statistical Analysis**

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1. **Potential Risks Arising from Study**

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|  | Will the study induce discomfort or distress? |  |
|  | Is the study more invasive than usual management? |  |
|  | Will the study increases physical or psychological risk? |  |
|  | Does the study involve a potential toxin, mutagen or teratogen? |  |
|  | Does the study involve radiation or radioactive substance? |  |
|  | Does the study incur other hazards? |  |
|  | If yes to any of the above, please provide details: |  |
|  | Significant difference(s) from usual management: |  |

1. **Anticipated Benefits to Study Subjects**

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1. **Research Participant Protection**

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|  | Will participant be provided with a name card indicating their participation in study and means of urgent contact? |  |
| 1. 1 | Does protocol comply with the Helsinki Declaration? |  |

1. **Information and Consent**

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| --- | --- | --- |
|  | In what form will consent be obtained? *(If no, please state reason to waive consent requirement)* |  |
|  | Will an interpreter be available upon request? |  |
|  | In obtaining informed consent from participants, after explaining protocols, what is the minimal time given to participants to grant consent? |  |
|  | Who will carry out the informed consent process?   1. *PI* 2. *Research assistant* 3. *Co-investigators* 4. *Others (please specify)* |  |
|  | If participants are unable to give consent, to whom will the study be explained? |  |
|  | Minors (<18 years old) who cannot give consent can provide assent. However, both participating minors and their parents/guardians must be informed. Please state how will these requirements be met in case of minors are used in the study. |  |

1. **Data and Sample Monitoring**

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|  | Describe plans for storage and security of identifiable/coded samples. |  |
|  | Describe security measures that are in place for the equipment that houses identifiable data. |  |
|  | Who will have access to samples? How will access be managed? |  |
|  | Describe plans for storage or destruction of identifiable sample after the project is finished. |  |

1. **Confidentiality and Use of Results**

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| --- | --- | --- |
|  | How will data be handled and stored during and after completion of the study, and who will be responsible for its safekeeping? |  |
|  | Who will have access to the data or study record during or after the study? |  |
|  | How long will the data be kept? |  |
|  | What will be done with data after completion of storage period? |  |

**PART III: BUDGET AND USE OF RESOURCES**

1. **Source of Funding**

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| --- | --- | --- | --- |
|  | Internal funding: | Source of funding (1) |  |
| Source of funding (2) |  |
| Source of funding (3) |  |
|  | External funding: | Source of funding (1) |  |
| Source of funding (2) |  |
| Source of funding (3) |  |

1. **Resource Implications and Potential Conflict of Interest**

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| --- | --- | --- |
|  | Will this study use resources from a participating hospital?  *(If yes, please provide details)* |  |
|  | How will this affect the waiting time of other patients with competing needs? |  |
|  | Will study site (hospital) receive reimbursement for the study? |  |
|  | Is there non-monetary (drug, consumable, equipment or research assistant) sponsorship?  *(If yes, please provide details)* |  |

1. **Financial Costs and Payment to Participants**

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| --- | --- | --- |
|  | Will the participants be charged for the study article/service? |  |
|  | Will the study article continue to be available to participants after study *(if participants benefited from it)* until it is commercially available? |  |
|  | If yes to either 20.1/20.2, how will the cost be met and by whom? |  |
|  | Did the informed consent document explain the above arrangement? |  |
|  | Will participants receive compensation?  *(If yes, specify the nature of compensation, the amount and payment schedule)* |  |

**PART IV: DECLARATION by Investigators**

1. I/We declare that the information supplied in this application is to the best of our knowledge and accurate.
2. I/We agree to uphold the protection of research subjects’ rights and safety through adherence to local laws, Helsinki Declaration and institutional policies.
3. I/We understand that approval by the Sub-panel is subject to regular renewal according to policy.
4. I/We agree to report to the Sub-panel for
   1. Any planned change(s) to the study, and further agree not to implement any change(s) without receiving prior approval, except to eliminate immediate hazard to research subjects or when the change(s) involve only logistical or administrative issues.
   2. Any unanticipated problems involving risks to subjects such as severe adverse event within 24 hours of its identification
   3. Any new information on the project that adversely influences the risk/benefit ratio.
   4. Progress report(s) (12 months upon the ethics approval) and a final report (after completion of study).
5. I/We agree to keep all study documents for a period of at least three years after study closure.
6. I/We agree to maintain adequate records and to make them available for audit/inspection.
7. I/We agree to ensure that all associates, colleagues, and employees assisting in the conduct of the study are informed about their obligations in meeting the above commitments.

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| *For academic’s research project:* | **Title and Name** | **Signature** | **Date (dd/mm/yyyy)** |
| **Principal investigator (PI)** |  |  |  |
| *For student’s research project:* | **Title and Name** | **Signature** | **Date (dd/mm/yyyy)** |
| **Academic Supervisor** |  |  |  |
| **Student** |  |  |  |