Ethical Review Guidelines for Research by CNM students

What is the Institutional Review Board (IRB)?

It is a committee that is given the responsibility by an institution (e.g. university or research organisation) to approve, monitor, and review research projects involving human subjects and human data/ tissues/cells. For example, a research project involving interviews with or surveys of people would require such review. In NUS, the committee comprises senior faculty members with extensive research experience.

What is the origin of the IRB?

During World War II, doctors in Nazi-held concentration camps conducted brutal experiments with human subjects which tested the effects of extreme cold, high altitude, exposure to noxious substances, poisons, disease etc on human beings. These atrocities impelled the establishment of the Nuremberg Code which seeks to define the ethics of medical experimentation involving human subjects.

Why is there a need for research to be reviewed by an IRB?

Research projects are reviewed by the IRB to ensure that they do not, in the course of research, violate or undermine the research subjects' welfare and their rights to privacy, fair and ethical treatment etc.

What exactly does the IRB do in its review of a research project?

It reviews research protocols (a detailed document explaining exactly what the research method will involve and what the subjects will have to do in the course of the research) and related materials e.g., informed consent documents and investigator brochures, to ensure that the rights and welfare of the human subjects are upheld. In so doing, the review helps to ensure that the research methods are ethical, promote fully informed and voluntary participation by subjects and maximize the safety of the subjects once they are enrolled in the research project.

What are the ethical principles which research involving human subjects should abide by?

- Voluntary participation – participants should participate in the research of their own free will and not under duress or coercion
- Reasonable risk – the risk which subjects should be reasonable based on the potential benefits which society can accrue from it
- No exposure to harm – the research should not expose the subjects to harm of any sort, whether physical or psychological
- Societal benefit – the research must be of benefit to society
- Clear and well-defined need – the research should be well-motivated and should not be random or unnecessary

Do students' research projects need to be reviewed by the IRB? Why?

If your project is part of a class assignment and you do not plan to publish the results, ethical review is not required. In such a case, your project is considered an educational exercise rather than a research project. Nevertheless, CNM requires all honours and graduate students to obtain IRB approval for their thesis/dissertation studies if human subjects are involved. Since your thesis/dissertation study comprises careful investigations of critical issues and could contribute to generalizable knowledge, it is considered research and thus, IRB oversight is required. When students plan to use their research results in future publications, getting the project reviewed by the IRB is essential.

What procedure do students have to follow in getting their research projects reviewed by the IRB?

1. All proposed research involving the use of human subjects requires ethical review and approval *before* the research is initiated. The NUS-IRB does not allow retrospective reviews.

2. Visit the NUS IRB website and familiarise yourself with the information about the procedures.

3. The NUS-IRB Application Form (Social Sciences) and NUS-IRB Guidelines can be downloaded at the NUS-IRB site: http://www.nus.edu.sg/irb. Please fill in all the necessary information and get approval from your superior. Following which, please submit a hardcopy of your application to Sumi Ateck Binte Kaspan at the CNM general office.

4. Download the forms and check to see what other documents you need to provide. Depending on the research design, you will need to prepare different kinds of documents.

5. If you have any questions or doubts about the forms or information they request, contact the IRB for clarifications. Do not rely on your friends' experiences as there are likely to be differences between their research and your own (i.e. your sampling, research designs, types of research questions and etc).

6. For undergraduates, the "Principal Investigator" of a research project must be their supervisors. Graduate students may apply with their supervisors acting as the "Principal Investigator" or "Supervising Co-investigator."

7. After your application has been submitted, an NUS-IRB coordinator will determine whether the application is complete. If changes are required, your application will be sent to you and your supervisor for revision via email. If no changes are needed, your application will be sent to the IRB panel for review and approval.

How long does the review process take?

Usually, the IRB reverts quite promptly from when application forms are first submitted, usually within a week. However, application forms and other documents must provide the necessary information about your research. Failing which, an IRB representative will ask you follow-up questions regarding your research including sampling methods, samples, types of research questions (whether they are too sensitive or invasive), use of personal information, and so on until all their doubts are cleared. Only then will your application be put into the review process.

The duration of the review process varies and depends on the type of IRB review. The NUS-IRB coordinator will assist you in determining the appropriate review type:

Type of review	Nature of research	Estimated duration
Full review	Involving greater than minimal risk (physical, social, psychological, and financial risks) to the subjects	A full review involves the full Board that meets monthly. Revisions suggested by the full Board may be brought back to the Board for final approval. This may takes 6 to 8 weeks.
Expedited review	The involvement of human subjects is considered low risk	It usually takes 3 to 4 weeks.
Exemption from IRB review	Research that presents little or no risk to human subjects (non-vulnerable subjects)	Usually within a week.

Bearing the above in mind, it is advisable to factor the IRB process and its established duration into your research plan.

What if the IRB does not approve my research project? Is there an opportunity for resubmission?

The IRB may reject your research project because it violates general ethical principles or it may require further revisions. If amendments are required, you and your supervisor should revise the application and resubmit it to the IRB for approval. With guidance from the IRB coordinator and your supervisor, your resubmission should stand a higher chance of approval.