Guidelines for Preparing Form
RO Research Outline

The IRB requires that a description of the planned research be submitted that adheres to the following outline. Each section in bold face print must appear and be addressed in the RO.

Rationale and Aims

This should contain a concise statement of the background or rationale for the study, stressing its significance to the area of inquiry. What are the specific goals of this study? How do the methods employed pertain to reaching the goals? What, in particular, is expected to be found or learned from this study? This should include hypotheses to be assessed concerning subjects' observed behavior, experimental outcomes, or responses to survey/interview questions in the context of the relevant literature. There should be a brief statement on what the final product of the research will be, such as a Masters or Honors thesis, conference presentation, or journal article.

Methods and Procedures

A clear and full disclosure of the methods and procedures is required, including procedures for debriefing subjects, when necessary, after a subject's participation is complete. For example, subjects must be debriefed when an approved study uses any type of deception. This section should be clear and complete enough to allow the IRB to assess the expected benefits and potential risks to subjects throughout all stages of the experimental protocol. With that in mind, the following questions should be addressed:

- How will the subjects be recruited? If the researcher intends to post flyers or signs in order to recruit subjects, a copy of them must be submitted with the application. The IRB will stamp approved signs, which can then be posted for recruiting subjects.
    - If the researcher intends to recruit subjects from organizations such as schools, hospitals, workplaces, or other institutions, a copy of written permission from a senior administrator in each organization must be included in the application. Administrators should acknowledge that they have been informed about the study, provide permission for subjects to be recruited from their organization, and state their occupational position in their organization when signing their letter. If preferred, permission letters can be sent to the researcher by email. When recruiting subjects from institutions that have their own Institutional Research Board (this includes most colleges, universities, and health facilities), it is the researcher's responsibility to contact the IRB at the institutions to determine if their approval is needed in addition to Le Moyne IRB approval before recruiting subjects and collecting data. If the approval of an external IRB is obtained, the researcher should forward a copy of the approval to the Le Moyne College

IRB once it has been received.

- If the researcher will be recruiting subjects via email or announcements on a listserv or social media, a copy of the recruiting statement must be submitted with the application to the IRB. These statements should identify who you are, what your study is about, and any qualifications that are needed to be a subject. If the study will take place at a specific location and time, subjects should be provided this information as well. If the announcement is for an online survey, the researcher should also provide the link to the survey and information on how long the survey will be posted online for subjects to answer. If email is used, we request that you either send out individual emails or use the blind copy feature of your email service if you send them out all at once. When planning to announce studies on social media, researchers much list each site to which the announcement will be posted. For each site, you must indicate whether it is an open site to which you can freely post an announcement, it requires a researcher to join the site in order to post, or it requires permission of the site owner or administrator to post.

- How will the data be collected? This should include specific statements concerning the method of observation or collection of information, such as the use of survey instruments, interviews, laboratory experiments or medical tests.
- Where will the subjects participate in the research project? For example, will they all be together in one room, or will there be privacy for each subject? The researcher should describe the steps taken to ensure the confidentiality of data during and after the time it is collected.
- How long is the subjects' participation in the experiment (or survey, interview, etc.) expected to last?
- What is the timeline for completing the data collection? If surveys will be made available to subjects online or sent to them, how long will they have to complete and submit the surveys?
- How will the collected data be presented and analyzed in the final product? For example, in the case of quantitative data, the researcher should state if they intend to use descriptive statistics such as means, percentages, or frequency distributions, and/or use statistical models to test hypotheses or otherwise assess the significance of the study's findings. Will quantitative data be disaggregated by group or type of subject? (See the Subject Population section below for further description of the information that must be provided if results are disaggregated into sample subgroups.) How will any written, spoken, or visual responses be presented? For example, will direct quotes be used? If so, how will individual subjects be referred to in the final product? The researcher should indicate if other methods will be used to summarize the results of non-quantitative data. In all cases, the researcher should make sure that the methods and procedures are consistent with the degree of confidentiality to be maintained and that is described in the rest of the RO and the Consent Form.

For applications that include the use of online surveys, the researcher should comply with the instructions provided under the Online Survey Tab on the Le Moyne College IRB website.

Researchers who ask participants to respond to surveys or interviews must include copies of their questions with their applications. Copies of online surveys should be final versions downloaded from the website on which they are posted.

Any protocol submitted to the IRB that is of insufficient clarity or lacking the details necessary for a fair and complete review will be returned to the investigator without review and with a request for revision.

Subject Population

Describe the subject population. State specifically any reason for using a special population such as children, the mentally disabled, or other groups whose ability to give a proper informed consent is questionable.

Provide an estimate of the total number of subjects to be recruited. The researcher should also provide estimates of the number of subjects who can be identified as a member of any subgroup used to categorize data or its presentation in the final product. Examples would include information about age, sex, race, occupation, or any other personal characteristics that could possibly be used to associate an individual or small group of individuals with specific results in the final product. The IRB considers this type of data to be potentially identifying information. Providing subgroup information is especially important when there are only a few potential subjects who would be expected to be members of a subgroup, even when a high participation rate is obtained. Risks to confidentiality would increase if only a few subjects can fall into a particular subgroup. When researchers collect this type of data, they must provide a description of how it will be used in their study. If no specific use is anticipated, potentially identifying information must not be collected.

Potential Risks

Describe carefully the potential risks (physical, psychological, social, legal, or other) and assess the likelihood and seriousness of such risks. If methods are used which create certain risks, an explanation of why these methods will be used and not others is required. What alternative methods are available?

This section should also discuss the extent to which the researcher plans to maintain anonymity and/or confidentiality. In general, research that intends to maintain privacy, confidentiality, and/or anonymity of subjects and/or their responses runs the risk of a breach of privacy/confidentiality/anonymity, even though the risk may be less than minimal; the potential for such a breach must therefore be identified as risk in the Research Outline and on the consent form. Anonymity means that a subject's name is not known to the researcher at all. If the researcher knows subjects' names, even if she/he cannot match data with specific individuals, then the most that can be claimed is that the researcher will maintain the confidentiality of subjects' identities and the data collected from them.

The degree of confidentiality is the extent to which the names, private information and data provided by subjects will be protected by the researcher from release. Describing risks to the confidentiality of names, private information and data that could arise during the entire research process is an important part of the Research Outline.

If an online survey will be used to collect information, a separate risk associated with the use of the internet and storage of data on an external server must be included as well.

Informed Consent Procedures

Outline the procedures for obtaining informed consent, including how, where and by whom informed consent will be sought. How will the consent forms be distributed and collected? The researcher should describe the process so as to ensure that no unauthorized individuals will have access to the consent forms at any time. The researcher must also indicate that the subject will receive a copy of the signed consent form as part of this process.

A copy of the informed consent must accompany this application. If anonymity and/or confidentiality are being claimed, this section should include the steps being taken to maintain them during the consent process.

Specific procedures for obtaining consent when using an online survey are provided under the Online Survey Tab on the IRB website.

Safeguarding Against Risks

Describe particular procedures (e.g. proper screening of risk-prone individuals, availability of psychological or medical aid, methods of detecting illness) that will be taken to safeguard the welfare of the subjects.

Researchers that intend to use online surveys must describe the steps that will be taken to ensure subject confidentiality, as well as the security of the data during transmission of the survey responses and for the time period that the data is stored on any external server or site. (see the Online Survey Tab on the IRB website).

Researchers also have an obligation to inform the IRB in the RO and potential subjects in the Consent Form (1) how their data will be used; (2) who will have access to it; (3) what procedures will be in place to ensure that unauthorized individuals will not have access to this information, including how the data will be stored during the study; and (4) what, if any, limitations exist to these confidentiality procedures. In order to comply with federal guidelines, all records related to human subject activities (including signed consent forms and collected data) approved by Expedited review (Form B) or Full Board review (Form C) must be retained for at least three years after completion of your research. These records must be accessible for inspection by the IRB, authorized

representatives of Le Moyne College, any relevant granting institution, and the federal Department of Health and Human Services. Retention of data is also a good way to protect the researcher against charges of research misconduct. For those researchers who do not remain at Le Moyne College for three years after their research is completed, you should indicate which individual or college department will store your research records after you leave. In all cases, this section of your RO should provide the relevant information to enable the IRB to know the method and location of storage should access to them become necessary. Applications approved for Exempt Status (Form A) should state what will become of the collected data after the completion of the study.

Indicate how the data collected will be presented in the final product to minimize the risk of disclosing identities if that is a potential risk. Even when names are not linked to specific data, there is always a possibility, however remote, that a subject's identity could become known based upon the specific content of their response and/or the number and type of subjects who participate.

The IRB needs to know who will have access to the results and/or see the final product. This would normally include readers of a thesis as well as any subjects or their supervisors who may receive the study's results.

Benefits and Risks

Assess the potential benefits of the investigation for other researchers studying your topic, your field of study, and for society in general. Summarize your view of the expected benefits versus the potential risks for this project.