Frequently Asked Questions

1. What is human subjects research?

The sort of research that falls under the review of the MCC Institutional Review Board (IRB) is defined as the systematic investigation, including research development, testing, and evaluation using human subjects as participants, that is specifically designed to develop or contribute to generalizable knowledge.

A human subject means a living individual about whom the investigator conducting research obtains data by direct **intervention** or **interaction** with that individual, or by obtaining **identifiable private information** from or about that individual.

Intervention can include either physical procedures by which data are gathered, such as an exercise regimen or taking a blood sample, or the investigation of the subject's environment, which are performed for research purposes.

Interaction can include communication with or interpersonal contact between the investigator and the subject, such as a survey or an interview.

Identifiable private information may include information about behavior that occurs in a context in which the subject may reasonably expect that no observation or recording is taking place, or information that has been provided for specific purposes by the subject and which they can reasonably expect will not be made public, such as a health record or records of personal activities or behaviors.

2. So, what is a Institutional Review Board?

The MCC Institutional Review Board (IRB) exists to review all research that directly or indirectly involves human participants as study subjects and to develop institutional policies to oversee such research. Our primary role is to ensure the protection of human participants as subjects of research at MCC. We also want to ensure the safety and responsibility of student researchers and faculty mentors in following best practices for responsible research. We do this by reviewing study proposals and by providing educational workshops and training for students and faculty. We also serve as a resource for anyone with questions or concerns about human subjects research.

The MCC Institutional Review Board office is located in Math, Wellness & Fitness (MWF) 122. This also is the office for the Highlander Undergraduate Research Initiative (HURI).

3. Do I have to submit a proposal to the IRB before I start my study?

Maybe. If a research project involves human participants as described above, it must be submitted to the IRB for review and approval **before** beginning the study. This includes research involving existing data or any advertising or other recruitment procedures. Please consult the IRB Human Subjects Research Checklist to see if your study needs to be submitted for IRB review.

4. Who can be an investigator?

At MCC, all full-time faculty and staff and full-time students may act as investigators. Under special circumstances, part-time students may act as investigators, and part-time faculty may serve as mentors, but the IRB must approve their doing so. All student investigators must have a faculty mentor.

5. Do I need any specific training to be an investigator?

Yes. All student investigators and faculty mentors must complete the free online Protecting Human Research Participants (PHRP) training course prior to becoming an investigator or mentor. It is MCC IRB policy that PHRP training be renewed every two years. Alternatively, MCC recognizes the Collaborative Institutional Training Initiative (CITI) as being acceptable training to be an investigator. CITI training also may be completed online, but there is a cost involved. Once PHRP training is completed, you must print the Certificate of Completion to include with your IRB submission.

6. If I propose a project that is required for a class, do I need IRB approval?

If the project fits the definitions of "research" and "human participants" as described above, then you may need to get IRB approval. However, if the purpose of the project is **only** to learn proper research methods, the project may not constitute human participant research. This means, however, that none of the data can be used for publication, presentation, or other research purposes. If, at a later date, you want to use the data obtained from a class project to present at Scholar's Day, or some other venue, you must submit a request to the IRB. In such a case, Informed Consent must be obtained from everyone who provided the data. Such persons must consent to allow their data to be used outside the classroom and only for some specific purpose; only at this point is using prior data allowed.

7. What types of IRB review are there?

There are three types of IRB review: **Full Committee**, **Expedited**, and **Exempt**.

Full Committee review is done by the full IRB committee at its regularly scheduled meetings. Reasons for full committee review can include the use of vulnerable populations (explained below) as study subjects, projects which may involve deception, or projects which seek to obtain particularly sensitive information. This does not mean no other types of proposals will go before the full committee, nor does it mean that all others may be either expedited or exempt. The Chair of the IRB will make a determination of the type of review required.

Expedited review means that the study does not require full board review but is still subject to the same scrutiny regarding protecting human research subjects. You may not begin any research activities until you have received written approval from the IRB.

Exempt means that all of the research activities outlined in the proposal fall under one or more of the exemption categories specified by federal regulations. Exempt status does not lessen the ethical obligations toward human research subjects. You may request that your study qualify as exempt, but that does not mean your proposal will be granted exempt status; the IRB Chair will review all requests for exempt status and will notify you of the decision.

If the Chair determines that your study does not qualify as exempt, you will be required to submit the regular IRB application. Even if your proposal is exempt, you still must submit all supporting documentation, such as surveys, and you still are required to complete PHRP training and submit a Certificate of Completion.

8. What happens if my study needs Full Committee review?

Full board review means that, for any number of reasons, the decision was made to have the full board take a look at your proposal. This does not mean you did something wrong or improper; it could mean that the study seeks to investigate an issue that the Chair is not familiar with and wishes the rest of the board to look at it. (The IRB has some very talented and knowledgeable members, but we are not all experts in everything.)

It can sometimes happen that the board wants to talk to you about your study, usually to clarify some point or method. In such cases, the IRB Chair will notify you to attend a IRB meeting and will explain to you why you are being asked to attend. If this occurs, **DON'T PANIC!** In nearly all cases, we may only need some point clarified. When you arrive, we will invite you to come in and talk to us about your project. You will be given the opportunity to ask the board any question you like. The only rules are that you keep confidential what is

discussed, and you are not permitted to be present during any deliberation or voting.

9. Can I make changes to my study after it has been approved?

Yes. There is an Amendment form that may be used for most purposes to make changes to an approved study. This form is found on the IRB Forms link. The IRB Chair must approve any changes made to an approved study **before** the changes are implemented.

Also, remember that a study is approved only for one year from the date of approval; if you want to continue the study beyond one year, you must fill out a Continuing Review form. Amending your study does **not** change its anniversary date, which is one year from the date of the initial approval.

10. What do I do when I have completed my study?

There is a closure form that must be submitted to the IRB to officially close a study. (The closure form can be found in the IRB "Information & Forms" section of the website.) Once you have received notification that the study is closed, you may not continue to recruit new study subjects or collect new data; however, you may continue to analyze the data you already obtained and to prepare that analysis for presentation/publication.

If you want to reopen a study which has been closed, you must submit a new proposal to the IRB.

11. My study involves deception. Are there any special considerations?

Yes. Deception in human subjects research is not prohibited by either federal regulations or by MCC. The use of deception in research can be very useful in obtaining data not possible otherwise, but it also can be seen as a violation of the trust that the participant puts in the researcher. It is important to be able to justify using deception. Investigators need to be able to describe to the IRB the method of the research, including a clear statement that no other study method would be able to yield equally valid data, and there must be a process for the study participants to be informed at the end of their participation that deception was a component of the study.

Participants subject to deception in a study must be fully debriefed when their participation is over, and it must be explained to them very clearly why it was necessary that they be deceived. Great care should be taken not only in crafting a study where deception is a component but also in the debriefing of participants afterward. Remember, most people do not take kindly to being intentionally deceived. You must be very careful about how you inform study participants that deception was a part of the study. A script of the debrief must be included with your IRB application, and the IRB will examine it with special attention.

12. What is a "vulnerable population"?

A vulnerable population refers to members of a group who may have a diminished capacity to give informed consent. **Informed consent** means that the subject:

- Is fully informed of and understands the purpose and method of the study;
- Has been informed about all foreseeable benefits and risks;
- Has been able to ask questions and given answers regarding the study;
- Is free to volunteer to participate or not; and
- Is aware that s/he can discontinue their participation at any time without any penalty or loss of rights to which they might otherwise be entitled.

Persons who are unable to meet this standard of consent still may be study subjects, but because of their diminished capacity to give informed consent, special considerations are necessary to ensure that they receive the fullest protections possible.

Federal regulations do not clearly specify all vulnerable groups. The MCC IRB considers minors (meaning, by law, anyone under the age of 18), prisoners or those under court-ordered restrictions, the mentally and/or cognitively challenged, persons over the age of 65, and persons who are being recruited because they have suffered from various types of addiction or abuse, as requiring greater considerations.

Often studies involving vulnerable populations require full committee review; this is to ensure that the fullest protections are in place for their rights to be secured. This is not to discourage targeting a vulnerable population as study subjects, however, the IRB wants be very careful that the participants are treated with the utmost respect and consideration.

13. What is informed consent?

Much of the justification for the existence of research review committees has to do with studies that were conducted in which the participants were forced to participate, were not told what exactly what was going to be done to them, were lied to about the purpose of the study they were participating in, or were never told they were even subjects in a study. Examples include accounts of "medical" experiments conducted in Nazi and Japanese prisoner of war camps and the Tuskegee Syphilis Study in the U.S. The need for medical studies using live human participants must be balanced by issues of respect for the participants, the balance of risks and benefits, and simple justice regarding the selection of study subjects.

The Belmont Report, issued in 1979, provided a summary of these considerations. As a result of this report, federal legislation was passed requiring

that all studies involving human subjects undergo review to ensure the fullest protections for the rights of the study participants.
(See: http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html). One result was the creation of institutional review boards, or IRBs, to independently review all research proposals that involve human participants, to ensure informed consent, especially of risks and benefits, and the prevention of conflicts of interest. At MCC, our review board is called the Institutional Review Board, but its mandate is the same.

IRB-approved research, unless it is exempt, must include informed consent forms. Study participants must sign an Informed Consent form prior to the initiation of your study. Guidelines for obtaining informed consent are available on the IRB Forms link.

14. Can I do a study entirely online? How do I get informed consent if my study is conducted online?

Informed consent is a standard, not a document. It can sometimes be the case that the recruitment, consent, and the study itself, all are designed to be completed entirely online. The IRB application allows you to obtain consent without an actual written and signed document. There is a separate form called the "Waiver of Written Informed Consent" which is used to allow for obtaining unsigned consent under certain circumstances; these can include implied and verbal consent. Consent will still be obtained from participants; the difference is that they will not be required to sign the consent form. Examples in which the IRB may waive the requirement to obtain a signed consent form can be where the only record linking the research participant to the research would be the consent document itself, and the only risk would be potential harm resulting from a breach of confidentiality or that the research presents no more than minimal risk of harm to participants.

15. Do I always need to obtain informed consent? How is it different from a "waiver of written consent"?

You can request a waiver of informed consent; this means that you are requesting to omit obtaining consent. Examples of types of studies in which some or all elements of consent can be waived include retrospective literature reviews or studies that involve no more than minimal risk and where waiving consent will in no way affect the rights of the study subjects. If you are not sure, it is best to try to get informed consent. You can contact the IRB to help clarify this point.

A waiver of written consent means that you still obtain consent, just not in the form of a written and signed document. Again, though, it remains your

responsibility to ensure that participants are fully informed about your study, whether they have to sign a document or not.

16. I am not collecting any personally identifying information. Do I still need to obtain informed consent?

Yes. You can do this by informing the participant about all of the elements of consent, but the signature line on the consent form is replaced with a statement saying that the completion and return of the study instrument(s) is considered to be tacit, or implied, consent.

Implied consent is the agreement to participate in research by engaging in research activities. By completing the research activities, such as a survey or questionnaire, the subject has demonstrated that he/she has agreed to be a participant in the study. An example could be an online survey; when a study participant clicks the option to begin or continue, they are by doing so agreeing to participate in the study. If it is clearly stated what the study is about, what their participation will require, and that clicking to begin or continue means they agree to participate, the standard of informed consent is met.

17. Can I conduct research off campus? Does it require IRB approval?

If you are an MCC faculty,staff, or student, and you are the Primary Investigator (PI), you will need IRB approval to conduct your research regardless of where the research takes place. If the study site has its own review committee (an IRB or something similar), we may require that this other committee send us their approval for you to do your study. If the site is a school, or other organization, we will require that they provide permission for you to do your research on their site. Written permission is best, but an email that identifies the local authority can work.

18. If I have approval from another IRB, will I still need to get MCC IRB approval?

You may do collaborative research under the authority of another IRB, but the IRB must be informed. In cases where the other IRB recruits local study participants or Co-PIs, some version of an inter-institutional Authorization Agreement must be submitted; this effectively cedes control and responsibility for the oversight of the research and the researchers to the other IRB. The MCC participants and/or researchers are still obliged to abide by the ethical research guidelines of MCC, regardless of who is in charge of the study.

The IRB will require documentation of the other IRB's approval of the study, and the approved IRB form from that institution; in some cases, we may require the completion of an MCC IRB study proposal application, regardless of the study being approved by another IRB. Such decisions are made by the IRB Chair

and may involve full board review and approval. In either case, no research activities may begin until the MCC IRB has reviewed and approved the study.

19. Does the IRB provide any other training for investigators?

Yes. We can schedule training sessions for both students and faculty. The Chair of the IRB is available to meet with individuals and classes, as requested, to do presentations on the application process, as well as more general presentations about human subjects research. Contact the IRB Chair at bchristian@mclennan.edu to schedule training or presentations.

20. What do I do if an unanticipated problem involving risks to participants or to others arises?

A serious adverse event usually means injury or death to a study subject or a researcher, even if the event was not directly related to the research itself. Though very rare, in such cases the research activities will be suspended until an investigation into the adverse event has been completed. If a serious adverse event occurs, it must be reported to the IRB Chair immediately, and the PI must submit a written report within 24 hours of the PI becoming aware of the event. In these cases, it is likely that research activities will be suspended, pending the outcome of an investigation.

Less serious unanticipated problems, such as the loss of data security or violations of confidentiality, should be reported by the PI to the IRB Chair within 7 days of first becoming aware of the problem. Prompt reporting is important, since unanticipated problems may require the modification of study procedures, protocols, and/or informed consent. Any modifications to an approved study will require submitting the proper form and are subject to the review and approval of the IRB.

21. How long can I keep my data?

As long as you want to keep it, provided it has been "de-identified." This means that all potentially personally identifiable information has been erased or deleted. This can include names, dates of birth, addresses, hometown, high school attended, college major, and identifying medical conditions; in short, you can only keep data results if they are stripped of anything that might identify any of the participants.

Data that contains identifiable information may only be kept for the approved duration of the study. If you want to keep the data longer, this amounts to a continuation of the study itself, so you will be required to submit the Continuing Review form and specify why you want to keep your identifiable data longer.

By law, Informed Consent forms are to be kept under secure storage for a minimum of three years; after that, you can destroy them. Just throwing them in the trash is **not** an acceptable way of disposal. You may bring the consent forms to the IRB office, and we will dispose of them properly.