1.0 INTRODUCTION

1.1 Authority of the IMU Joint Committee of Research and Ethics Committee (IMU-JC)

(a) To evaluate proposals on all types of research, including biomedical and clinical research.
(b) To approve, disapprove or modify the proposed studies.
(c) To require progress reports from the investigators.
(d) To suspend or terminate the approval of a study
(e) To place restrictions on a study.

1.2 Membership of the IMU-JC

(a) The composition of IMU-JC membership is in compliance with the Malaysian GCP Guidelines, which consists of:
   i) At least five members.
   ii) At least one member whose primary area of interest is in a non-scientific area.
   iii) At least one member who is independent of the institutional/trial site.
(b) Selection of IMU-JC members is based on nomination and endorsement by the committee.
(c) The duration of IMU-JC membership is for two years.
(d) For renewal of membership, a letter will be sent to the particular member after endorsement by the IMU-JC.
(e) For resignation, the member should submit a resignation letter to be endorsed by the IMU-JC.
(f) Replacement of any members should be proposed and endorsed by IMU-JC.
(g) Membership can be terminated if the member does not attend three meetings in a year without valid reasons.

1.2.1 All IMU-JC members, secretariat and observers are required to sign a confidentiality agreement.

1.2.2 All IMU-JC members should voluntarily declare their conflict of interest (COI) and shall not participate in deliberations and voting in the event that a COI exists.

1.2.3 The Chairperson/President will abstain from making any decision on issues or matters that will create any conflict of interests with other members or the researcher(s).

1.2.4 IHH Healthcare Berhad is the ultimate shareholder of IMU Education Bhd. IMU-JC is the Research and Ethical Committee of IMU Education Bhd. Chartis Malaysia Insurance Bhd is the official insurance company that provides liability coverage to members affiliated to IMU including IMU-JC members.

1.2.5 The establishment of the IMU-JC is approved and endorsed by Senate Members of the International Medical University.
1.2.6 The remit of IMU-JC members is stipulated in the appointment letter.

1.2.7 The quorum for IMU-JC meeting shall be at least **eight members**, and the composition should comply with the Malaysia GCP Guidelines, which consists of:

   ii) At least one member whose primary area of interest is in a non-scientific area.
   iii) At least one member who is independent of the institutional/trial site.

1.2.8 The IMU-JC Office consists of the following:

   i) Vice President, Research
   ii) Associate Dean, Research
   iii) Associate Dean, Postgraduate
   iv) Asst Manager, Postgraduate Studies Unit
   v) Executive, Research Unit
   vi) Manager, IMU Research Lab
   vii) Part-time Officer(s)

1.2.9 The internal procedures will follow closely with the remit of the IMU-JC following the governance structure of the IMU.

1.3 Review Procedures of the IEC/IRB

1.3 (i) Conduct/Frequency of Meeting

The IMU-JC shall meet once every month. At the discretion of the Chairman, additional meetings may be convened or a scheduled meeting postponed (if there is no issue to be discussed).

IMU-JC meetings shall be conducted in accordance with the “Good Clinical Practice” (GCP), “Good Laboratory Practice” (GLP) and “International Guiding Principles for Animal Research”.

Calling notice will be sent to all members three (3) weeks before the date of meeting.

**Meeting package/documents will be sent out / emailed to the IMU-JC members within Five (5) working days prior to the meeting date.**

1.3 (ii) Review of Protocols / Procedure

The IMU-JC will evaluate and make appropriate recommendations on all research proposals including all ethical issues guided by the codes of good practice as set in the guidelines for “Good Clinical Practice” (GCP), “Good Laboratory Practice” (GLP) and “International Guiding Principles for Animal Research”.

Decision making process will be by consensus of all the IMU-JC members.

To review an application on elements such as scientific design and conduct of the study, recruitment of research participants, care and protection of research participants, protection of research participant's confidentiality, informed consent process and community considerations. The Informed Consent will be reviewed according to the requirement set in the Malaysian Guidelines for GCP. All amendments to the protocol, Informed Consent and other documents related to the research process received should be submitted to the IMU-JC for review and comments. In addition the insurance coverage for all subjects participated in the study will be reviewed by the IMU-JC members.

IMU-JC members with conflict of interest will not participate in the discussion, review and approval process of any project proposals submitted by the person.

The decision on the proposal could be 'highly recommended', 'recommended' or 'rejected'. The researcher may be requested to amend and resubmit the proposal, taking into the consideration of the comments of IMU-JC. The decision of the IMU-JC on the proposal will be communicated to the researcher within 14 days
from the date of the proposal evaluation. The decision of the IMU-JC is final. No appeal will be allowed for any rejected protocols or proposals.

In the event a follow-up is required on protocol amendments that are likely to affect the rights, safety and wellbeing of subjects; all serious and unexpected adverse events and any event or new information that may affect the benefit-risk ratio of the study, the investigator/sponsor is required to submit all the documents to be reviewed by the IMU-JC. A decision will be made at the IMU-JC meeting and a letter will be issued within fourteen (14) working days.

1.3(iii) Responsibilities of Applicants on any clinical trials or stem cells research are as follows:

a. To notify to the IMU-JC on all protocols, recruitment material, Patients/Study Information Sheet, Informed Consent form and participants’ information amendments.
b. To inform of any serious and unexpected adverse event reports be it serious or not.
c. To inform the IMU-JC of any termination of study or study is put on hold.

2 OBJECTIVE

To ensure that all research projects are managed efficiently so as to ensure the smooth running of the School of Postgraduate Studies and Research Office.

3 SCOPE

This SOP covers the procedures involved from application to the completion of the research project.

4.0 DEFINITION

3.1 PGSR School of Postgraduate Studies and Research
3.2 IMU-JC IMU Joint Committee of the Research and Ethics Committee

5.0 RESPONSIBILITY

The Dean and Executive of the School of Postgraduate Studies and Research Office are responsible for this SOP.

6.0 PROCEDURE DETAILS – Refer Chart attached.

7.0 NOTES

Note (a) There are two types of research projects; therefore, a research proposal must be submitted in the designated proposal form. For an IMU funded project, the Application Form as shown in Appendix 1 should be used. Where the research proposal is to be submitted to an external funding agency (e.g. MOSTI,
Foundations and Private Companies) the appropriate form of the agency should be used. Besides filling up the forms from the designated agency, a copy of the IMU Research Application Form has to be filled-up too, submitted and presented at the IMU Joint-Committee of the Research and Ethics Committee (IMU-JC) for approval.

However, as and when required, the Principal Investigator have to fill in additional forms shown in Appendix 1a, 1b, 1c, 1d or 1e for their research project.

If the investigator needs to submit the research proposal to an external agency for funding consideration urgently before the IMU-JC can meet to consider it, the proposal can be submitted first after discussion with and a provisional approval by the Chairman of IMU-JC or his representative. The proposal will need to be submitted for consideration and approval by the IMU Joint-Committee of the Research and Ethics Committee at the next scheduled meeting.

Research on stem cells /clinical trials should comply with the Ministry of Health (MOH) requirements and guidelines as specified in Malaysian GCP.

The following documents are required to be submitted for any new submission of research on stem cells/clinical trials:

a. Study Protocol / Amendments
b. Updates of Consent form
c. Recent Investigator’s Brochure
d. Advertisement (if necessary)
e. Insurance Coverage
f. Indemnity Agreement
g. Investigator’s curriculum vitae, qualification (GCP certificate accredited by NCCR)
h. Payment and Compensation
i. Recruitment procedure

All amendments to the protocol, informed consent form and trial related documents need to be submitted to the IMU-JC for review and approval. Any supplementary information should be submitted to the Secretariat two (2) weeks after the meeting/before the commencement of the project.

Institutional Biosafety Committee (IMU-IBC)
With the recent formation of the IMU Institutional Biosafety Committee (IMU-IBC), it was decided that all researchers need to comply to the new regulations stipulated in the Biosafety Act 2007 and Biosafety Regulations 2010. (Please refer to L-Drive under Biosafety). They are required to fill up additional forms such as Approval Forms A/B/C/D and Notification Forms E and F (where necessary/applicable) and submit together with the proposal forms (Appendix 1).
“Section 3 of the IBC report requires principle investigators within an institution to declare contained use of **ANY** living modified organism (LMO) for their research, even if these LMOs fall within the exemption list in the Biosafety Regulations 2010, First Schedule”

All requirements are stated in the new Project Proposal Forms.

The IMU-JC will ensure that adequate funds are available for the IMU funded research if it is approved, before the proposal is accepted for consideration.

The date of receipt of a proposal must be stamped on the first page of the proposal itself when it is accepted for consideration.

The Secretary of IMU-JC will inform the Principal Investigator of the date when the IMU-JC will meet. The Principal Investigator or his/ her designated representative is required to present the research proposal to the IMU-JC.

**In submitting the new research project proposals to be considered and approved by the IMU-JC, principal investigators/staff who has completed their previous research project(s) (if any) are required to submit the End-of-Project Report once the project has completed. If this is not complied by the Principal Investigator, the Secretariat of the IMU-JC will not table any new research project submission from the Principal Investigator/staff concerned. This is to avoid any incompliance of the SOP. Principal Investigator/staff is required to refer to the schedule (sent to all academic staff) for the deadlines/dates of IMU-JC meeting for submission of new research proposal and reports.**

**Note (b)**  The IMU-JC will consider the research proposal as according to its remit (Appendix 3).

**Note (c)** Some approved research proposals may require minor revisions or amendments; If the IMU-JC recommends that the research proposal be revised it is the responsibility of the Principal Investigator and the Secretary of IMU-JC to ensure that the revisions are made according to the IMU-JC's recommendations. – (Appendix 4) where necessary/where applicable.

The date of receipt of a revised/amended proposal must be stamped on the first page of the revised/amended proposal itself.

**All Principal Investigators are required to submit a final copy of the approved project proposals in soft copy to the Secretariat after all modification and amendments have been made/done by the respective researcher after the IMU-JC Meeting is conducted once a month. (This project proposal will be kept/filed/archived for use by the IMU-JC)**

**Note (d)** If the consideration is a “no”, the Principal Investigator will be informed officially after the meeting with a Letter of Rejection to be followed. (Appendix 5).
Note (e) Once a research proposal has been approved by the IMU Joint-Committee of the Research and Ethics Committee, the decision of the IMU-JC shall be conveyed to the Principal Investigator(s) by the Secretary in the prescribed IMU-JC Approval Form (Appendix 6) within fourteen (14) working days after the IMU-JC Meeting each month.

Note (f) The Secretary of the IMU-JC will communicate this in writing to the Chief Financial Officer. A copy of the approved proposal, the signed IMU-JC Approval Form together with a Letter of Notification for Approval and Issuance of Research Project ID Number (Appendix 7) will be sent to the Chief Financial Officer. The Chief Financial Officer will then reply to the IMU-JC Secretary to inform on the budget approved and the assigned Research Project ID Number to be used by the Principal Investigator. This should be done within fourteen (14) working days after receiving all the required documents from the Secretary/Secretariat of IMU-JC.

The IMU-JC Secretary will write an official letter to the Principal Investigator informing him/her of the Research Project ID Number and to use it for all future correspondence related to the Project (Appendix 8) once the approval for research grant and the ID No. is received from the Chief Financial Officer.

The Principal Investigator will start the research once a Research Project ID Number has been assigned to him/her.

A letter will also be sent to the Vice President, Research / Dean, School of Postgraduate Studies and Research who is in charge of the Research Laboratory (IMU-RL) if bench space is required by the researcher and his/her research team members (Appendix 9) within fourteen (14) working days upon receipt of approval from Secretary of IMU-JC and ID No. is received from the Chief Financial Officer.

Once the Research Project ID Number is assigned to the Principal Investigator a form is created and it is called a “Tracking Form” (Appendix 10) for each of the project approved. It contains all the information related to the research project such as:

1. Reference ID Number
2. Date Received
3. Title and Name of Principal Investigators and Co-Investigators involved
4. Approval date of Joint-Committee of the IMU-RC and IMU-EC
5. Duration of Project
6. Amount
7. Date of Commencement
8. Submission of Progress Report
9. Completion Date
10. Other Information relevant

The Executive is in charge of filling up the form and attached it together with the other forms and documents (kept in a file) related to the project and keep track of
the ongoing project until the completion date.

Note (g) A Principal Investigator who wishes to employ temporary research assistant may submit his/her request (Appendix 11) to the Co-Chairman of IMU-JC together with a copy of the approved research proposal and Confirmation of Approval letter from the IMU-JC. His/her request will be decided upon by the Co-Chairman of IMU-JC within fourteen (14) working days after receiving the application from the Principal Investigator.

Upon approval by the Co-Chairman of IMU-JC, the Principal Investigator will forward the approval form to the Human Resource Manager and a copy to the Chief Financial Officer for recruitment purposes. A copy of the Appointment Letter received from Human Resource Dept will also be kept in the Research File of the Principal Investigator by the Secretariat of IMU-JC.

Note (h) The Principal Investigator is required to submit a Six (6) Monthly Progress Report (Appendix 12) to the IMU-JC and at the required intervals to its funding agency if the research is funded externally as stated in the Letter of Confirmation of Approval of Research Project Proposal (Appendix 8) whereby it is stated that “Note: Please be informed that with the issuance of this approval letter you are also required by the IMU-JC to be responsible in submitting the Six-Monthly Progress and Financial Report and the End-of-Project Report on time when it is due for submission”.

Should the Principal Investigator fail to submit their report(s) on time, an email will be sent to the respective Principal Investigator reminding them to submit the reports. A valid reason must be given by the Principal Investigator and approved by the Chairman/Co-Chairman of the IMU-JC for any late submission or any other reasons deem fit. If this is still not complied with, the Principal Investigator will be asked to appear before the IMU-JC; the research will be put on hold/terminated if the IMU-JC finds his/her explanation unsatisfactory. They are also required to submit their reports in soft copy to the Secretariat. These documents will be kept/filed/archived for use by the IMU-JC.

If the IMU-JC finds the submitted progress report unsatisfactory, the principal investigator will be asked to rewrite the report or appear before the IMU-JC for explanation.

A research project with a satisfactory research progress report will be allowed to proceed.

If a Principal Investigator wishes to make an extension period to his/her research project, a formal letter must be written to the Chairman/Secretary of the IMU-JC with a valid reasons and the duration period of extension and it will be tabled at the IMU-JC Meeting. If the reasons given are satisfactory and approved by the IMU-JC a letter will be sent by the IMU-JC Secretary to the Principal Investigator and the new completion date will be recorded in the Tracking Form (Appendix 10).

Besides the above notification, a monthly email is also sent out to all the academic
staff to remind them of the deadline to submit new research proposals and also the submission of the Six Monthly Progress Report and End-of-Project Report (for all reports which are due for submission - for existing researchers) for consideration by the IMU-JC.

**Note (i)**  
If Project is terminated (due to an unforeseen circumstances).  
Principal Investigator is required to write a letter to explain the situation to the Co-Chairman of the IMU-JC/Dean of Postgraduate Studies and Research. The case will then be tabled at the IMU-JC Meeting. If the reasons are valid and approved by the IMU-JC, the Secretary will reply to the Principal Investigator via letter. The file will be closed and all balance of the research grant will be put back to the IMU Research Grant. A copy of letter will also be forwarded to Finance Dept to notify them of the closure of the file.

**Note (j)**  
Withdrawal of Project – (resignation/not enough fund/other unforeseen circumstances)  
Principal Investigator is required to write a letter to explain the situation to the Co-Chairman of the IMU-JC/Dean of Postgraduate Studies and Research. The case will then be tabled at the IMU-JC Meeting. If the reasons are valid and approved by the IMU-JC, the Secretary will reply to the Principal Investigator via letter. The file will be closed and all balance of the research grant will be put back to the IMU Research Grant. A copy of letter will also be forwarded to Finance Dept to notify them of the closure of the file. In other circumstances, if there are co-investigators involved in the same project, they are advised to take over the project until completion.

**If it involves external funding for both the above cases, The Principal Investigator holding the grant is responsible to inform the Dean of Postgraduate Studies and Research and the funding agency. The matter will also be tabled at the IMU-JC.**

**Note (k)**  
As required by most funding agencies, the Principal Investigator is required to submit an End of Project Report (Appendix 14) no later than three (3) months from the date of completion to the IMU-JC and its funding agency if the research is funded externally.

Please take note of the following clause:

i. All projects will be automatically closed after two months from the approved completion date unless extension of date of completion is applied and approved by IMU-JC.

ii. Principal Investigators/Supervisors (for student(s) projects) will be informed/reminded at least two months before the approved completion date of the automated closure of account and application of extension period, if required/applicable.

iii. The recommendation letter from PGSR Department on end-of-project report / approval letter on extension of project must be prepared and
sent/emailed to Finance Department (Ms. Christy Chiu/Ms. Gan Hua Li) within four weeks after the End-of-Project Report /Letter of Extension of Project is tabled at the IMU-JC Meeting in order for Finance Department to officially close the account in another one month's time.

iv. It was agreed that any balance of grant money left from the completed projects will be parked in a common account for publication expenses of all researchers.

v. Any other matters pertaining to the above, to be discussed during the IMU-JC meeting which is held monthly. (if any)

Note (I) The IMU-JC will inform the Principal Investigator, Chief Financial Officer and Staff in charge of IMU-RL of the decision and recommendations made on the End-of-Project report (Appendix 15), if any.

They are also required to submit their reports in soft copy to the Secretariat. These documents will be kept/filed/archived for use by the IMU-JC.

IMU and where specified by the funding agency, expects researchers to publish and present their research findings after submitting the End-of-Project report and completing their project. The Principal Investigator is advised to adhere to the guidelines stipulated by the IMU and funding agency at all times.

A soft copy of each published paper arising from the project must be submitted to the Secretariat as soon as it is available.

The IMU-JC should retain all relevant records (e.g. written procedures, membership list, list of occupation / affiliations of members, submitted documents, minutes of meetings, and correspondence) for a period of at least 10 years after completion of the trial and make them available upon request from the regulatory authority(ies).
### 8.0 RECORD

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<tr>
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<th>Type of Record</th>
<th>Retention Period</th>
<th>Responsibility</th>
<th>Location</th>
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<td>b.</td>
<td>Minutes of IMU-EC Meetings</td>
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<td>c.</td>
<td>Minutes of the IMU Joint-Committee of the Research and Ethics Committee Meetings</td>
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<td>d.</td>
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<td>e.</td>
<td>Withdrawn, Terminated &amp; Rejected etc...Project File</td>
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### 9.0 APPENDICES

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<td>Appendix 1 (c)</td>
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<td>Appendix 1 (e)</td>
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| Appendix 2 (a) | Application Form for Laboratory Space Requirement |
| Appendix 2 (b) | Application Form for Protected Time |

| Appendix 3 | Remit of the IMU Research Committee |
| Appendix 4 | Sample of Resubmission Letter by IMU-JC |
| Appendix 5 | Sample of Rejection Letter by IMU-JC |
| Appendix 6 | IMU-JC Approval Form |
| Appendix 7 | Sample Letter to Chief Financial Officer (Approval of Research Grant and allocation of Project Identification Number) |
| Appendix 8 | Sample Letter to Principal Investigator on Approval of Research Grant and Research Project ID No. |
| Appendix 9  | Sample Letter to Dean of School of PGSR in charge of Research Laboratory (if Bench Space is required) |
| Appendix 10 | Tracking Form (for each project that has been approved) |
| Appendix 11 | Request Form for Research Assistant |
| Appendix 12 | Six (6) Monthly Progress and Financial Report Form |
| Appendix 13 | Sample Form - Decision Made by IMU-JC on Research Progress and Financial Report (if any) |
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