Guidelines for Submitting an Application for Review of Human Subjects Research

Each numbered item below corresponds to a numbered item on the IRB Application for Human Subjects Research and is intended to explain what is required for each item when completing the application. Please follow these guidelines closely. If you have any questions, feel free to contact the IRB Chair Bradley Christian at bchristian@mclennan.edu.

1. **Description of study:** Describe the purpose of the study in enough detail that we can ascertain what the study is about. Describe why it is being done and the importance of the projected results. Explain how the study is intended to contribute to general knowledge.
2. **Description of participants:** Describe the subjects you intend to recruit for this project, the method(s) of recruitment, and where recruitment of subjects will occur. If you will be recruiting from MCC classes, please attach an email from the instructor granting permission. If the recruiting will occur in the classroom, describe how you intend to minimize undue influence or coercion during recruitment. If you plan to recruit from outside institutions or organizations, please attach an email granting permission to recruit from a person authorized to do so, including his/her title and contact information. If you intend to use an oral or written script or any materials such as a flyer or email to recruit research subjects, attach a copy of these scripts/documents.
3. **Number of participants:** How many subjects do you expect to participate in your study? Provide an explanation for that number.
4. **Vulnerable populations:** Vulnerable populations may include minors (<18 years old), pregnant women and neonates, prisoners, cognitively/developmentally impaired persons, or seniors (>65 years old). If you will be specifically including or targeting any members of a vulnerable population for your study, please explain why you are doing so, and provide details about the additional safeguards you intend to use to protect their rights and interests.
5. **Methods:** Describe the methods you will use for the study, such as interviews, measurements or observations of the participants, what will happen to them during the study, and how long you estimate their actual

participation is expected to take. If you will use a questionnaire, a survey, or other written instruments, please attach a copy.

6. **Location of study:** Where will your study actually be conducted? If on campus at MCC, include the building and room number (or other campus location); if off-site, provide the name of the site and an address.
7. **Medical clearance:** If the study involves tissue or blood sampling, the administration of food or drugs, physical exercise or conditioning, medical clearance will need to be secured prior to participation. Explain how this is to be done and include copies of medical clearance for each participant.
8. **Risk(s) to participants:** There are many different types of risks associated with human subjects research including physical stress, psychological stress, economic and/or legal risks, exposure to infectious disease or radiation, personal information about the participant and/or their family, confidential information or records regarding employment, educational background, medical conditions, criminal history, or exposure to materials participants may consider offensive or inappropriate.
   For each type of risk, describe the amount of risk or harm anticipated, justify why the risk is necessary, and explain how the risk will be minimized.
9. **Retrospective data review:** Will you be using existing data? If so, identify the source(s) of the data and, if relevant, how the data will be de-identified.
10. **Biologic sample disposal:** If your study involves collecting tissue or blood samples, please specify the procedures for disposal.
11. **Deception:** Will the subjects be deceived or misled in any way? If so, describe the type of deception or omission, justify the necessity, and explain how and when subjects will be debriefed. If a specific script is used to debrief, please attach.
12. **Consent:** How will you obtain the consent of the participants? If you are using a written consent form, submit a copy with the study application. If minors or those unable to sign a consent form will be study participants, explain how you will obtain consent from them. Explain where consenting will occur and procedures for securing the signed forms. This includes a master code sheet, if one is used.
13. **Audio or visual imaging:** If you will be making any audio and/or video recordings, taking photographs or any other digital images of the study participants, explain why this is necessary, how the privacy and identity of the participants will be guaranteed, and detail specific methods to dispose of these materials after they have been analyzed. An explanation of the necessity of using audio and/or visual images must be included on the Informed Consent form, and the participants must specifically consent to the obtaining of these images/recordings.

14. **Data storage and security:** Describe how you plan to ensure the security of the data once it has been obtained. Explain where and how it will be stored, how long you plan to keep it, and who will have access. Once the study is completed, identify who will be responsible for destroying the data and how it is to be done, (e.g., shredding surveys, destructive electronic deletion of files, etc.).
15. **Signed Informed Consent Forms:** Federal regulations require that signed consent forms be kept for a minimum of three (3) years. Explain when, how, and by whom the Informed Consent forms will be destroyed.
16. **Benefits of participation for subjects:** While it is not necessary that study participants directly benefit from their participation, if there is some direct benefit, describe what itmay be.
17. **Benefits of your study to society:** Even if the participants in your study do not directly benefit, explain how this study may be of general value to society as a whole.