

Frequently Asked Questions (FAQ)

IMU Joint Research and Ethics Committee (IMU-JC)

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General

Where is the IMU-JC administrative office?

The IMU-JC administrative office is located at the IRDI Office on the 1st floor at the International Medical University, No.126 Jalan Jalil Perkasa 19, Bukit Jalil, 57000 Kuala Lumpur, Malaysia.

Who do I contact if I have questions?

You can contact the Research Management Centre (RMC) via email (imujc@imu.edu.my), or telephone 03 2731 7073. You can also come to the IRDI Office, hours 8:30 a.m. - 5:30 p.m. Monday through Friday.

What guidelines does the IMU-JC follow?

The IMU-JC is 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”.

How are people appointed to the IMU-JC?

The selection of IMU-JC members is based on nomination and endorsement by the committee.

Submission of Research Proposal

Are there examples of successful proposals to which students and faculty could have access? Do these examples include an array of research designs?

Because research proposals are considered confidential, IMU-JC does not make copies of them available to the public. However, one can always request a copy of a successful research proposal directly from the researcher(s) who submitted it.

If I am a qualitative researcher, do I need to go through the IMU-JC?

Yes. All research to be conducted at IMU must obtained IMU-JC approval prior to initiating any research work.

I plan to conduct online research. Are there any special things I need to do?

Online research must be reviewed by the IMU-JC just the same as any other research. However, there probably are issues related to online research, such as informed consent, that you may need to handle differently from “in-person” research. Therefore, it may be a good idea to become familiar with information concerning justifications for waiving written documentation of consent (getting signatures on a consent form). The distinction between confidentiality and anonymity also comes to mind as something that may be relevant to online research (but not exclusively to online research).

When is a modification necessary?

A modification is necessary whenever a PI deviates from the approved protocol.

Can I make changes to my protocol and inform the IMU-JC later?

No, the IMU-JC must approve any changes prior to implementation

Review Process

When is IMU-JC review required?

Any study to be conducted at IMU, regardless of whether it is involving human participants or animals, and meets the definition of “Research”, must gain IMU-JC approval prior to initiating any research activity. Research is defined as “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge”.

What if I don't get approval from the IMU-JC prior to conducting my study?

Individuals that do not acquire IMU-JC approval prior to data collection are noncompliant and are liable for any and all negative outcomes.

Is there such a thing as “retroactive” approval?

No. All projects must be reviewed and approved prior to data collection.

Is there a way to get feedback on proposals before formal submission to the IMU-JC?

Proposals can be submitted to the Chair, or any other member of the IMU-JC for advice prior review. However, such advice does not guaranteed approval by the IMU-JC as the decision for approval is based on consensus decision of all members.

Does the committee give feedback on proposals that were not approved? What if I don't agree with the feedback?

If the investigators do not agree with the IMU-JC decision, they can write-in and request for the same proposal to be presented to the IMU-JC with strong justification.

Consent

Why do I have to get informed consent?

Informed consent assures that prospective human participants will understand the nature of the research and can knowledgeably and voluntarily decide whether or not to participate

What information needs to be in the informed consent form?

- (1) a statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
- (2) a description of any reasonably foreseeable risks or discomforts to the participant;
- (3) a description of any benefits to the participant or to others which may reasonably be expected from the research;
- (4) a disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant;
- (5) a statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained;
- (6) for research involving more than minimal risk, an explanation as to whether any compensation will be made and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
- (7) an explanation of whom to contact for answers to pertinent questions about the research and research participants' rights; and
- (8) a statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, and the participant may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

Do I always need to have a consent form signed and dated?

In most cases, yes. The informed consent document has to be signed and dated. The regulations allow for waiving this requirement if the subject's signature poses more risk than the absence of the signature, such as in particularly sensitive projects for which knowledge that a person merely participated might be deemed damaging in some way, or for projects in which obtaining signatures places an undue burden upon the researcher that it would severely, negatively impact the likelihood

of accomplishing the research. The IMU-JC can determine if the research meets the criteria for waiving documentation (signed informed consent).

Is it possible to get a waiver of informed consent or elements of informed consent?

In most cases, some form of informed consent is required. The IMU-JC can determine if certain elements of informed consent can be waived or the entire process of obtaining informed consent.

Where can I find samples of informed consent forms?

You can find a template at IMU-JC website under Forms, Policies and Guidelines.

Training

What options do I have for obtaining my training?

CITI (online module)

Which CITI modules are accepted by the IMU-JC?

All investigators are encouraged to complete at least the 3 basic modules on:

- Responsible Conduct of Research (RCR)
- Conflicts of Interest (COI)
- Information Privacy & Security (IPS)

Investigators who are conducting research involving human subjects should complete the module on:

- Human Subjects Research (HSR)

Investigators who are conducting research involving animals should complete the module on:

- Animal Care and Use (ACU)

Additional curricula, such as “Good Clinical Practice (GCP)” under the CITI Program might be useful for introducing researchers to the general principle of GCP, but do not qualify as sufficient training for conducting clinical trials in Malaysia. Investigators who are conducting clinical trials must complete the Malaysian “Good Clinical Practice” curriculum which is recognized by the National Pharmaceutical Regulatory Agency (NPRA), Ministry of Health Malaysia.

Those who wish to know more about the IRB, are contemplating serving on the IRB, or are actively serving on the IRB should complete the “IRB Members” curriculum.

Does everyone on a research project need a certificate of training?

Yes, the Principal Investigator and any other researchers listed on the IMU-JC Application must complete the relevant mandatory training.

Do ALL faculty have to take the online CITI course or just those submitting to the IMU-JC?

Any individual affiliated with IMU who wishes to conduct research at IMU is encouraged to complete training that has been approved by the IMU-JC. This includes anyone connected with a particular research project. However, someone who has recently completed training for one project need not complete additional training when collaborating on a different project. Faculty who do not intend to conduct research, either individually or in collaboration with others, need not complete the training.

Is training required before faculty can do research and, if so, where can we get the training?

Yes, training is required. The IRDI website contains URL(s) for approved on-line training. Other types of training may satisfy the requirement, but such training needs to be approved by the Chair of the IMU-JC in advance.

Student Research Projects

Do course assignments that deal with human subjects need to go through the IMU-JC?

If the project involves accessing humans and constitute a “systematic investigation designed to develop or contribute to generalizable knowledge,” then it needs to be submitted to the IMU-JC.

How might a faculty member coordinating the final year project (FYP) of undergraduate program manage the submission of high volume of proposals to the IMU-JC?

One suggestion is to alert the IMU-JC Secretariat of the large number of incoming proposals so that the Secretariat can make arrangements (extra meetings, etc.) to ensure timely review of the proposals. The review process is faster when research proposals have been completed properly, so the faculty member can speed up the process by ensuring that only adequate research proposals are submitted to the IMU-JC. Advice from other faculty members who have supervised multiple projects simultaneously should be sought as well. Having the IMU-JC Chair, or some other IMU-JC Member, visit the class to explain what is required in a research proposal would certainly be helpful.

What is the turn-around time students project?

Turn-around time is difficult to estimate because each project must be reviewed on its own merits and there are many conditions that affect turn-around time (complexity of the project, quality of the proposals, etc.). The IMU-JC Chair will make every attempt to schedule additional IMU-JC meetings to meet demands for reviews.

Related to a research module, given that we have 14-16 weeks, what should one do in the event of indecision about whether it is research or inquiry?

As noted elsewhere, the IMU-JC is tasked with deciding whether or not a project meet the requirement of its scientific merits and regulations. It is advised that the proposal submitted to the IMU-JC as early as possible.

Do members of the IRB come to talk with classes to provide an overview and give insight into expectations?

There currently exists no organized program for classroom visits. However, if necessary, the program director or module coordinator can arrange for the IMU-JC Chair or any IMU-JC member to meet with any class within normal scheduling reservations. Interested individuals are encouraged to contact the IMU-JC Secretariat concerning such visits.

If a faculty member does not know the answer to questions about the IMU-JC, should the faculty member contact a member of the IMU-JC or should the student do that?

Ideally, the faculty member should contact the IMU-JC; that way, the faculty member will know the answer for the next student who asks that question. Practically, however, it doesn't matter who contacts the IMU-JC, so long as the answer is relayed to all members of the research team.

Conducting research in classes or with students as participants

Is it possible to go to another professor's class to recruit students as potential participants?

Researchers are expected to seek prior permission from the professor of the course (or instructor if the teacher is a lecturer or sessional) to speak with their students regarding participation in a study. However, most professors or course instructors will not provide class time for researchers to recruit students for studies as they do not have the time to give up. Researchers should never assume or expect other professors or instructors to give up class time or that this is an endorsed or supported recruitment method within their Department.

If recruitment is to take place in the classroom, minimal teaching time must be used (e.g., less than 10 minutes). A better practice would be for researchers to advise students to stay a few minutes after class or come early to the next class to learn more about the study or to distribute a contact card that students can complete if they are interested in hearing more about the research. The researchers can then email or telephone the students with more information.

Is it appropriate to ask the students I teach to participate in my research?

Yes, but a third party, who is not connected with the research, nor has any power or authority over the students, must be part of the consent process. Researchers need to remove the undue influence that students can feel to be real or perceived to ensure that participation is truly voluntary. For example, the Chair of the Department or Dean of the Faculty should not be part of the recruitment or consent process as students may feel influenced to participate in the research. A department assistant or faculty administrator who has no influence or authority over the student's marks could

send a recruitment email to students and indicate that he/she is sending the email on behalf of the researchers. In addition, the information-consent letter must explain and provide assurances to the students that no penalties will result by not agreeing to participate in the research (or experience no penalties by not allowing materials/course work or grades to be used for research purposes).

As the instructor and researcher, you must wait until the end of the professor-student relationship before accessing the consent forms collected by the third party (i.e., after all marks have been submitted to the Registrar's Office). This will mitigate any real, or perceived, influence that you may have toward the student's grades. Identifiable data must be analysed only after grades have been submitted to the Registrar's Office so that any real, or perceived, influence on the student's grades no longer exists.

Students under the supervision of any member of the research team (e.g., for an internship, co-op job, etc.), even though they may not be connected to the research, should not act as the third party as a power relationship also exists between the researcher and the student. It is conceivable that a student may pressure other students to participate, perhaps inadvertently, to ensure the success of their supervisor's research.

Is it possible to invite some students to participate in my research and not others?

If you, the course instructor and researcher, intend to involve some students as participants, and not others, a third party must be involved in recruitment and selection to provide distance between the course instructor/researcher and the student/participant. You, the course instructor/researcher, should not be aware of who has agreed to participate while the instructor-student relationship still exists.

Can I conduct a deception study using my students as study participants?

Deception studies should only be used in conjunction with in-class experimentation when no other method is suitable. A clear and strong justification must be provided in the research ethics application form for why deception is necessary.

What do I need to do if I want to use student's course work or access their grades for my research?

Permission must be sought from students if any of their course materials (e.g. papers, assignments, tests, exams, marks, etc.) are to be used for research purposes as use of a student's course materials would be secondary use of identifiable information for research purposes. Secondary use refers to the "use in research of information originally collected for a purpose other than the current research purpose". This includes school records originally created or collected for educational purposes but are now being sought for use in research.

Reasons to conduct secondary analyses of data may include the avoidance of duplication in primary collection and the associated reduction of burdens on participants. However, privacy concerns and questions about the need to seek consent arise especially when information provided for secondary use in research can be linked to individuals, and when the possibility exists that individuals can be identified in published reports or through data linkage. In certain situations, confidentiality becomes a concern because of the small number of participants or cases being investigated and the fact that indirect identifiers, including writing style, word usage, etc., will identify a particular individual.

If the secondary analyses of data involve non-identifiable information (i.e., anonymous data), then individual consent might not be required. Anonymous means the information or data never had identifiers associated with it and risk of identification of individuals is low or very low.

If the researcher, who is not the course instructor, wishes to access a student's grades for research purposes, permission must also be sought from the student to allow the Registrar's Office to release this information. Researchers must contact the Registrar's Office in the early stages of planning their study as it is not always possible or feasible for the Registrar's Office to provide access to student grades.

If you are looking for aggregate or average grades for a course, the researcher can contact the course instructor directly for this information. A student's consent is not needed to report on the aggregate or average grade for an entire class.

Is it possible to use teaching time to conduct my research?

For researchers to use teaching time the research must be: a) of educational value, and b) directly related to the course objectives as outlined in the course syllabus. Moreover, the research activity or exercise to be examined must be integrated into regular classroom activities and involve the entire class.

A professor/instructor wishing to provide in-class time to research (either for their own research or that of other investigators) must insert the details of the study, as other pedagogical content, in the course syllabus. In addition, it is recommended that professors/instructors seek an arm's length independent assessment of the educational merit of the research from someone not involved in their research or from their Department Chair or Dean. This should be done prior to the beginning of term and a copy of the course syllabus is to be submitted with the research ethics application.

Are there alternatives to using teaching time to conduct my research?

Three options have been presented that will ensure free, informed consent of participants, and guarantee anonymity of research participants and confidentiality of data. In such cases, the educational value of the research conducted may not be relevant to the specific course. Other alternatives may also be acceptable. A few examples include:

- Ask the professor teaching the course for a few minutes at the beginning or end of class to distribute questionnaires and ask the students to return the questionnaire, completed or not, in a sealed envelope at the next class, or have students drop the questionnaires off at a specified location.
- Briefly explain the research project to students in class and invite them to fill out questionnaires outside of class time at a specified location and time.
- Distribute a letter to students in the class that includes a URL to an online survey they can complete outside of class time.

I want to conduct an observational study of students in a class setting. Is this considered to be a public space? If not, what would I need to do to get permission to observe a class?

University classes are not normally considered to be public places by professors and students. A small seminar group, for example, would not be viewed as being public (i.e., where anyone can attend) as there is likely to be a great deal of interaction or involvement among the professor and students. However, a large lecture hall may be considered to be more like a public space by those in attendance.

Researchers conducting qualitative studies where they wish to observe students in a class setting may do so considered that:

- the observation is “non-participant” such that the researcher observes, but is not a participant in, the action (also known as naturalistic observation);
- the professor whose students are to be observed, approves of the research and the dates and times for observation;
- the researcher sits in a location that is deemed acceptable and not intrusive to the professor or students;
- the professor uses minimal teaching time to introduce the researcher and explain the reasons for their attendance in the class;
- no identifying information is collected or recorded about the students or the professor;
- students are provided with an opportunity to receive feedback about the study results upon completion of the research; and
- the study complies with the principles of Human Subjects protection and has received prior research ethics clearance through the IMU-JC.

What things do I need to know before planning an in-class experiment or involving students whom I teach as participants?

When planning a research study that will involve students, researchers need to carefully consider the potential negative impacts of the research on a student, their marks, or their education. You need to ask yourself the following questions and design the study such that these questions will be addressed:

- Should I be concerned with research fatigue if students are constantly being asked to participate in my research or that of my colleagues?
- How generalizable will my results be if I only recruit students or the students that I teach?
- How will I ensure students/study participants who decline to participate will not be penalized or perceive they are being penalized?
- By what means will I ensure that participation is voluntary?
- Should I consider using another group of students, for example, those who I do not currently teach? Are there better alternatives?
- How will I ensure that students/study participants are truly free to participate or to decline to participate?
- What are the advantages and disadvantages of using a population with whom I have a prior, and ongoing, relationship, especially when that relationship is one where I may have authority over the population?

- Are there any additional statements that I need to include in the information-consent letter when conducting an in-class experiment with students as participants?

The study information sheet must clearly explain:

- the educational value of the research and how the research relates to the course objectives;
- declining to participate is a definite option and students will not receive any penalty by doing so;
- students can choose to not be involved in any aspect of the study such as declining to complete a study task or leaving a survey question blank;
- anonymity of participation such that the questionnaire or study task will be distributed to everyone and those who wish to not participate can either spoil the materials or leave them blank before returning them;
- participants will not be unfairly advantaged in any way as a result of taking part in the research;
- the alternative option for those who do not wish to participate in the research study;
- the course instructor/professor will not be told who participated in the study or not until after the final marks have been submitted; and
- participants' responses will be summarized and no individual results to the study task or questionnaire will be shared with the course instructor/professor.

Children

Can children consent to participate in research?

No, children give their assent to participate in research

Are the elements of informed consent the same as those for assent?

For the most part yes but the age and cognitive abilities of the kid may merit a waiver of some of the elements.

Do I have to obtain permission from the child's parent before working with the child?

Yes, parental permission should be obtained prior to the child assent

Do both parents have to sign the informed consent form?

Only when the research is of high risk and/or there is not direct benefit to the child

Is it possible to get a waiver of child assent?

Yes, but the PI should provide adequate justification to the IMU-JC.

Is it possible to get a waiver of parental permission?

Yes, but the PI should provide adequate justification to the IMU-JC

In research involving minors, is 'assent' always required from the children?

The presumptive answer is "yes," but each project is different (and each project is reviewed independent of other projects). Obviously, very young children are not in apposition to provide assent. A justified request to waive 'assent' can be included in the research proposal.

Conducting Research Involving Schools

If I conduct research in the school, do I need approval from the district or just the school in which I plan to conduct the research?

All school systems don't follow the same rules regarding conducting research in their school and the PI should discuss the policy with the school. Some school systems require an independent review of the research by a research review committee similar to an IRB. While others only need the principal to review and approve the research.

If both the school system and IMU-JC need to review the protocol, who do I submit to first?

This decision is up to the investigator, however IMU recommends the PI submit the protocol to either IMU-JC or the school system for review first, but not simultaneously.

Visiting Researchers

Do individuals that are not currently employed or enrolled at IMU need IMU-JC approval before conducting the study?

Yes, if the project is conducted on IMU campus or through IMU facilities.

If I am conducting research somewhere else, do I still need to submit the project to IMU-JC?

Yes. The purview of the IMU-JC extends to any research conducted by anyone affiliated with IMU. The only time you need not submit an "elsewhere" project is when your participation includes absolutely no connection with IMU (no IMU affiliation in the publication, presentation, or publicity release, no submission to fulfil any job requirements at IMU, etc.)

Closing a protocol

If I am leaving the university and I have an open protocol, what should I do?

The PI will need to write-in to inform the IMU-JC on the appointment of new PI. If the PI leaving the university and continue to work on the project, then the PI/Student will need to seek approval for that study at the new institution since IMU-JC will no longer be responsible for the protocol.

Reporting

What should a PI do if a participant is physically injured, suffers personal loss, or psychologically traumatized when participating in an approved research study?

The PI is responsible for reporting any unexpected project outcomes or events to the IMU-JC in writing.

Record Keeping

How long should records be kept for IMU-JC?

Research records are confidential records and they are university property. Records must be stored safely in your university office or your department or another approved location at the university. Records to be kept include approved IMU-JC documents, as well as case-report forms, tapes or transcripts, and all other data-collection instruments and source documents. Principal Investigators are responsible for maintaining records that mirror IMU-JC Records. All records must be kept for 10 years after completion of all research activities.

What records should researchers maintain?

Researchers should maintain a file of all documents relevant to the IMU-JC review of the research project. The principal investigator's records should be a mirror image of the IMU-JC's records, meaning that all documents submitted by the researcher to the IMU-JC and all correspondence between the IMU-JC and the researcher should be kept on file by the researcher.

Documents researchers should have on file include but are not limited to:

- Research proposal submitted to the IMU-JC, including consent and/or assent form(s);
- IMU-JC's response or request for additional information or revisions;
- Responses to the IMU-JC's requests for additional information or revisions;
- Notice of final approval;
- Correspondence between the investigator and the IMU-JC;
- Progress Report forms and attachments (if applicable);
- Copies of any inspection or audit reports from internal or external entities;

- Renewal of Approval, where applicable;
- Amendment forms and attachments (if applicable);
- Amendment approval (if applicable);
- Original letters of collaboration from other institutions; and
- All approved research study materials (e.g., consent forms, recruitment materials, data collection instruments or forms, etc.)

Contact Us

IMU Joint Research and Ethics Committee (IMU-JC)

Email: norsalinasalim@imu.edu.my

Tel: 603 2731 7581 ext 1303