**Research Ethics Application Form**

\*Note: The MREC only accepts online submission. This template is only for reference and discussion with co-investigators before submission. All applicants must log into the website, complete the online form and submit it online.

**Step 1: General Information**

1. Project Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
2. Is protocol number available?

Yes, please state the protocol number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

No

1. Please select the category/ies relevant to your study: (you can choose more than one)

Clinical trial of an investigational medicinal product

Clinical investigation of a medical device  Clinical trial to compare other interventions in clinical practice  Imaging or other diagnostic tests investigation  Study administering questionnaires/interviews for quantitative or mixed-methods analysis  Study involving qualitative methods only  Study involving taking new tissue/biological samples from human subjects  Study limited to working with archived human tissue/biological samples  Study limited to working with existing data  Others: Please specify \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. Research Type

Clinical  Health Management  Health System  Health Policy  Basic / Biomedical  Public Health / Epidemiology

Health Social Science / Behavioural  Others

1. Clinical Research Sub-Type

Interventional Study: Clinical Trial / Clinical Research

Observational Study: Clinical Economics

Observational Study: Clinical Epidemiology

Observational Study: Patient Registry / Clinical Database

Others

1. General Area

Basic / Biomedical Research

Public Health Research

Clinical Database / Disease

Clinical Research

Epidemiology Research

Health Economics

Health Management Research

Health Social Science / Behavioural Research

Health System Research

Diagnostic

Others

1. Therapeutic Area

Accident & Emergency

Anaesthesiology

Cardiology

Dermatology

Diabetes Mellitus

Endocrine / Metabolic

ENT

Gastroenterology

Haematology

Hypertension

Infectious Disease

Medicine

Neonatology

Nephrology

Neurology

Neurosurgery

Oncology

Ophthalmology

Primary Care

Rheumatology

Surgery

Transplantation

Traumatology

Urology

Others

1. Disease Area

|  |  |  |  |
| --- | --- | --- | --- |
| **Cancer** | **Haematology disorder** | **Cardiovascular disorder** | **Metabolic /  Endocrine disorder** |
| Cancer including Leukaemia | Anaemia | Hypertension  Cerebrovascular disorder / Stroke  Coronary artery disease  Heart Failure | Diabetes Mellitus  Hyperlipidaemias  Obesity  Metabolic Syndrome |
|  | Others: | Others: | Others: |
| **Psychiatry disorder** | **Rhematological disorder** | **Immunology / Inflammatory disorder** | **Kidney disease** |
| Depression  Psychotic disorder/ Schizophrenia | Osteoarthritis  Rheumatoid arthritis | SLE | Kidney / Organ Transplant  ESRD / Dialysis  Chronic kidney disease |
|  | Others: | Others: | Others: |
| **Urological disorder** | **Oral, Gastrointestinal or Liver disorder** | **Respiratory disorder** | **Infectious Disease** |
| Benign Prostatic Hypertrophy  Erectile dysfunction | Acid related / Gastro-esophageal reflux disorder  Diarrhoeal disorder/ Gastroenteritis | Asthma  Chronic Obstructive Airway disorder | Dengue  Malaria  Hepatitis |
|  | Others: | Others: | Others: |
| **Neurological disorder** | **Reproductive disorder** | **Skin Disorder** |  |
| Epilepsy | Infertility  Contraception  Childbirth & Complication of newborns  Congenital Disorder | Dermatitis/ Eczema  Psoariasis |  |
|  | Others: | Others: | Others: |

1. Is this application linked to a previous study approved by the UMMC MREC or another current application to the UMMC MREC?

Yes, please state the MREC ID Number of the previous study: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

No

1. Has this or a similar application been previously approved by a research ethics committee in Malaysia or another country?

Yes, please state the name of the research ethics committee: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

No

1. Has this or a similar application been previously rejected by a research ethics committee in Malaysia or another country?

Yes, please state the name of the research ethics committee: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

No

**Step 2: Investigator’s Details**

1. Applicant Name (Principal Investigator): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*\* For studies originating from outside FOM/UMMC, an investigator from FOM/UMMC has to be named as the ‘Principal Investigator’ for the purpose of this MREC application.*

*\* Please search and select for your name in the database.*

Please attach your latest Curriculum Vitae: [UPLOAD]

Is Good Clinical Practice (GCP) certificate available?

Yes, please attach [UPLOAD]

No

1. Applicant’s status:

FOM/UMMC Staff  UM Staff  FOM Student, please state your student matric number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  None of the above

1. Which department are you from? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
2. Please list ALL investigators including staff and students.

No other investigator

Add investigator/s

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Applicant category** (FOM/UMMC staff OR  Non FOM/UMMC staff) | **Name** | **Department** | **Phone No.** | **Email** | **CV** | **GCP Cert** |
|  |  |  |  |  | [Upload] | [Upload] |
|  |  |  |  |  | [Upload] | [Upload] |
|  |  |  |  |  | [Upload] | [Upload] |
|  |  |  |  |  | [Upload] | [Upload] |
|  |  |  |  |  | [Upload] | [Upload] |
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|  |  |  |  |  | [Upload] | [Upload] |
|  |  |  |  |  | [Upload] | [Upload] |
|  |  |  |  |  | [Upload] | [Upload] |

1. Please state whether this project is a partial fulfilment of postgraduate / basic degree

Yes, Qualification:

Diploma

Bachelor

Master

Clinical Master

PhD

Others

No

**Step 3: Project Information**

1. Project Summary

*(Max 1000 characters)*

Please provide a brief summary of the research using language easily understood by lay reviewers and members of the public. Below are questions you may wish to address when writing the summary:

|  |  |
| --- | --- |
| Why? | Why is it important to conduct this study? |
| What? | What is the research question? What area (disease, therapy or service) is being studied? For therapeutic studies, what is the drug, device or procedure being tested? |
| Who? | Who is eligible as a participant? |
| Where? | Where will this study be conducted? |
| How? | How do you plan to conduct this study? |

1. Have similar studies been done before?

*(Max 3000 characters)*

Please provide a summary of the evidence and references. Justify the need to conduct this study if similar studies have been conducted before

Summary:

References (5 to 10):

*(Max 2000 characters)*

1. Why is it important to conduct this study?

*(Max 3000 characters)*

1. Objectives and outcomes of the study

|  |  |  |
| --- | --- | --- |
| No | Objective | Expected Outcome (if any) |
|  |  |  |
|  |  |  |
|  |  |  |

1. Time Frame

Expected Start Date : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (Day/Month/Year)

Expected End Date : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (Day/Month/Year)

1. Research Funding

No Funding

Industrial sponsor

Name of funder: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Amount of funding: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Research Grant

Name of funder: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Amount of funding: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. Does this study involve collection of data (e.g. patient information) or collaboration with a department/unit/laboratory OUTSIDE YOUR DEPARTMENT?

No

Yes, please list the related department/s:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Step 4: Methodology**

1. Research Protocol

Please upload your research protocol here and state the version and date of the protocol

Version No : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Version Date : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (Day/Month/Year)

[UPLOAD YOUR RESEARCH PROTOCOL]

1. This research protocol has been approved by: (You can choose more than one)

A funding agency

An external scientific review committee outside the university

The faculty or departmental research committee within the university

The supervisor (for student)

Not reviewed

1. Please choose the appropriate methodology description for your study: (You can choose more than one)

Randomised controlled trial

Controlled trial without randomisation

Case series/case note review

Case control

Cohort observation

Cross-sectional study

Database analysis

Epidemiological Study

Feasibility/pilot study

Laboratory study

Questionaire-based

Qualitative research

Retrospective study

Others

1. Are patient folders needed?

No

Yes, Number of folders:

Year: From \_\_\_\_\_\_\_\_\_\_ until \_\_\_\_\_\_\_\_\_

*Note: You must seek approval from the Medical Record Unit after receiving the MREC approval. For industry sponsored research, the Medical Record Unit imposes a charge for every folder requested.*

1. Are human subjects involved?

No

Yes, please tick the relevant box below and **state the sample size**

Patients in UMMC: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Healthy Individual (conducted in UMMC): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Members of the public: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Healthcare professionals: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(eg. doctors, nurses, pharmacists, medical students, nursing students etc.)

1. How was the sample size decided upon?

*(Max 500 characters)*

If a formal sample size calculation was used, indicate how this was done, giving sufficient information to justify and reproduce the calculation.

1. Does the study involve individuals from a vulnerable group?

Individuals whose willingness to volunteer in a clinical trial may be unduly influenced by the expectation, whether justified or not, of benefits associated with participation, or of a retaliatory response from senior members of a hierarchy in case of refusal to participate. Examples:

• medical, pharmacy, dental and nursing students

• subordinate hospital and laboratory personnel

• employees of the pharmaceutical industry

• members of the armed forces

• persons kept in detention

• children

• pregnant women

• patients with incurable diseases

• persons in nursing homes

• unemployed persons

• impoverished persons

• patients in emergency situations

• ethnic minority groups

• homeless persons

• nomads

• refugees

• minors

• those incapable of giving consent.

No

Yes, please indicate the group and describe what steps you would take to ensure that they are not being disadvantaged.

1. Who will be included in the study?

*(Max 2000 characters)*

Please describe the inclusion and exclusion criteria of selecting the participants.

1. Who will be recruiting the participants?

*(Max 1000 characters)*

Please describe the recruitment process.

1. Who will perform the data collection?

*(Max 1000 characters)*

Please describe the data collection process.

1. How long do you expect each participant to be in the study?

*(Max 500 characters)*

1. Are new procedures/drugs being tested?

No

Yes, please the procedures/drugs to be used *(max 1000 characters)*

1. Have the new procedures/drugs been granted licence by the government?

Yes

No

Not applicable

1. Are the procedures invasive?

Not applicable

No

Yes, please state the procedures *(Max 1000 characters)*

1. Does the study involve the use of any ionising radiation?

No

Yes, please describe the steps that will be taken to reduce the radiation harm to the participant and researcher. *(Max 1000 characters)*

1. Will you be taking tissue/biological samples from human subjects?

No

Yes, are these samples taken in addition to routine practice?

No

Yes, if the samples are additional to routine practice, please describe the samples you will be taking and what steps will be taken to reduce harm to the participant. *(Max 1000 characters)*

1. Will you be using archived human tissue/biological samples?

No

Yes, please describe the samples you will be taking and from which tissue bank/custodian? *(Max 1000 characters)*

**Step 5: Ethical Issues**

1. What are the benefits of the study to the research subjects?

*(Max 1000 characters)*

1. a) What are the potential risks and burdens to the research subject and how will you minimise them?

*(Max 2000 characters)*

For all studies, describe any potential adverse effects, pain, discomfort, distress, intrusion, inconvenience or changes to lifestyle. Only describe risks or burdens that could occur as a result of participation in the research. State what steps would be taken to minimise risks and burdens as far as possible.

b) What are the potential risks and burdens to the researchers and public. How will you minimise them?

(Max 1000 *characters*)

c) Does the study involve stem cell or genomic testing / treatment?

No

Yes, please complete and upload form **(APPENDIX 1)** with other relevant documents at item 57. Upload Other Documents.

1. Will the interview/ questionnaire include topics that might be sensitive, embarrassing or upsetting? Is it possible that criminal or other disclosures requiring action could occur during the study?

Not applicable

No

Yes, please explain what you will do to minimise the issue. *(Max 1000 characters )*

Please upload your questionnaire/interview topic guide here.

[UPLOAD]

1. Will participants’ details be anonymized?

Yes

No, please explain what you will do to ensure participants’ confidentiality is protected.

*(Max 500 characters)*

1. Where will the data be kept?

*(Max 500 characters)*

1. Who will have access to the research data?

*(Max 500 characters)*

1. How long will the data be kept?

*(Max 500 characters)*

1. How do you intend to report and disseminate the results of the study?

*(Max 500 characters)*

1. To ensure participants’ confidentiality, I agree to comply to the Caldicott Principles as follows:

I will not use patient identifiable information unless it is necessary

I will only use the minimum necessary patient-identifiable information

I will ensure that access to patient identifiable information will be on a strictly need-to-know basis

I will ensure that everyone with access to patient identifiable information is aware of their responsibilities

I understand and will comply with the law

I understand that the duty to share information can be as important as the duty to protect patient confidentiality

1. Is there any continuity of treatment provided to patients after the study is completed?

Yes

Not applicable

No, please explain why. *(Max 500 characters)*

1. Will you provide information and obtain informed consent from the participant?

Not applicable

Yes, you may use the template provided **(APPENDIX 2, APPENDIX 3)** or design your own form but it should contain all the components in the template provided.

[UPLOAD PATIENT INFORMATION SHEET]

[UPLOAD INFORMED CONSENT FORM]

1. Are expenses of research test, procedure or treatment charged to the research subjects?

Yes, state the expenses charged. *(Max 500 characters)*

No, state how the expenses are provided for *(Max 1000 characters)*

1. a) Does any of the investigators in this study have conflict of interest to declare?

No

Yes, please state the conflict of interest. *(Max 1000 characters)*

b) Is personal payment given to the principal investigator for conducting this study?

No

Yes, please state the amount.

c) Is payment given to persons for recruiting research subjects?

No

Yes, please state the amount.

1. Will compensation for inconvenience be offered to research subjects?

No

Yes, please state the amount.

1. Is there any insurance coverage for this study?

No

Yes, please state the insurance coverage details *(Max 500 characters)*

[UPLOAD INSURANCE CERTIFICATE]

1. Other information?

*(Max 1000 characters)*

1. Upload other documents.

*Please do not upload the study questionnaire, interview topic guide, participant information sheet and consent forms here but at the relevant sections. Please make sure there are no special symbols such as +,'' when labelling the document.*

[ ADD DOCUMENT/S]

1. Does this study comply with the Malaysian Good Clinical Practice (GCP) guidelines?

Yes

Not applicable

**APPENDIX 1**

**42c. Checklist for research on stem cell and cell-based therapies**

Please check the boxes and submit the related documents to the MREC.

|  |  |  |  |
| --- | --- | --- | --- |
| **Phase/Process** | **Key requirements**  **42c.** | **Researcher**  **(Please check the box)** | **MREC Secretariat**  **(Please check the box)** |
| 1. Pre-clinical studies (investigators must show their own data and not from other laboratories) | * Approval letter from animal ethics committee is recommended |  |  |
| * Accreditation of animal research facility in institution requiring GLP compliance |  |  |
| * Evidence that the pre-clinical studies was subjected to rigorous and independent peer review and regulatory oversight |  |  |
| * Safety data in small animals |  |  |
| * Safety data in large animals |  |  |
| * Comprehensive toxicology data in small animals (including contamination, acute infusional toxicity, deleterious immune responses, unexpected behavior of the cellular product, and tumorigenesis) |  |  |
| * Comprehensive toxicology data in large animals (including risks of contamination, acute infusional toxicity, deleterious immune responses, unexpected behavior of the cellular product, and tumorigenesis) |  |  |
| * Proof of principle of the desired effect (that the cells have repaired the damage/disease) – unequivocal efficacy data |  |  |
| * Show biological distribution data |  |  |
| * Show evidence of physiologic integration and long-lived tissue reconstitution |  |  |
| * Show that differentiation (either *in vitro* before transplantation or *in vivo* after transplantation) occur only along the desired lineages |  |  |
| * Design based on clinical expectations |  |  |
| * Mechanistic studies to show biology (done by the group) |  |  |
| * GLP compliant |  |  |
| * Evidence that the pre-clinical data has been submitted to the NPCB |  |  |
| 2. Phase I trials | * Comprehensive pre-clinical studies have been done and data showed safety and efficacy in animals (performed by the group) is recommended |  |  |
| * Procedures on how the cells be tracked in terms of homing to the target area, viability and longevity of the cells |  |  |
| * Procedures on how the safety be monitored |  |  |
| * Procedures to assess risks of tumorigenicity by an independent body must be implemented |  |  |
| * Procedures to assess short, medium and long term side effects |  |  |
| * GCP compliance |  |  |
| 3. Phase II trials | * Data from Phase I trials (performed by the group themselves and if the trial is not performed by the group, explain why the data should be used for this trial) |  |  |
| * Procedures on how the cells be tracked in terms of homing to the target area and viability of the cells |  |  |
| * Optimisation of dose, route, regimen, patient population, endpoints, and controlled |  |  |
| * Procedures on how the safety be monitored |  |  |
| * Independent data safety monitoring board |  |  |
| * Plan to assess short, medium and long term side effects |  |  |
| * GCP compliance |  |  |
| 4. Phase III trials | * Data from Phase II trials (performed by the group themselves) |  |  |
| * Design to show safety and efficacy |  |  |
| * Independent data safety monitoring board |  |  |
| * GCP compliance |  |  |
| * Conduct ‘randomised’ control |  |  |
| 5. Cell processing and manufacturing | * Evidence by a letter of conformance for GMP compliance and issued by relevant authority |  |  |
| * Show evidence of relevant processes: Standard operating procedures, quality standards, environmental control, equipment qualification, analytical methods, audits, staff training, etc. |  |  |
| * Cell processing and manufacture of any product must be conducted under scrupulous, expert, and independent review |  |  |
| * Demonstrate that the product is safe, pure and potent |  |  |
| 6. Product registration | * Show that the product has been registered with the National Pharmaceutical Control Bureau before use in human trials |  |  |
| * License for clinical trial has been obtained |  |  |
| 7. Cell characterization ( pre-requisite to clinical trials) | * History of the cells in the stem cell or cell- based product |  |  |
| * Biological characterisation of cell type |  |  |
| * Demonstration of purity |  |  |
| * Demonstration of potency (e.g. cells produce insulin in a physiological manner) |  |  |
| * Manufacturing standards and independent certification, where relevant |  |  |
| * Evidence that cells are free from contamination |  |  |
| * Evidence of viability and longevity of cells after transplantation (to determine the likely duration of the therapeutic effect) |  |  |
| * Evidence that cells will home into the area of damage or repair |  |  |
| * Evidence of genomic stability during culture |  |  |
| 8. Investigators and researchers | * Is the Principal Investigator trained in cell transplantation? (Show evidence of credentialing) |  |  |
| * Are other investigators trained in cell transplantation? (Show evidence of credentialing) |  |  |
| * Qualifications of scientists and researchers |  |  |
| * Registration with National Medical Research Register, Ministry of Health (MOH) |  |  |
| 9. Centres performing therapy (Information for patients) | * Registration with PHCFS Act, Ministry of Health |  |  |
| * Informing subjects about the human embryonic cell source, if applicable |  |  |
| * The unique risks; and disclose honestly that the treatment have not been tried before |  |  |
| * Utmost clarity on the potential benefit |  |  |
| * Disclosing financial and non-financial conflicts of interest |  |  |
| * Provide monitoring patients long term |  |  |
| * Providing a clear, timely, and effective plan for adverse event reporting |  |  |

**APPENDIX 2**



PARTICIPANT INFORMATION SHEET

**Study Title:**

**Version No:**

**Version Date:**

We would like to invite you to take part in a research study. Before you decide whether to participate, you need to understand why the research is being done and what it would involve. Please take time to read the following information carefully; talk to others about the study if you wish.

Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

***Attention to the investigator: Please fill in simple layman language as you would speak to research subjects.***

1. **What is the purpose of this study?**
2. **Why is this study important?**
3. **What type of study is this?**
4. **What is the procedure that is being tested? (If applicable)**
5. **Does the investigatory product contain cultural sensitive ingredients eg: bovine or porcine? (if applicable)**
6. **Why have I been invited to participate in this study?**
7. **Who should not participate in the study?**
8. **Can I refuse to take part in the study?**
9. **What will happen to me if I take part?**
10. **How long will I be involved in this study?**
11. **What are the possible disadvantages and risks?**
12. **What are the possible benefits to me?**
13. **Who will have access to my medical records and research data?**
14. **Will my records/data be kept confidential?**
15. **What will happen to any samples I give? (If applicable)**
16. **What will happen if I don’t want to carry on with the study?**
17. **What if relevant new information about the procedure/ drug/ intervention becomes available? (If applicable)**
18. **What happens when the research study stops? (If applicable)**
19. **What will happen to the results of the research study?**
20. **Will I receive compensation for participating in this study?**
21. **Who funds this study?**
22. **Who should I contact if I have additional questions/problems during the course of the study?**

Name of investigator 1

Affiliation

Telephone number (Mobile number)

Name of investigator 2

Affiliation

Telephone number (Mobile number)

1. **Who should I contact if I am unhappy with how the study is being conducted?**

Medical Research Ethics Committee

University of Malaya Medical Centre

Telephone number: 03-7949 3209/2251

**BK-MIS-1116-E03**