Institutional Review Board

Policies and Procedures

Fall 2022

Table of Contents

I. Institutional Review and Approval

All research conducted at Le Moyne College, or under its sponsorship at another location, involving human subjects (participants) which is not explicitly determined to be exempt (see below), must be reviewed and approved by the Institutional Review Board for the Protection of Human Subjects (hereafter referred to as the IRB). Review is also required for research carried out under the sponsorship of an institution other than Le Moyne College, even if the research has already been approved by the IRB at the sponsoring institution or elsewhere.

These policies covering all human subjects research at Le Moyne College result from:

1. The College's self-imposed commitment, based on its fundamental mission and values, to equally safeguard the rights and welfare of human participants in all instances of research under its sponsorship and to serve as their protector on behalf of the community of persons of which the College is a part.

2. The desire of the College to comply with federal regulations concerning the protection of human research participants and the establishment of such a board. (See Title 45, Part 46 of the Code of Federal Regulations – CFR.) The College has also signed an agreement with the New York State Department of Health that requires all human subjects research to be conducted in compliance with these federal regulations, whether or not the research is funded by an agency of the federal government.

3. The recognition that professional journals and other media of professional communication require that published reports based on human subjects research have IRB approval.

4. The need for the College to reasonably manage institutional risk.

The IRB, whose goal is the safeguarding of the rights and welfare of individual research participants, provides an independent determination concerning whether research participants are placed at minimal risk (defined below) or greater than minimal risk; and, if greater than minimal risk is involved, to assure that:

1. The risks to the research participants are substantively outweighed by the sum of the benefits to the participants and the importance of the knowledge to be gained, so as to warrant a decision to allow a participant, who has been properly informed of the potential risk (see discussion of informed consent below), to accept such risk.

2. Legally effective informed consent will be obtained by adequate and appropriate means.

3. The conduct of the activity will be reviewed at timely intervals.

Research covered by this policy that has been approved by the IRB may be subject to further review by the officials of the College. (For example, in the case of application for external funding see Le Moyne College Policies and Procedures for External Funding.) However, those officials may not approve the research if it has not been approved by the IRB or if written assurances have not been provided that it will be submitted for review at the next scheduled IRB meeting.

II. Definitions

Activities within the scope of the IRB's responsibilities include research, development, and related activities which would normally be construed as biological, behavioral, or psychological investigations involving human subjects. Included are studies involving not only adults and children, but also investigations of prenatal life. Research involving tissue from a fetus must be conducted in accordance with any applicable federal, state, or local laws and regulations regarding such activities. Studies or procedures utilizing organs, tissues, or bodily fluids of a human being are also included, as are the use of graphic, written, or recorded information about individuals even when this information has been collected by other institutions or investigators.

For the purpose of the IRB review, Le Moyne College stipulates the following definitions:

Human Subject - A human subject is defined as a living individual about whom an investigator conducting research (a) obtains information or biospecimens through intervention or interaction with the individual and uses, studies, or analyzes the information or biospecimens; or (b) obtains, uses, studies analyzes or generates identifiable private information or identifiable biospecimens.

Research – Research is any systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalized knowledge. Activities which meet this definition constitute "research" for the IRB, whether or not they are considered research in other contexts. Excluded from this definition are activities whose sole purpose is instructional; also excluded are activities whose purpose is related to routine course or program development.

Research activity would normally include the following:

1. Persons or programs requesting extramural (federal, state, or private) funds for research or training.

2. Individual faculty members as well as members of the staff and administration engaged in research as part of their professional role within the College or as part of their job assignment.

3. Students doing research which is of the nature of a thesis or capstone course and is part of a degree program.

4. Students performing research as part of an independent study, departmental honors, or the Integral Honors program.

5. Individuals (including students or persons from outside the College) other than faculty, staff, or administration, conducting research at Le Moyne College.

6. Students performing human subjects research for a course that is of a particularly sensitive nature or involves more than minimal risk.

Minimal Risk – Minimal risk exists when the probability of and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or

psychological examinations or tests (see 45 CFR 46.102 [i]). (Investigators have the obligation to request a clarification by the IRB when there are any questions regarding whether planned activities or procedures involve only minimal risk.)

IRB Approval – Approval means that the IRB has reviewed the research and that the research may be conducted at Le Moyne within the policies and procedures outlined in this document and within the constraints of other institutional and federal requirements. IRB approval does not necessarily imply approbation for the research itself.

III. IRB Membership

The IRB will be constituted with a minimum of eight members, to be appointed as follows:

1. The Provost will appoint two co-chairs of the IRB from within faculty or administrative ranks of the College. If one or both co-chairs are from administrative ranks, the Provost will appoint additional faculty members so that the Board has a total of five faculty members, as outlined in #3 below.

2. The Provost will appoint to the IRB a qualified person from outside the College community who is not part of the immediate family of a person affiliated with the College.

3. The Provost will appoint three faculty members to the Committee, in addition to the faculty co-chairs. If one or both of the co-chairs are from the administrative ranks, the Provost will appoint additional faculty members so that the Board has a total of five faculty members-representing at least four of the following six academic areas of the College: Humanities, Social Sciences, Business & Management, Natural and Quantitative Sciences, Education, and Health-related professions.

4. Upon the recommendation of faculty, department chairs, the Vice President for Student Life, and the three Academic Deans, the Provost will appoint a student to the IRB. The student may be an undergraduate or graduate student and must have completed the CITI training course in his/her discipline.

5. Upon the recommendation of the Vice President for Student Life, the Provost will appoint a member of Student Life's professional staff who has at least a masters degree. The IRB shall be sufficiently qualified through the experience, expertise, and diversity of its members, including their racial, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human research participants. In addition to possessing the professional competence necessary to review specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. Every nondiscriminatory effort will be made to ensure that the IRB does not consist entirely of men or entirely of women.

IRB members are ordinarily appointed to two-year terms and may be reappointed for two additional terms when their initial term expires. The term of any given IRB will run from the first day of the Fall semester of each academic year to the last day prior to the start of the next academic year. Half of the initial appointees to the IRB shall be appointed for one-year terms, so that in the years that follow the establishment of the IRB a maximum of only half of the IRB membership will be replaced in any given year.

If the IRB regularly reviews research that involves a protected category of participants, such as children, prisoners, or mentally disabled persons, consideration shall be given in the appointment process to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these participants.

The IRB may, at its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote on the IRB.

Procedures followed by the IRB for review and approval of research involving human subjects are described in detail on the following pages of this document.

IV. Scope of IRB Review

The following items are required for all applications sent to the IRB regardless of whether the researcher is applying for Exempt Status, Expedited Review, or Full Formal Review:

- Detailed Research Outline (see attachments 4 and 5)
- Appropriate Informed Consent Form (see attachments 7-10)
- Written recruitment materials (fliers, emails, etc.)
- Any surveys, interview questions or related materials used in the research

1. Research Exempt from IRB Oversight

Investigators conducting human subjects research exempt from IRB oversight shall give notice to the IRB chairpersons of such research on Form A: Notice of Exempt Research. Form A may be downloaded from the IRB website. Form A will require a statement that the research is in one of the following categories:

a) Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

b) Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met: (i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects; (ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or (iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and the IRB conducts a review to make the determination that there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

c) Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met: (i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects; (ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or (iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and the IRB conducts a review to make the determination that there

are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

d) Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met: (i) The identifiable private information or identifiable biospecimens are publicly available; (ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects; (iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated by HIPAA; or (iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with relevant privacy protections.

e) Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads, and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs.

f) Taste and food quality evaluation and consumer acceptance studies: (i) If wholesome foods without additives are consumed, or(ii) If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

g) Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if the IRB conducts a limited review and makes the determinations that: (i) Broad consent for storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens was obtained; (ii) Broad consent is appropriately documented or waiver of documentation is appropriate;

and (iii) If there is a change made for research purposes in the way the identifiable private information or identifiable biospecimens are stored or maintained, and there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

h) Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met: (i) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained; (ii) Documentation of informed consent or waiver of documentation of consent was obtained; (iii) The IRB conducts a review and makes the determination that the research to be conducted is within the scope of the broad consent and there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data; and (iv) The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

2. Expedited Review

The IRB may review some research through an expedited review procedure, if the research involves no more than minimal risk and is included in the list of research activities provided below. This procedure is initiated by the filing of an Application for Expedited Review (Form B), which can be downloaded at the IRB website, and the review may be carried out by the IRB Chairpersons or by one or more experienced reviewers designated by the Chairpersons from among members of the IRB. In reviewing the research, the reviewers may exercise all of the authority of the IRB except the reviewers may not disapprove the research. A research activity may be disapproved only after review in accordance with the full formal review procedure set forth below. The Chairpersons shall inform all IRB members of research proposals approved under the expedited review procedures.

Research activities involving no more than minimal risk and in which the only involvement of human subjects will be in one or more of the following categories (carried out through standard methods) may be reviewed by the IRB through the expedited review procedure. (Please note that instances a) through e) are more relevant to Le Moyne College) :

a) Moderate exercise by healthy volunteers.

b) The study of existing data, documents, records, pathological specimens, or diagnostic specimens, if the individuals from whom the data collected are identifiable.

c) Research on individual or group behavior or characteristics of individuals, such as studies of perception, cognition, game theory, or test development, where the investigator does not manipulate subjects' behavior and the research will not involve stress to subjects.

d) Collection of: hair and nail clippings, in a non-disfiguring manner; deciduous teeth; and permanent teeth if patient care indicates a need for extraction.

e) Collection of excreta and external secretions including sweat, uncannulated saliva, placenta removed at delivery, and amniotic fluid at the time of rupture of the membrane prior to or during labor.

f) Recording of data collected from subjects 18 years of age or older in the course of noninvasive procedures routinely employed by professionally certified/licensed individuals in the clinical practice of medicine,psychology and social work. This includes the use of physical practice sensors that are applied either to the surface of the body or at a distance and do not involve input of matter or significant amounts of energy into the subject or an invasion of the subject's privacy. It also includes such procedures as weighing, testing sensory acuity, electrocardiography, electro-encephalography, thermography, detection of naturally occurring radioactivity, diagnostic echography, and electroretinography. It does not include exposure to electromagnetic radiation outside the visible range (e.g. x-rays, microwaves.)

g) Collection of blood samples by venipuncture, in amounts not exceeding 450 milliliters in an eight-week period and no more often than two times per week, from subjects 18 years of age or older and who are in good health and not pregnant

h) Collection of both supra- and subgingival dental plaque and calculus, provided the procedure is not more invasive than routing prophylastic scaling of the teeth and the process is accomplished in accordance with accepted prophylastic techniques.

3. Full Formal Review

Application for full formal review may be made to the IRB through the submission of a completed "IRB Form C: Application for Review of Research," a Research Outline (described below) and an informed consent form (see Section VIII), unless the investigator believes the proposed research meets the criteria for exemption from formal review or expedited review. A copy of Form C can be downloaded from the IRB website. A new application for review is required for each research project that differs significantly in terms of procedures or subject populations from a previously approved application.

The ultimate determination of whether subjects are at greater than minimal risk and therefore require full formal review can be made only by the IRB. If, however, the investigator believes subjects will be placed at more than minimal risk (as defined above), then the IRB must approve the Research Outline and the required informed consent form to be used. The IRB must approve both the form and the procedure by which consent is obtained for any study involving children (under 18 years of age) and other vulnerable populations, no matter what the condition of risk.

Researchers intending to conduct studies in a normal educational setting with children under 18 years of age may submit a Form A application (Research Exempt from Continuing IRB Oversight) if it involves educational tests, observation of public behavior, or normal educational practices that are not likely to adversely affect students' opportunity to learn or the assessment of educators. Research with children may not be exempted when it involves interviews with children, surveys of children, or observation in which the researcher participates in the activities observed.

The procedures necessary for a proper informed consent are described below. Examples of approved informed consent forms for adult subjects and parents/guardians of minor subjects as well as detailed guidelines for consent forms (attachments 7-10), may be downloaded from the

IRB website. When reviewing research proposals, the IRB is primarily interested in safeguarding the rights and well-being of the human subject and in assessing the ethical implications of the proposed procedures.

When reviewing research descriptions, the IRB may pass judgment on "research design", but only to the extent that such design affects the rights or well-being of human subjects. If the IRB's analysis reveals serious flaws in the research design that influence the risk/benefit ratio of the proposed research activity, the IRB Chairpersons or an experienced member of the IRB will consult with the investigator with the goal of clarifying the concern and resolving it. For those reasons, it is essential that the research be described to the IRB in a manner that allows adequate review of all these aspects of the research.

The IRB recommends that research descriptions adhere to the following outline. Detailed guidelines for the Research Outline are provided as attachments 4 and 5 at the end of this document.

a) Rationale and Aims – This includes 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 the study? What, in particular, is expected to the found or learned from this study?

b) Methods and Procedures – A clear and full disclosure of the methods and procedures, including necessary debriefing, used to conduct a study is absolutely necessary to secure adequate review of a research proposal. Any protocol submitted for review that is of insufficient clarity or lacking in the reporting of details necessary for a fair and complete review will be returned to the investigator without review and with a request for revision.

c) Subject Population – Describe the subject population, stating 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.

d) 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 that create certain risks, explain why these methods are used and not others. What alternative methods are available?

e) Informed Consent Procedures – Outline the procedures for obtaining informed consent, including how and where informed consent will be obtained. A copy of the informed consent form to be used must accompany the application.

f) Safeguarding Against Risks – Describe particular procedures (e.g. proper screening of risk prone individuals, availability of psychological or medical aid, methods for detecting illness, etc.) which will be taken to safeguard the subjects.

g) Benefits and Risks – Assess the potential benefits of the investigation for the subject and for society in general. Summarize your view of the risk/benefit ratio for this particular investigation.

V. Operation of the IRB

1. Meetings

The IRB Chairpersons will schedule monthly meetings throughout the academic year and convene them if proposals requiring review have been submitted or if other business requires discussion. It is also the responsibility of the IRB Chairs to monitor the IRB email account for applications during the summer months and to assure that the IRB personnel are available throughout the summer to review Full Formal applications (Form C). Any Le Moyne investigator who anticipates submitting a proposal for funding to an external organization that requires IRB approval should provide substantial prior notice (at least four to six weeks) of this fact to the IRB Chairpersons so that an IRB meeting may be scheduled with sufficient time to allow the investigator to meet the granting organization's deadlines.

In special circumstances, the IRB may conduct business via telephone, secure computer-based conferencing or mail. The times of all IRB meetings are to be posted on the IRB web page. Changes in times and/or dates of the meetings will be communicated to all concerned.

2. Who May Submit a Proposal for Review

A review and approval of research activities will be made by the IRB only for studies sponsored or supervised by members of the faculty, staff, or administration of Le Moyne College. In those instances where individuals from an institution other than Le Moyne College wish to conduct research on its campus, a faculty member, staff person or administrator of the College must sponsor the application to the IRB.

3. Required CITI Training

The IRB will maintain a database of individuals who have up-to-date completion reports for the CITI course relevant to their areas of research or administrative interest. All investigators and sponsors listed on an application to the IRB must have current completion reports before participating in research with human subjects. They will remain valid until the individual must take a refresher course, normally four years after initial course completion, which is required for maintaining certification. College administrators with IRB oversight responsibilities and members of the IRB must also have current completion reports.

4. Student Research

Students attending Le Moyne College are bound by the same procedures and policies as the faculty, staff, and administration. Moreover, no applications to the IRB from a student will be reviewed unless sponsored by a faculty member, staff person or administrator familiar with the student and the proposed activity. Specific guidelines for the review and approval of student research are presented below.

5. Deadline for Submission of Applications

All Form C applications to the IRB must be submitted at least one week prior to the date of the IRB meeting. Investigators whose applications are received too late to permit proper review may expect that their proposals will be deferred until the next regularly scheduled IRB meeting. Individuals unable to comply with this deadline should contact the Chairpersons of the IRB.

Form A and Form B applications may be submitted at any time and are reviewed by the co-chairs in the order that they are received.

6. Review and Approval

Specific review and approval procedures of the IRB are as follows:

a) All researchers must submit their applications to the IRB email account at irb@lemoyne.edu. They must include the appropriate Form A, Form B, or Form C document, the Research Outline, the Informed Consent Form, and any other materials related to their research that will be used with participants during the study (e.g., recruitment materials, surveys, interview questions, etc.).

b) Upon the request of the IRB, the investigator may be asked to provide additional information or to meet with the Board to provide additional information or to meet with the Board to present a more complete explanation of risks and protection for the research participants. Any investigator may ask to appear before the Board to describe the proposed research.

c) The Research and Development Committee (R & D) should assure that funding for proposals approved by R & D involving human research participants that require IRB approval will not be released until this approval has been obtained by the researcher.

d) In cases where it is deemed necessary by the IRB, consultants to the IRB may be asked to comment on a proposed research activity.

e) A necessary quorum for the IRB to consider a proposal is a majority of the total membership, including at least one member whose primary concerns are in non-scientific areas. No IRB may have a member participate in the board's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

f) The IRB will decide by a majority of the members present:

   i) to approve the proposal
   ii) to approve the proposal with restrictions or conditions
   iii) to defer the proposal, pending changes in the application or receipt of additional information from the investigator or consultants to the IRB
   iv) to disapprove the proposal

g) Minutes will be taken at all IRB meetings.

h) Records, including minutes of meetings, applications and their supporting materials, consultants' reports, IRB correspondence and other official materials related to the work of the IRB will be retained by the IRB for a period of three years after the review of projects rejected by the IRB or the completion of projects that have received IRB approval. Electronic files of all applications and meeting minutes will be stored on the Google Drive.

i) The IRB Chairpersons will inform the principal investigator in writing of the decision of the Board within seven (7) calendar days of full formal review:

j) If changes are recommended by the board, the IRB Chairpersons or designated members will communicate these in writing to the investigator.

i) The IRB chairpersons or designated member will be responsible for review and approval of the investigator's submitted changes.

ii) If the investigator deems it necessary to make further changes, these can be submitted to the Chairpersons or designated IRB member for review and approval.

iii) If there are changes in the study which the Chairpersons or designated board member feel may change the level of risk to research participants, the investigator will be requested in writing to submit the proposal to the full board for further review.

iv) If the IRB decision is to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.

k) Adverse decisions may be appealed by requesting review of the proposal. Appeals will be heard only when the proposal has been revised and/or additional information has been provided.

l) The IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with IRB requirements or that has been associated with unexpected harm to participants. A list of the reasons for any suspension or termination will be provided to the investigator, all appropriate department heads, deans, and the Vice President for Institutional Advancement and the Vice President for Finance and Planning in the case of sponsored research.

m) It is the responsibility of investigators who have received IRB approval to provide reports to the IRB of any "exceptional occurrences" that may influence the IRB's initial determination that the research merited IRB approval.

7. Continuing Review

If a Form C approved project will last longer than twelve months, the investigator must file a short Application for Continuing Approval (see attachment 12) one month prior to the end of each twelve-month period. Continuing Aproval is not required if the project has progressed to where only data analysis is being conducted The IRB co-chairs or administrative support staff will contact researchers by email when this form is due. In the case of grant applications for which continuing applications must be submitted yearly, the continuing application must be submitted to the IRB to conform with continuing review policy.

8. Changes to an IRB Approved Project

If changes in the protocol are to be made to any type of approved or exempt research project (Form A, B or C), the investigator must submit a Request to Change an Approved Study (see attachment 11) to the IRB. The IRB must approve all changes before they are implemented, unless immediate changes must be made to protect participants from imminent grave harm or risk. In such cases, the IRB must be notified promptly of such changes.

9. Project Closure

Upon completion of all Form C approved research projects, this Project Closure Form must be submitted to the Institutional Review Board (see attachment 13).

10. Maintenance of Forms and Records

Electronic files of all applications (including non-final and final drafts, stamped approval letters, consent forms, and recruitment materials) will be stored on the Google Drive. Meeting minutes will also be stored on the Google Drive.

The IRB web site will have all relevant information and forms for researchers, administrators, and the public including: information regarding IRB membership, meeting dates, and application submission procedures; all necessary forms, guidelines for preparing an application, and sample consent forms; the IRB Policies and Procedures document; and additional information and links related to human research protections.

11. Methods of Communicating with Researchers and Subjects

From the time a study is submitted to the IRB for review until it is formally closed, and if any issues or complaints arise after it is closed, there are three ways that researchers and participants can contact the IRB:

- By email: irb@lemoyne.edu. This account is monitored on a daily basis by the Co-Chairs and the administrative assistant for the IRB. All routine business is carried out via this email account.
- By phone: 315-445-4573. This number reaches the administrative assistant for the IRB.
- By mail: Office of the Provost, Le Moyne College, 1419 Salt Springs Road, Syracuse, NY 13214.

Routine business involves the sending of initial or revised applications to the IRB for review as well as the responses from the IRB to researchers. All such correspondence and all project approval materials (e.g., stamped approval letters, consent forms, and flyers) are sent by the IRB to researchers via email.

As indicated on all project consent forms, research participants are encouraged to contact the IRB if they have questions or concerns about their rights as a research participant or if they have complaints about the conduct of the researcher during the project or after it is completed. Participants may use the communication method of their choice. Unless the participant agrees otherwise, all correspondence between a research participant and the IRB will be confidential.

VI. Student Research

A student intending to do research involving human subjects as a part of an individual project (i.e. undergraduate honors thesis, graduate master's thesis, doctoral dissertation, or independent research) should discuss the project with his or her major advisor.

1. If it is decided that the project is exempt from IRB review, the student must submit a Form A application, a Research Outline, an Informed Consent Form, and all related materials used in the research. The IRB will make the final determination on whether or not the project will be granted Exempt Status.

2 If it is decided that the project is not exempt from review and involves no more than minimal risk, the student and advisor must <u>together</u> complete IRB Form B requesting expedited review and submit this application to the IRB. The application must include a Research Outline, an Informed Consent Form, and all related materials used in the research.

3. If it is decided that the project <u>may</u> involve more than minimal risk, then the student and the advisor shall <u>together</u> prepare a description of the project in the manner described above and submit the full application to the IRB.

In all cases the applications should be submitted to the IRB email account at irb@lemoyne.edu.

VII. Course Related Research

When the classroom activity is strictly for pedagogical purposes and is not intended to contribute to generalizable knowledge or will not result in publications, public presentations, or posting on any type of electronic media, then the project is generally not subject to IRB review.

However, course-related research is subject to IRB review if it involves human subjects and meets one or more of the following criteria:

1. The research is <u>not</u> a routine procedure that is employed on a regular basis in the course.
2. The research involves more than minimal risk.
3. The research includes topics of a sensitive nature.*
4. The research includes minors or other protected populations as participants**
5. The research is required for a degree: capstone course, Honor's thesis, Master's thesis, Doctoral dissertation.

*Sensitive Information – Examples include, but are not limited to:

- Information relating to an individual's psychological well-being or mental health
- Information relating to sexual attitudes, preferences, or practices
- Information relating to the use of alcohol or drugs
- Information relating to illegal behavior
- Information that if released could reasonably place the individual at risk of criminal or civil liability or be damaging to the individual's financial standing, employability, or reputation
- Information that would normally be recorded in a patient's medical record and the disclosure could reasonably lead to discrimination, stigmatization, etc.

**Protected Populations – Examples include, but are not limited to:

- Children/Minors (under the age of 18)
- Prisoners (including non-publicly available secondary data)
- People with diminished capacity to give consent
- Mentally or physically challenged individuals

In all cases requiring IRB review, the appropriate Form (A, B, or C), a Research Outline, Informed Consent Form and related research materials must be submitted to the IRB. Approval given to course related research projects, i.e. those projects routinely carried out by students as part of their research methods training, shall remain in effect for <u>three years</u> unless significant changes have occurred that may influence the IRB's initial assessment. In this case, it is the responsibility of the instructor to communicate this information concerning the change(s) to the IRB in a timely manner.

Faculty teaching courses (and their students) with projects involving human subjects that require IRB review must complete the appropriate CITI training course for their area of research and ensure that such projects are conducted in accordance with IRB standards.

VIII. Informed Consent

In all research activities, the informed consent of each of the participants must be obtained by the investigator; or, in the case of those not able to give consent (e.g. children, mentally disabled), consent must ordinarily be obtained from their guardians or legal representatives. A copy of the document giving informed consent should ordinarily be given to the person giving consent. The IRB must approve all consent documents and copies of such are to be kept on file by the IRB. Any exception to the use of these provisions must be obtained from the IRB explicitly. The informed consent document should inform subjects, or research participants, in clear and non-technical language of:

1. The fact that the study is research.

2. The purposes of the research.

3. The expected duration of the subject's participation.

4. The procedures to be followed, and an identification of those which are experimental.

5. Any reasonably foreseeable risks or discomforts.

6. The benefits to the subject or to others which may reasonably be expected from the research.

7. Appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.

8. The extent, if any, to which confidentiality of data and privacy of subjects will be maintained.

9. For research involving more than minimal risk, whether any compensation and whether any medical or other treatments are available if injury occurs.

10. Who to contact for answers to pertinent questions about the research, subjects' rights, and research related injuries to subjects.

11. The fact that participation is voluntary and that the subject may withdraw his or her consent at any time without penalty or loss of benefits.

There are three procedures which may be used to obtain informed consent:

1. The subject or subject's legal representative signs a written consent document, which embodies the eleven elements above.

2. The subject or legal representative signs a document indicating that the subject had the above eleven elements explained to him or her orally, and that s/he understands this oral description and agrees to participate in the activity described. In this case, however, an auditor-witness to the oral presentation must be present. A written summary of the oral presentation must be submitted to and approved by the IRB. A copy of this presentation is to be retained by the IRB.

3. In the case of online surveys, the first page of the survey must contain the usual consent form which the subject can read before making a fully-informed decision about whether or not to participate in the research. If the subject wishes to participate, s/he checks a box that accompanies a statement in which the subject confirms that s/he has read the consent form, understands it, and agrees to participate in the study. If the subject does not wish to participate, s/he should not be able to access the next page, on which the survey would begin. In all cases, responses from subjects who did not check the consent to participate box may not be used in any of the researcher's subsequent work. A full description of IRB policies and procedures when using online surveys is provided in attachment 6.

There may be cases in which the use of these procedures for obtaining informed consent may be considered inappropriate by the investigator because it would adversely affect the research design or procurement of valid results. Accordingly, modifications to the above informed consent procedures can be recommended to the IRB. The IRB may approve an informed consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirements to obtain informed consent <u>provided the IRB finds and documents that all of the following conditions exist:</u>

1. The research involves no more than minimal risk to the participants.

2. The waiver or alteration will not adversely affect the rights and welfare of the participant(s).

3. The research could not practicably be carried out without the waiver or alteration. When using private information or identifiable biospecimens, the research could not practicably be carried out without accessing or using such information or biospecimens in an identifiable format. Non-identified information should be used whenever possible to respect participants' interests in protecting the confidentiality of their information and biospecimens.

4. Whenever appropriate, the participant(s) will be provided with additional pertinent information after participation.

Other cases when the IRB may approve an informed consent procedure which does not include, or which alters, some or all of the elements of informed consent, or waive the requirements to obtain informed consent are:

1. If the research involves children under 18 years of age in an educational setting, and if the criteria in the paragraph above regarding modifications of normal informed consent procedures are satisfied. The researcher may request that the Board consider approving a consent procedure for any student as long as their parent or guardian did not return a permission form which stated that their child was not permitted to participate in the study. That is, unless a parent or guardian puts in writing that their child is not permitted to participate, the researcher may have participants under the age of 18 if the Board determines that it is appropriate. The Board would require that the researcher follow the usual processes of seeking permission from all parents or guardians using an approved permission form and providing students with an opportunity to give assent (or not) when presented with participation in the study.
2. If the participants or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, the research presents no more than minimal risk of harm to participants, and there is an appropriate alternative mechanism for documenting that informed consent was obtained. In cases

such as these, the investigator must submit a written justification and explanation with their application. Modifications will be considered on a case-by-case basis and must be approved by the full IRB prior to the implementation of the proposed research. This approval must be recorded in the board's minutes if a Full Formal Review is required.

Please see Attachment 7 of these Policies and Procedures and the Adult Consent Form Instructions posted on the **Forms** page of the IRB website for additional material on the information that must be provided to research participants on the consent form.

Broad Consent: A researcher may apply for approval of broad consent regarding future use of collected data that contain identifiable private information and/or identifiable biospecimens. **If applicable, the application for broad consent should be included as part of the standard adult research participation consent form.** Researchers can use de-identified information and de-identified biospecimens for secondary research without getting a participant's broad consent as long as the secondary research project has been approved by the IRB. However, if a participant is asked to provide broad consent and refuses, that participant's data may not be used for any future secondary research project that relies on broad consent, nor can the researcher apply for a waiver of informed consent for said project. Please see Attachment 9 of these Policies and Procedures for additional material on the use of broad consent and the information that must be provided to research participants on the broad consent form.

Waiver or Alteration of Consent in Research Involving Public Benefit and Service Programs Conducted by or Subject to the Approval of State or Local Officials: In order for the IRB to waive or alter consent for these types of research, the researcher must document that: i. The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine: a. Public benefit or service programs; b. Procedures for obtaining benefits or services under those programs; c. Possible changes in or alternatives to those programs or procedures; or d. Possible changes in methods or levels of payment for benefits or services under those programs; and ii. The research could not practicably be carried out without the waiver or alteration.

IX. Responsibilities of Investigators

1. Familiarize themselves with these guidelines and those on the IRB webpage on the Le Moyne College website, and to discuss with members of the IRB any questions regarding proposed research activities.

2. Successfully complete the CITI Program training course in their field of research and provide documentation of training to the IRB. To fulfill this requirement, researchers and mentors should attach a copy of their completion report with their application to the IRB. Administrators should send a copy of their completion report to irb@lemoyne.edu.

3. Submit either an adequately prepared IRB Form A, Form B, or Form C to the IRB for each research project involving human subjects. In all cases, a Research Outline, Informed Consent Form and all related research materials must be included in the application. All forms and instructions can be found on the IRB web site.

4. Notify the IRB and the departmental chairpersons of any injury – physical, psychological, or social – suffered by a research participant because of his or her participation in a research activity.

5. Submit an Application for Continuing IRB Approval if the research was approved after a full formal review and extends beyond a twelve-month period.

6. Submit a Request to Change an Approved Study if the researcher intends to change an IRB approved study. This applies to all studies including those granted Exempt Status as well as those approved after an Expedited or Full Formal Review.

7. Submit a Project Closure Form upon the completion of a study approved after a Full Formal Review.

8. Make provisions to keep adequate records, documents, and executed informed consent forms related to IRB approved research for at least three years following the completion of the project or activity.

9. Take proper measures to ensure confidentiality and security of all information obtained from the participants.

10. Take proper measures to ensure, where appropriate, that research activities involving human subjects are in compliance with the applicable federal and state regulations related to environmental risks as administered by the College's Chemical Hygiene Officer.

X. Implementation and Operation of the IRB

It is the responsibility of the Provost to:

1. Implement these policies and procedures.

2. Provide the administrative and clerical support necessary for the proper functioning of the IRB.

3. Provide a secure repository for the records of the IRB as required by these policies and procedures.

XI. Enforcement of the IRB Policies and Procedures

Other than denying or withdrawing IRB approval for a research project, the IRB has no authority to impose sanctions. If the IRB determines that an infraction of its policies has occurred and no resolution of the matter can be reached informally by the IRB acting through its co-chairs with the researcher, the IRB will forward a report of its finding that an infraction of the IRB policy has occurred to the departmental chair or other College administrator most directly responsible for the supervision of the researcher suspected of a policy infraction. The administrator will act upon this report by following existing procedures pertaining to the administrator's unit of the college.

XII. Guidelines for Conducting Internal Audits of IRB-approved Human Subjects Research

The intent of internal IRB audits is to verify researcher compliance with approved study protocols, federal guidelines, and Le Moyne College Policies and Procedures for protecting participants in human subjects research. IRB audits are supervised and conducted by the IRB co-chairs and other members of the IRB as necessary.

Requirements for implementing a not-for-cause Internal IRB Audit

1. The auditor should obtain a list of all Form B and Form C studies approved over the past two years. For each study, tabulate the following: IRB project number, title, name and email address of the investigator, department or program of origin, date of approval, and the date of the last audit.
2. On an annual basis, from the list of approved studies, the IRB co-chairs will select at least one faculty study and at least one student study from different departments to undergo a not-for-cause audit.
3. Selected studies should not have been audited over the past year. In addition, the not-for-cause faculty audit may be deferred in a given year if every active faculty researcher has been audited once in the preceding five years.

Requirements for implementing a for-cause Internal IRB Audit

1. For-cause internal audits are performed in response to particular concerns about an ongoing or completed IRB study. Concerns which may prompt these audits include, but are not limited to, the following:
   a) Complaints made by a research participant, a parent or guardian of a research participant, a member of the research team, or any employee of the College.
   b) Knowledge of concerns expressed by other College committees, federal agencies, or any organization connected to the activities of the research team or associated with the research participants. Examples of the latter include employers of participants or those legally responsible for the welfare of participants during the research team's interactions with the participants.
   c) Projects with documented unanticipated problems, noncompliance, or deviations from approved research protocols.
2. The audit process should begin immediately after a credible complaint or documented concern has been received by the IRB or its supervising institutional officer, the Provost, or his designated administrative representative.

Le Moyne College Audit Report Form

IRB #:
Title:
Principal Investigator:
CITI Training: ☐ Current ☐ Not Current
Sponsor: ☐ N/A
Sponsor CITI Training: ☐ Current ☐ Not Current ☐ N/A
Date of Audit:
Site of Audit:
Review Level: ☐ Exempt ☐ Expedited ☐ Full Board
List all other Co-Investigators/Key Personnel on the project:

Name	Role	CITI Certification
		☐ Current ☐ Not Current
		☐ Current ☐ Not Current
		☐ Current ☐ Not Current
		☐ Current ☐ Not Current
		☐ Current ☐ Not Current

Original Approval Date:
Last Renewal Date:
Expiration Date:
# of Subjects Approved:
# of Subjects Enrolled:
# of Subjects Withdrawn:

Consent Process:

Was a written Consent Form required?
☐ Yes ☐ No ☐ N/A

If required, was an IRB approved/stamped Consent Form available, signed, and dated by each subject?
☐ Yes ☐ No ☐ N/A

If required, was it the correct approved/stamped version? (Check Expiration Date)
☐ Yes ☐ No ☐ N/A

Was a verbal consent process required (not written)?
☐ Yes ☐ No ☐ N/A

If verbal, was the approved script used?
☐ Yes ☐ No ☐ N/A

Was another type of consent process required/approved?
☐ Yes ☐ No ☐ N/A

If other, was the IRB approved process followed and documented?
☐ Yes ☐ No ☐ N/A

Comments:

Other Subject Safeguards:

Was participation voluntary?
☐ Yes ☐ No ☐ N/A

Was there protection for vulnerable subjects?
☐ Yes ☐ No ☐ N/A

Was confidentiality maintained throughout the research process?

☐ Yes ☐ No ☐ N/A

Eligibility: *All inclusion/exclusion criteria listed within the protocol should be carefully checked including age, gender, race, any vulnerable populations, etc.* **Explain any deficiencies found:**

If any deficiencies/deviations were found, were they reported to the IRB in a timely manner?

☐ Yes ☐ No ☐ N/A

All subjects were eligible?

☐ Yes ☐ No ☐ N/A

Comments:

Recruitment:

Did the recruitment process follow the IRB approved protocol?

☐ Yes ☐ No ☐ N/A

Did the advertisement materials match those approved?

☐ Yes ☐ No ☐ N/A

Comments:

Unanticipated Problems: *Review all unanticipated problems claimed, reviewed, and verified.* **Explain any deficiencies found:**

Are unanticipated problems recorded in the research records?

☐ Yes ☐ No ☐ N/A

Was the IRB notified of unanticipated problems?

☐ Yes ☐ No ☐ N/A

Are complaints recorded in the research records?

☐ Yes ☐ No ☐ N/A

Was the IRB notified of complaints?

☐ Yes ☐ No ☐ N/A

Did the investigator respond to the complaints?

☐ Yes ☐ No ☐ N/A

Comments:

Recordkeeping/Security:

Were the records legible and organized?

☐ Yes ☐ No ☐ N/A

Did electronic data match the paper records?

☐ Yes ☐ No ☐ N/A

Was all required and necessary information provided?

☐ Yes ☐ No ☐ N/A

Were security measures in place to protect privacy and confidentiality (locked, coded, etc.)?

☐ Yes ☐ No ☐ N/A

Did security measures follow the approved protocol?

☐ Yes ☐ No ☐ N/A

Comments:

Audit Summary and Recommendations:

Were any project changes recommended?

☐ Yes ☐ No

Were minor project changes recommended?

☐ Yes ☐ No

Comments:

Were significant project changes recommended? (e.g., discontinuation of data collection until approved protocol implemented or a Request to Change an Approved Study needed)

☐ Yes ☐ No

Comments:

Were there major concerns requiring project suspension and full IRB review?

(Suspensions are reported to the full IRB, the researchers and sponsors, and the College Provost.)

☐ Yes ☐ No

These concerns include:

Significantly greater risk than in approved protocol:

☐ Yes ☐ No

Report of unapproved deception:

☐ Yes ☐ No

Subjects are reporting cases of documented mistreatment:

☐ Yes ☐ No

Comments:

Additional information regarding this Audit:

Audit reported and reviewed by the Le Moyne College Research Integrity Officer.

☐ Yes ☐ No ☐ N/A

Comments:

Officer's Signature: _____

Date:_____

This Audit will be presented to the Convened IRB on Meeting Date:

Auditor Name (Print):

Auditor Signature: _____

Date:_____

Auditor Name (Print):

Auditor Signature: _____

Date:_____

Others involved with this Audit:

XIII. Guidelines for Unanticipated Problems and Adverse Events

This section applies to non-exempt human subjects research conducted by researchers at Le Moyne College. It is based on guidance provided by the federal government for research supported by HHS. Specifically, it relates to the review and reporting of (a) unanticipated problems involving risks to research participants or others (**hereafter referred to as unanticipated problems**); and (b) adverse events. In general terms, only a small subset of adverse events occurring to human subjects participating in research are unanticipated problems that must be reported under federal guidelines. These standards are intended to help ensure that the review and reporting of unanticipated problems and adverse events occur in a timely, meaningful way so that participants can be better protected from avoidable harms while reducing unnecessary burden.

1. Unanticipated problem: Any incident, experience, or outcome that meets all of the following criteria:
    a) Unexpected in terms of its nature, severity, or frequency given the contents of the approved research project and the subject population being studied
    b) Related or possibly related to participation in the research; and
    c) The ongoing research places participants or others at risk of harm (physical, psychological, economic, or social) on a level higher than that which was previously known or approved

    A verified unanticipated problem may lead to required steps such as changes in research protocol, suspension of enrollment of new participants, suspension of all participant-related research procedures, or modification of informed consent documents to include a description of newly recognized risks.

2. Adverse event: Any untoward or unfavorable occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject's participation in the research, whether or not it is considered related to the subject's participation in the research. Adverse events encompass both physical and psychological harms. They occur most commonly in the context of biomedical research, although on occasion, they can occur in the context of social and behavioral research.

3. An unanticipated problem or adverse event may be reported by a participant, the relative of a participant, a person who has authority over the participant at the time of the event, a project investigator, a health care professional, or any other person who becomes aware of the problem or event.

    Upon becoming aware of any incident, experience, or outcome (even if not related to an adverse event) that may represent an unanticipated problem, the investigator should assess whether the incident, experience, or outcome represents an unanticipated problem. If the investigator determines that the incident, experience, or outcome represents an unanticipated problem, the investigator must report it promptly to the IRB.

4. Research reviewed by HHS indicates:

    a) The vast majority of adverse events occurring in human subjects are not unanticipated problems.
    b) A small proportion of adverse events are unanticipated problems.
    c) Unanticipated problems include other incidents, experiences, and outcomes that are not adverse events.

An adverse event represents an unanticipated problem when it meets the three criteria listed above as requirements for concluding that an unanticipated problem has occurred. If an unanticipated adverse event has occurred, it must be reported in a timely manner to the IRB. In the case of a federally-funded project, it must also be reported directly to the sponsoring government agency or department. If an unanticipated adverse event is associated with serious harm, the IRB has the authority to suspend or terminate the approval of a research project.

5. Content of reports of unanticipated problems submitted to IRBs:

Investigators must include the following information when reporting an adverse event, or any other incident, experience, or outcome as an unanticipated problem to the IRB:

a) appropriate identifying information for the research protocol, including the title, investigator's name, and the IRB project number;
b) a detailed description of the adverse event, incident, experience, or outcome;
c) an explanation of the basis for determining that the adverse event, incident, experience, or outcome represents an unanticipated problem; and
d) a description of any changes to the protocol or other corrective actions that have been taken or are proposed in response to the unanticipated problem.

6. IRB review and further reporting of unanticipated problems:

In all cases, the IRB co-chairs and the Provost must be notified when adverse events that are unanticipated problems occur. An unanticipated problem will be reviewed by the IRB co-chairs followed by a meeting of the full IRB. The IRB will determine whether the affected research protocol still satisfies the requirements for IRB approval under the College's policies and procedures. In particular, the IRB will consider whether risks to participants are still minimized and reasonable in relation to the anticipated benefits, if any, to the participants and the importance of the knowledge that may reasonably be expected to result.

When reviewing a particular incident, experience, or outcome reported as an unanticipated problem by the investigator, the IRB may determine that the incident, experience, or outcome does not meet all three criteria for an unanticipated problem. In such cases, further reporting to appropriate College officials, and to OHRP and the sponsoring agency or department when federal funds are involved, would not be required under College and HHS regulations.

Any proposed changes to a research study in response to an unanticipated problem must be reviewed and approved by the IRB before being implemented, except when necessary to eliminate apparent immediate hazards to research participants. If the changes are more than minor, the changes must be reviewed and approved by the full IRB. In this case, the Provost must be notified of the IRB's final decision.

Among the actions that may be taken by the IRB are:

a) Accept the report with no changes
b) Accept the report with changes to the risk/benefit ratio, the protocol, or the informed consent documents
c) Require modification of the protocol or consent(s), modification of the information disclosed during consenting, and/or re-consenting all participants with the new information

d) Defer a final response to the reportable event if significant modifications directly related to the approval criteria are required. The investigator's response must be reviewed and approved by the Full Board.
e) Require minor modifications that meet criteria for expedited review, or are explicit changes verifiable by the co-chairs
f) Request further information from the investigator
g) Increase the frequency of continuing review
h) Impose additional monitoring by the IRB
i) Halt enrollment pending receipt of further information
j) Report findings as appropriate depending on the nature of the event
k) Suspend any or all of the following activities:
    i. Screening and enrollment
    ii. Recruitment
    iii. Intervention and interaction
    iv. Follow up activities
l) Terminate IRB approval of the study according to IRB policy
m) Consider whether the event represents serious and/or continuing noncompliance

7. Reporting requirements for federally funded research:

Unanticipated problems occurring in research covered by an OHRP-approved assurance must also be reported by the institution to the supporting HHS agency head and OHRP. The IRB co-chairs are responsible for reporting unanticipated problems to the supporting HHS agency head and OHRP.

HHS regulations require *prompt* reporting of unanticipated problems to the IRB, appropriate institutional officials, any supporting department or agency head, and OHRP. The purpose of prompt reporting is to ensure that appropriate steps are taken in a timely manner to protect other participants from avoidable harm.

The appropriate time frame for prompt reporting will vary depending on the specific nature of the unanticipated problem, the nature of the research associated with the problem, and the entity to which reports are to be submitted. Le Moyne College's IRB uses the following OHRP guidelines in order to satisfy the requirement for *prompt* reporting:

a) Unanticipated problems that are serious adverse events should be reported to the IRB within 1 week of the investigator becoming aware of the event.
b) Any other unanticipated problem should be reported to the IRB within 2 weeks of the investigator becoming aware of the problem.
c) All unanticipated problems should be reported to appropriate College officials, the supporting agency head, and OHRP within one month of the IRB's receipt of the report of the problem from the investigator.

In some cases, the requirements for prompt reporting may be met by submitting a preliminary report to the IRB, appropriate College officials, the supporting HHS agency head, and OHRP, with a follow-up report submitted at a later date when more information is available. Determining the appropriate time frame for reporting a particular unanticipated problem requires careful judgment by persons knowledgeable about human subject protections. The primary consideration in making these judgments is the need to take timely action to prevent avoidable harms to other participants.

8. This subsection applies to non-exempt human subjects research conducted by investigators at Le Moyne when the research is supported by HHS. It provides guidance about procedures the College may use to file incident reports with OHRP. Incident reports included here cover reports of unanticipated problems and adverse events involving risks to participants or others.

    a) In general, these reporting requirements apply to all nonexempt human subjects research that is:

        i. conducted or supported by HHS
        ii. conducted or supported by any non-HHS federal department or agency that has adopted the Common Rule and is covered by a Federalwide Assurance (FWA) determined to be appropriate for such research; or
        iii. covered by an FWA, regardless of funding source.

    b) Federal departments or agencies other than HHS that have adopted the Common Rule may determine that the FWA is not appropriate for certain research that they conduct or support. These incident reporting requirements are not applicable to such research. In such cases, the IRB should contact the non-HHS department or agency that supports the research about reporting requirements.
    c) Information to be included in incident reports for unanticipated problems involving risks to research participants or others:

        i. Name of Le Moyne College
        ii. Title of the research project and/or grant proposal in which the problem occurred
        iii. Name of the principal investigator on the protocol
        iv. Number of the research project assigned by the IRB and the number of any applicable federal award(s)
        v. A detailed description of the problem
        vi. Actions that Le Moyne College is taking or plans to take to address the problem (e.g., revise the protocol, suspend participant enrollment, terminate the research, revise the informed consent document, inform enrolled participants, increase monitoring of participants, etc.).

    d) Time frame for reporting incidents:

        Incident reports must be sent promptly to federal agencies. As determined by the IRB, for a more serious incident, this may mean reporting to OHRP within five days. For a less serious incident, two weeks may be sufficient. It may be appropriate to send an initial report, and indicate that a follow-up or final report will follow within one month or when an investigation has been completed or a corrective action plan has been implemented.

    e) When reviewing a report of an unanticipated problem, OHRP assesses most closely the adequacy of the actions taken by the College to address the problem. In particular, OHRP assesses whether or not the corrective actions will help ensure that the incident will not happen again, with the investigator or protocol in question, with any other investigator or protocol, or with the IRB. Therefore, OHRP recommends that, when appropriate, corrective actions be applied College-wide.

9. OHRP response to incident reports

After receiving and evaluating an incident report from an institution, OHRP will respond in writing and will either state that the report was adequate or request additional information. For further information or questions on reporting, contact the Director of the Division of Compliance Oversight, 240-453-6900 or 866- 447-4777.

XIV. Guidelines for Noncompliance, Suspensions, and Terminations

(This section provides information beyond that in section V.6.l. of these Policies and Procedures pertaining to findings of noncompliance or IRB oversight that leads to project suspension or termination.)

1. Noncompliance: A generic term that is used to describe behavior that is not expected or acceptable and may or may not be intentional. Noncompliance may require action by the IRB or the College. Specific types of noncompliance include:

    a) Initial noncompliance: Failure to follow federal, state or local regulations governing human research, requirements or determinations of the IRB, or institutional policies. This definition may include action of any college employee or agent, such as investigators, research staff, IRB members, IRB staff, employees, or Institutional Officials.
    b) Serious noncompliance: An action or omission by an individual (investigator, research staff, IRB member, IRB staff, employee, or Institutional Official) that any other reasonable individual would have foreseen as compromising the rights and welfare of a research participant or others.
    c) Continuing Noncompliance: A pattern of repeated actions or omissions by an individual (investigator, research staff, IRB member, IRB staff, employee, or Institutional Official) that 1) indicates a pattern of deficiency in the ability or willingness of an individual to comply with federal regulations or IRB policy; 2) if allowed to continue could reasonably be expected to develop into serious noncompliance; or 3) recurs after a report of the activity has been evaluated and corrective action has been mandated.

Reports of alleged noncompliance or inappropriate involvement of human subjects in research may come to the attention of the IRB from different sources and by various means. For example, alleged noncompliance may come from an IRB member, an investigator, a research participant or their family members, institutional personnel, institutional committees, anonymous sources, or the public. All reports of alleged noncompliance or inappropriate involvement of humans in research are investigated by the IRB.

2. When investigating allegations of noncompliance, the process should include:

    a) Assuring the safety of human participants
    b) Developing action plans to prevent reoccurrence, and promote future compliance
    c) Educating research staff on federal guidelines, regulations, and IRB policy
    d) Reporting serious or continuing noncompliance

3. Procedures for addressing reports of noncompliance

    a) When the IRB receives a verbal or written report of alleged noncompliance, a preliminary review is conducted by the IRB co-chairs. The materials used to make the determination of serious and/or continuing noncompliance may include a description of the allegation, the entire research file, medical/research charts, interviews with research personnel, and any participant complaints. If the IRB co-chairs determine the allegation has no merit, the matter will be closed.
    b) If the co-chairs determine there is merit, the matter is scheduled for review by the Full Board. If more information is needed, the co-chairs and other IRB members will conduct an investigation. The researcher is notified in writing of the for-cause investigation (audit). The completed audit report is presented at the next Full Board meeting. It will contain a notification of noncompliance, if applicable, and all pertinent

IRB correspondence (such as IRB applications, IRB approval letters, IRB approved informed consent).

c) The full IRB reviews the materials at a convened meeting. The discussion, actions, and determinations are noted in the minutes. Upon review, the IRB determines:

i. There is noncompliance that is neither serious nor continuing. The Full Board will formulate a corrective action plan, forward it to the investigator, and require a response from the investigator.
ii. There is serious or continuing noncompliance. The IRB will report this determination to the Provost and any funding agency of the research.
iii. There is insufficient information to make a determination. In this case, the IRB will request additional information and defer a determination to a later convened IRB meeting.

d) The full Board may determine the need for the following actions, where applicable:

i. Require modification of the protocol or consent(s), modification of the information disclosed during consenting, and/or re-consenting all participants with the new information.
ii. Defer a final response to the report if significant modifications directly related to the Board's approval criteria are required. The investigator's response must be reviewed and approved by the Full Board.
iii. Require minor modifications that meet criteria for expedited review or are explicit changes verifiable by the co-chairs
iv. Verification that subject selection is appropriate
v. Observation of the informed consent process by the IRB
vi. An increase in monitoring of the research activity
vii. Request a for-cause audit of targeted areas of concern
viii. Request a status report after a specified number of additional participants participate
ix. Shorten the continuing review cycle
x. Request additional investigator and staff education focused on human research protections given by the IRB or using other sources such CITI Program training
xi. Require notification to current and/or past participants, if information about the noncompliance might affect participants' willingness to continue participation
xii. Suspend the study
xiii. Terminate the study
xiv. If the event involves research misconduct, the IRB co-chairs will report this to Provost.

4. Suspension or Termination of IRB Approval

The IRB may suspend or terminate research on any study approved by the IRB when the IRB has an indication that circumstances warrant and there is cause (such as serious and continuing noncompliance, increased or undue risk, or unexpected serious harm to participants). Examples of actions that may cause suspensions or terminations include: inappropriate involvement of research participants; impairment of the rights or welfare of participants; serious or continuing noncompliance with federal regulations or IRB policies; and new information indicating increased risk to human participants. There is a regulatory difference between suspensions and terminations.

a) Suspension of IRB Approval for Research Study: A suspension exists when the IRB temporarily or permanently withdraws approval of some or all research activities in a protocol. While suspended, the research remains under the jurisdiction of the IRB.
b) Termination of IRB Approval for Research Study: Termination takes place when the IRB permanently withdraws approval of ALL research activities in a protocol. Terminated research is no longer required to undergo continuing review and does not remain under the jurisdiction of the IRB.

5. IRB Responsibilities

Before suspending IRB approval, the IRB or individual requesting the suspension must consider whether actions are necessary to protect the rights and welfare of currently enrolled participants (such as allowing participants to continue in the research and monitoring of current or former participants). The IRB may request an ad hoc review from an independent source with expertise in the type of research being conducted or expertise in the specific area of concern. The IRB may request the development of an education plan and/or the completion of a for-cause audit. The full IRB reviews the study and determines whether circumstances warrant suspension of IRB approval. Some examples of situations that may warrant suspension are:

a) Falsification of study safety data
b) Failure to comply with prior conditions imposed in writing by the IRB
c) Repeated or deliberate failure to obtain or document informed consent from human research participants, which may include:

i. Repeated or deliberate omission of a description of serious risks of the research intervention when obtaining informed consent
ii. Repeated or deliberate failure to provide informed consent in a language understandable to the participant

d) Repeated or deliberate failure to comply with conditions placed on the study by the College, IRB, federal sponsor, or other governmental agency
e) Repeated or deliberate failure to obtain prior review and approval of new protocols and on-going human subjects research by the IRB
f) Repeated or deliberate failure to follow the signed Investigator statement or protocol (for example, by enrolling participants who do not meet inclusion criteria)
g) Repeated or deliberate failure to maintain accurate study records or submit required adverse event reports to the IRB
h) Repeated or deliberate falsification, fabrication, or concealment of study records; for example, by substituting the results of biological samples from participants who met the inclusion criteria for samples of participants who do not meet the inclusion criteria, or by fabricating participants.

6. The College may determine that suspensions or terminations associated with a particular study or an investigator are repetitive and warrant action for issues of serious and continuing noncompliance.

7. The convened IRB and IRB co-chairs are authorized to suspend or terminate research. If there is an urgent situation requiring suspension or termination of a study, the IRB co-chairs may make this determination. If the IRB co-chairs terminate or suspend a study, the full IRB must be notified of the action at the next IRB meeting. The IRB promptly notifies the investigator, in writing, of all suspensions or terminations of IRB approval. The notification letter includes the following:

a) Identifies the suspended or terminated research
b) Includes a statement of the reasons for the IRB's action
c) Requires the principal investigator to submit proposed procedures for withdrawal of currently enrolled participants with consideration of participant rights and welfare. The IRB reviews the proposed procedures. The IRB may transfer this responsibility to another investigator to ensure implementation of these procedures.
d) Requires the investigator to submit a proposed script or letter notifying all currently enrolled participants that are impacted by the suspension or termination. The IRB reviews the proposed script or letter. If follow up with participants for safety reasons is permitted/required by the IRB, participants should be so informed. The IRB may directly contact participants to effect this notification.
e) As a condition of ending suspension or termination, the IRB may require oversight by the IRB co-chairs or other IRB members.

8. Reinstatement of Suspended Research

a) Reinstatement of suspended research studies occurs after corrective actions are completed to the IRB's satisfaction. The Full Board may approve the study with or without additional restrictions (such as mandating a monitoring committee to oversee the research at designated intervals, increasing the frequency of IRB review, or observing the consent process).

b) The IRB notifies the investigator in writing of IRB suspensions and communicates corrective actions to be taken by the investigator as applicable. Research activities must cease as specified in the suspension criteria, until the IRB has granted approval for the study to resume. Suspensions are within the authority of the IRB and remain in effect until the investigator complies with all corrective actions required by the IRB. Investigators who fail to comply with IRB directives or federal or state law or regulations may be subject to administrative and/or legal action by the College.

9. Investigator Responsibilities

When the IRB has suspended, terminated, or reinstated a project, the investigator must notify any research sponsor. The investigator is responsible for notifying all affected participants of the suspension, termination, or reinstatement of the research project (by phone, letter, or in person). The subject letter or script must be submitted by the investigator to the IRB for review and approval. The investigator must continue to report adverse events, unanticipated problems involving risks to participants or others, and serious or continuing noncompliance with federal regulations to the IRB during the period of suspension or termination.

10. IRB Reporting Requirements to Federal Agencies, College Committees or Others: This section describes IRB reporting requirements for serious or continuing noncompliance, suspensions, and terminations. The following events will be reported as appropriate to College officials and/or committees in accordance with this policy and procedure:

a) Any serious or continuing noncompliance with federal regulations or the requirements or determinations of the IRB
b) Any suspension or termination of IRB approval

11. Additionally, reporting to the appropriate federal agency will also take place if one of the above events require an action such as, but not limited to:

a) Changes to the research protocol initiated by the investigator prior to obtaining IRB approval to eliminate apparent immediate hazard to participants
b) Modification of inclusion or exclusion criteria to mitigate the newly identified risks
c) Implementation of additional procedures for monitoring participants
d) Suspension of enrollment of new participants
e) Suspension of research procedures for currently enrolled participants
f) Modification of informed consent procedures to include a description of newly recognized risks
g) Provision of additional information about newly recognized risks to previously enrolled participants

12. Report Contents

The report should include the following information:

a) Title of the research project and/or grant proposal that was suspended or terminated
b) Name of the investigator(s)
c) The study number assigned by the IRB, and the number of any applicable federal award(s)
d) A detailed description of the reason for the suspension or termination
e) The actions the College is taking or plans to take to address the problem, noncompliance or suspension or termination

Reports regarding determinations of investigator or researcher continuing noncompliance, unanticipated problems involving risks to participants or others, as well as suspension or termination of IRB approval will be submitted by the IRB co-chairs, to the Provost, the investigator(s), OHRP and the appropriate federal agency if federally funded, and any non-federal study sponsor (only if the report involves suspension or termination of research or is otherwise determined by the IRB to merit reporting to the sponsor). Reports are to be distributed to the parties described above within 21 days from the determination that the event is reportable. For more serious incidents, reports may be distributed within 7 days from the time at which the determination is made.

When the investigator provides documentation that the appropriate federal agency and/or study sponsor has been notified of the event, the IRB will not submit a duplicate report.

XV. Guidelines for the College's Compliance with OHRP Oversight Procedures for Evaluating Institutions

This section applies to non-exempt human subjects research conducted by researchers at Le Moyne College. It is based on guidance provided by the federal government for research supported by HHS. Specifically, it sets forth the College's interactions with the OHRP when the latter performs compliance oversight evaluations of human subjects research that is being conducted under an FWA and is therefore under OHRP's jurisdiction. An FWA approved by OHRP commits the entire College (including administrative officials, IRBs designated in the FWA, research investigators, and all other employees or agents) to full compliance with the HHS regulations whenever the College is engaged in HHS-conducted or supported human subjects research.

1. Determination of For-Cause Oversight Evaluations
   a) OHRP conducts a for-cause evaluation when it receives substantive written allegations or indications of non-compliance with the HHS regulations. Sources of such allegations or indications of noncompliance include, but are not limited to, research participants and their family members, individuals involved in the conduct of research such as investigators and study coordinators, College officials, and research publications.
   b) Complaints may be submitted for allegations of noncompliance by mail, e-mail, or fax to OHRP's Director of the Division of Compliance Oversight, 1101 Wootton Parkway, Suite 200, Rockville, MD, 20852 (email ohrp@hhs.gov; fax (240) 453-6909). OHRP accepts complaints submitted anonymously, and asks complainants who identify themselves to OHRP whether OHRP may reveal their identity to the College.
   c) OHRP may determine that it has jurisdiction to evaluate the allegations or indications of noncompliance when the possible noncompliance involves non-exempt human subjects research that is HHS-conducted or -supported, or covered by an applicable OHRP-approved FWA. If the College, through its FWA voluntarily applies the HHS regulations to all research regardless of support, OHRP has the authority to evaluate allegations or indications of noncompliance pertaining to all research to which the FWA applies, including research that is not federally conducted or supported. If OHRP receives an allegation or indication of noncompliance related to human subjects research that is covered by an OHRP-approved FWA and is conducted or supported solely by a Federal department or agency other than HHS, OHRP will refer the matter to the other department or agency for review and action as appropriate.

2. Procedures for For-Cause Oversight Evaluations

   If OHRP initiates a for-cause evaluation, College officials and investigators will receive an initial inquiry letter informing them that it will be evaluating human subjects research protections at the College. The initial inquiry letter describes the allegations or indications of noncompliance, and potential regulatory violations. In response, the College must:

   a) Conduct an investigation of the potential noncompliance. This investigation must follow the procedures of an internal for-cause audit and provide detailed information pertaining to the allegations of noncompliance or regulatory violations in the inquiry letter.
   b) Provide a written response to the allegations or indications of noncompliance as well as submit supporting documentation (including relevant IRB and research records) by a date specified by OHRP

c) Develop and submit a corrective action plan if the investigation conducted by the College reveals any noncompliance

3. No action is taken against the College before it has an opportunity to offer information that might refute the allegations or indications of noncompliance, except in very rare circumstances where serious concerns about participant safety require an immediate suspension of research activities. In general, all questions and concerns are to be resolved before the case is closed. If OHRP feels that discussion of pertinent issues with College employees, IRB members, research investigators, or others would assist OHRP's decision making, OHRP staff may conduct interviews via telephone or videoconference or an on-site visit of the College's human subjects protection program. On-site visits also are conducted when IRB record review, or evaluation of College facilities, is relevant to OHRP's determinations, or if OHRP has serious concerns about the College's system for protecting human subjects.

4. OHRP For Cause Decision Procedures

   a) The College will receive from OHRP a determination letter pertaining to (a) the complainant's specific allegations or indications of noncompliance with the HHS regulations and (b) the College's program for protecting human research participants, including IRB operating procedures and policies. If OHRP makes determinations of noncompliance, OHRP will describe in such letters any relevant corrective actions proposed or implemented by the College and the extent to which these corrective actions adequately address the noncompliance. If the College has not proposed an adequate corrective action plan to address one or more of OHRP's findings of noncompliance, OHRP will require the College to develop and submit in writing an appropriate corrective action plan by a specified date. The College must tailor its corrective actions both to the specific facts under evaluation and to OHRP's conclusions regarding the strength of the College's program for protecting human subjects. OHRP may offer assistance in developing a corrective action plan and make recommendations for specific improvements to its human subjects protections system.
   b) If OHRP makes no determinations of noncompliance, or if OHRP makes determinations of noncompliance but also determines that the College has adequately addressed them through corrective action, OHRP concludes the evaluation and informs the College of this final outcome in writing. The College may request that the Director of OHRP reconsider any determinations resulting from a for-cause compliance oversight evaluation.

5. Not-For-Cause Compliance Oversight Evaluations

   When OHRP decides to undertake a not-for-cause compliance oversight evaluation, OHRP proceeds as follows:

   a) College officials are notified in writing that OHRP intends to conduct an evaluation of human subject protections. The College must provide to OHRP by a specified date relevant information concerning its human subjects protection program, including:

      i. IRB policies and procedures
      ii. Minutes from recent IRB meetings
      iii. A list of active IRB protocols

b) If required, the College must arrange for OHRP officials to conduct interviews with College officials, IRB members, and research investigators. The College must also accommodate OHRP requests to conduct an on-site evaluation of human subject protections at the College if initial evaluations result in evidence of noncompliance with HHS regulations.

c) Following the evaluation, the College will receive a letter containing OHRP's determinations, concerns and recommendations regarding the institution's compliance with HHS regulations with respect to its human subject protection program, including its IRB operating policies and procedures. In addition, if OHRP makes determinations of noncompliance, the letter will describe any relevant corrective actions proposed or implemented by the College and the extent to which these corrective actions adequately address the noncompliance. If the College has not proposed an adequate corrective action plan to address one or more of OHRP's determinations of noncompliance, the College must develop and submit in writing an appropriate corrective action plan by a specified date. The College must tailor their corrective actions both to the specific facts under evaluation and to OHRP's conclusions regarding the strength of the institution's program for protecting human subjects. OHRP may offer assistance in developing a corrective action plan.

d) If OHRP makes no determinations of noncompliance, or if OHRP makes determinations of noncompliance but determines that they have been adequately addressed through corrective action, OHRP concludes the evaluation and informs the College in writing of this final outcome. The College may request that the Director of OHRP reconsider any determinations resulting from a not-for-cause compliance oversight evaluation.

6. Possible Outcomes of OHRP Compliance Oversight Evaluations:

OHRP for-cause and not-for-cause compliance oversight evaluations will result in one or more of the following outcomes for the College, in accordance with OHRP's authority under 45 CFR 46.103(e):

a) OHRP does not identify any areas of noncompliance with the HHS regulations.

b) OHRP recommends improvements to the College's human subject protection policies and procedures, such as better documentation of actions or communications in IRB protocol records, or clearer description of operational details in IRB written procedures.

c) OHRP determines that the College's policies and procedures for protecting human subjects in general are not in compliance with one or more requirements of the HHS regulations, or that the IRB review (or IRB records related to the review) of conduct of one or more specific research projects are not in compliance with one or more of the requirements of the HHS regulations. In these circumstances, the College must develop and implement corrective actions. Examples of corrective actions that the College may undertake to address OHRP determinations include:

i. Re-review by the IRB of research for which IRB determinations required for approval were not previously made;

ii. Implementing a new IRB database management strategy to ensure timely continuing review or review of amendments
iii. Increasing education and training for investigators and IRB members

d) OHRP determines that there is noncompliance with the HHS regulations and, as a result, restricts or attaches conditions to its approval of the College's FWA based on the nature and scope of noncompliance. Despite such restrictions or conditions, OHRP may allow some or all research projects to which the FWA applies to continue while the College satisfies the terms of the restriction or conditions placed upon OHRP's approval of the College's FWA. In this case, OHRP's response may include:

i. Requiring special reporting (such as quarterly reports) to OHRP
ii. Requiring that IRB members, College officials, investigators, or others receive appropriate education and training regarding human subjects research protections
iii. Restrictions, such as requiring prior OHRP review of some or all research projects to be conducted under the FWA and suspending the conduct of a specific research project, until specified protections or corrective actions have been implemented (in these circumstances, research activities involving participants already enrolled in the affected project may continue if it is in the best interests of the participants to do so).

e) OHRP determines that there is noncompliance with the HHS regulations and, as a result, suspends its approval of the College's FWA. In these circumstances, all Federally-conducted or -supported research activities to which the FWA applies must be suspended until OHRP approval of the FWA is reinstated, except that research activities involving already enrolled participants in such research may continue if it is in the best interests of the participants to do so. If an FWA is suspended, research funded by any other Federal agency that relies on the FWA also must stop unless the other Federal agency issues its own assurance to cover such research.

f) OHRP determines that there is noncompliance with the HHS regulations and, as a result, recommends to appropriate HHS officials that the College or an investigator be temporarily suspended or permanently removed from participation in specific projects; or that HHS scientific peer review groups be notified of the College's or an investigator's past noncompliance prior to review of new projects.

g) OHRP determines that there is noncompliance with the HHS regulations and, as a result, recommends to appropriate HHS officials that the College or investigators be debarred in accordance with the procedures specified at 45 CFR part 76. Debarment is a government-wide sanction.

h) OHRP refers the matter to another Federal department or agency for further review and action, if appropriate.

XVI. Guidelines for Conflicts of Interest

(This section describes conflicts of interest disclosures and management for research with human subjects. The focus is on conflicts of interest specific to investigators, IRB members, consultants, and Le Moyne College. It provides information beyond that in section V.6.e. of these Policies and Procedures pertaining to conflicts of interest for members of the IRB.)

A conflict of interest (COI) can arise when financial or non-financial considerations compromise, or have the appearance of compromising, an individual's professional judgment in proposing, conducting, supervising, or reporting research.

1. Individual COIs may include or involve, but are not limited to, the following:

    a) Equity: stocks or options, but not mutual funds
    b) Recruitment incentives (bonus payments)
    c) Consulting Fees
    d) Speaking Fees
    e) Travel Reimbursement
    f) Gifts
    g) Interaction with corporate officers or Board of Directors
    h) Other employment relationships
    i) Trademarks or copyrights
    j) Licensing agreements
    k) Royalty payments
    l) Patent holdings

2. An institutional COI may occur when a financial interest of the College has the potential to bias or coerce results of research conducted by its employees or students, or creates an unacceptable risk to research participants. An institutional COI is deemed "significant" when a research project includes human subjects and any of the following conditions applies:

    a) The College holds any private equity in an outside entity related to the research, or

    b) The College has the potential to receive cash payments from existing licensing arrangements with an outside entity, or

    c) The College maintains an ownership interest or an entitlement to equity in a publicly-traded sponsor of human subjects research as a result of technology licensing activities.

3. Le Moyne College Conflict of Interest Committee (CCIC)

    a) To address these conflicts (either individual or institutional), the College has established a group of qualified research faculty and financial administrators from which a committee can be drawn to fairly examine and manage COIs. The College Conflict of Interest Committee (CCIC) reviews COI disclosures and formulates recommendations to manage, reduce, or eliminate COIs. When investigators report an actual or apparent COI for a research activity, the research cannot begin or continue until a conflict management plan has been obtained from the CCIC.

    Investigators must comply with all components of the CCIC management plan. Once

the determination is made and/or management plan is issued, it must become part of the researchers' IRB application. CCIC management plans are reviewed and acknowledged by the IRB.

b) The IRB may not limit or reduce the conditions imposed by the management plan but may impose a higher standard, if necessary, to establish that the regulatory criteria for approval of the research have been satisfied. For studies that qualify for exempt or expedited review, the COI management plan will be evaluated and acknowledged by the exempt or expedited reviewers, respectively.

c) For full board studies, the convened IRB will document member receipt and acknowledgment of any edits of the COI management plan. Any IRB-required changes will be noted and may be returned to the PI for action, or referred back to the CCIC for further consideration. For COIs disclosed after full board approval of a study, the CCIC's review and management plan are provided to the PI, who must submit a Request to Change an Approved Study to the IRB. This Request must include the COI management plan and any changes to the Research Outline or Consent Form required by the management plan.

4. Investigator Conflict of Interest Disclosures

a) Disclosures in the IRB application: Potential or actual COIs must be disclosed at the time of submission of an initial or continuing review application to the IRB and at any time when the investigator establishes a new outside relationship or changes an existing relationship that creates a potential COI. Informed consent documents must disclose COIs, as applicable.

Conflicts of interest must be declared when the participating study investigators or other research personnel (or their immediate family/domestic partner) have an aggregated financial interest, and/or intellectual property interest in an external sponsor or products used with the project, **equal to or exceeding $5,000 per year**. Additionally, investigators must inform the IRB of monies received below $5,000 for specific conditions defined in the application. When these conditions are met, the potential COI is reviewed by the CCIC.

b) Researchers who are proposing or have received support from HHS (including NIH, CDC, HRSA, and AHRQ) or from a Federalwide Assurance participating agency must also make an annual disclosure of all financial interests related to their institutional responsibilities to the College, regardless of whether any of these interests give rise to a COI related to their research. The annual disclosure must be completed before a proposal can be submitted to HHS, and any identified conflicts must be managed before an account can be established. In addition, all HHS-supported investigators must complete training on COIs once every four years.

5. Institutional Conflict of Interest

a) An institutional COI may occur when a financial interest of the College has the potential to bias research conducted by its employees or students, or creates an unacceptable risk to human research participants. All institutional COIs that do not present a significant COI shall be managed by disclosing the College's relationship with the outside entity in all relevant publications, proposals, consent documents, and presentations.

b) Significant Institutional COIs are presumed to be unacceptable, unless compelling circumstances are present that justify allowing the research to proceed at the College despite the presence of a significant conflict. The Provost or a designated representative conducts a fact-specific inquiry to determine whether the circumstances are compelling or not. The Provost will determine on a case by case basis the need for an independent or internal IRB review of studies involving institutional COIs.

6. IRB Members and Consultants Conflicts of Interest

Conflict of Interest policy considerations apply to IRB members. The IRB prohibits the participation in IRB initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB. An IRB member is considered to have a COI if:

a) The IRB member or a Close Relation of the IRB member is involved in the conduct of the research

b) When the IRB member or Close Relation of the IRB member has a supervisory, managerial or ownership interest in the research sponsor or a company having an economic interest in the research

c) When the IRB member or a Close Relation holds an equity interest in a research sponsor, or licensee, or in any company having an economic interest in the research

d) Incentive payments, bonus payments or finder's fees relating to the proposal are paid to the IRB member or Close Relation

e) There are: consultation arrangements between the IRB member or Close Relation of an IRB member and an organization or individual having an economic interest in the research, which when aggregated for the IRB member and the Close Relations of the IRB member is equal to or exceeds $5,000; gifts, gratuities, or special favors from a research sponsor, which when aggregated for the IRB member and the Close Relations of the IRB member is equal to or exceeds $5,000; honoraria, travel expenses reimbursement, or other reimbursements from the sponsor, which when aggregated for the IRB member and the Close Relations of the IRB member is equal to or exceeds $5,000

f) There are intellectual property rights related to the research which accrue to the IRB member or the Close Relations of the IRB member

g) An arrangement has been entered into where the amount of compensation/value of an IRB member's ownership interests will be affected by the outcome of the research

The IRB member COI policy also applies to consultants hired to assist in IRB reviews. The IRB Chairs will be responsible for providing the consultant with a copy of the IRB member Conflict of Interest policy prior to their review of the study. Once the consultant has read the policy, the IRB Chairs will ask the consultant if a conflict exists. If answered in the affirmative, the consultant may not review the study. All consultants are required to maintain confidentiality and must be notified of this prior to reviewing proposed research for the IRB.

XVII. Authorization

These policies and procedures are approved by the Provost of Le Moyne College.

Signature Provost, Le Moyne College	Date

Attachment 1
Form A
Institutional Review Board
Le Moyne College

NOTICE OF EXEMPT RESEARCH

Name of Investigator(s)/Researcher_____
Date Submitted_____
Address_____
City_____Zip Code_____
Phone number_____
E-mail address_____
Program of Study_____
Name of faculty/staff sponsor (if different)_____
Phone number of sponsor _____
Proposed Date to Commence Data Collection_____
Title of Project:

Abstract of Project:

Type of Investigator and Nature of Activity (if required)
_____Faculty or staff of Le Moyne College
_____Student of Le Moyne College
_____Individuals other than faculty, staff, or students of Le Moyne College
(Please identify investigator and explain nature of research activity.)

Under which of the following categories are you claiming exemption from IRB review?
(Check One)

_____ (1) Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
_____ (2) Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met: (i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects; (ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil

liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or (iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and the IRB conducts a review to make the determination that there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

_____ (3)(a) Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met: (i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects; (ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or (iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and the IRB conducts a review to make the determination that there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

(b) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

(c) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

_____ (4) Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met: (i) The identifiable private information or identifiable biospecimens are publicly available; (ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects; (iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated by HIPAA; or (iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with relevant privacy protections.

_____ (5) Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency

heads, and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs.

_____ (6) Taste and food quality evaluation and consumer acceptance studies: (i) If wholesome foods without additives are consumed, or(ii) If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

_____ (7) Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if the IRB conducts a limited review and makes the determinations that: (i) Broad consent for storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens was obtained; (ii) Broad consent is appropriately documented or waiver of documentation is appropriate; and (iii) If there is a change made for research purposes in the way the identifiable private information or identifiable biospecimens are stored or maintained, and there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

_____ (8) Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met: (i) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained; (ii) Documentation of informed consent or waiver of documentation of consent was obtained; (iii) The IRB conducts a review and makes the determination that the research to be conducted is within the scope of the broad consent and there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data; and (iv) The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

Certification

1. I am familiar with the policies and procedures of Le Moyne College regarding human subjects. I subscribe to the standards described in the document, IRB Policies and Procedures for the Protection of Human Subjects.

2. I am familiar with the published guidelines for the ethical treatment of subjects associated with my particular field of inquiry (e.g. as published by the American Psychological Association, American Sociological Association.)

3. I am familiar with and will adhere to any official policies in my department concerning research with human subjects.

4. I understand that upon consideration of the nature of my project, the IRB may request a full application for review of my research at their discretion and convenience.

5. If changes in procedures involving human subjects become necessary, I will submit these

changes for review before initiating the changes.

DATE_____SIGNATURE_____
Investigator(s)/Researcher(s)

DATE_____SIGNATURE_____
Investigator(s)/Researcher(s)

All applicants from outside Le Moyne College and all student applicants must have a college sponsor whose signature is here affixed.

DATE_____SIGNATURE_____
Sponsor

Attachment 2

Form B
Institutional Review Board
Le Moyne College

APPLICATION FOR EXPEDITED REVIEW

Name of Investigator(s)/Researcher_____
Date Submitted_____
Address_____
City_____Zip Code_____
Phone number_____
E-mail address_____
Program of Study_____
Name of faculty/staff sponsor (if different)_____
Phone number of sponsor_____
Proposed date to commence data collection_____
Title of Project:

Abstract of Project:

Type of Investigator and Nature of Activity:
_____Faculty or staff of Le Moyne College
_____Student of Le Moyne College
_____Individuals other than faculty, staff, or students of Le Moyne College.

Note: All applications from applicants outside Le Moyne College and all student applicants must be co-signed by the faculty or administrator supervising the research activity.

Please answer the following questions with regard to the proposed research activity.
(An affirmative response to any of these might necessitate formal review.)

Does the research involve:	YES	NO
a. drugs or other controlled substances?	___	___
b. access to subjects through a cooperating institution?	___	___
c. subjects taking internally or having externally applied any substance(s)?	___	___
d. removing any fluids (e.g. blood) or tissue from subjects?	___	___
e. subjects experiencing stress (physiological or psychological) above a level that would be associated with normal everyday activities?	___	___
f. misleading subjects about any aspect of the research?	___	___
g. subjects who would be judged to have limited freedom of consent (e.g. minors, individuals with impaired decision-making ability, elderly)?	___	___
h. any procedures or activities that might place the subjects at more than minimal risk (psychological, physical or social)?	___	___
i. sensitive aspects of the person's own behavior, such as illegal conduct, drug use, sexual behavior, or alcohol use?	___	___

Under which of the following categories are you applying for EXPEDITED REVIEW? (check one)

_____Moderate exercise by healthy volunteers.

_____The study of existing data, documents, records, pathological specimens, or diagnostic specimens, if the individuals from whom the data collected are identifiable.

_____Research on individual or group behavior or characteristics of individuals, such as studies of perception, cognition, game theory, or test development, where the investigator does not manipulate subjects' behavior and the research will not involve stress to subjects.

_____Collection of: hair and nail clippings, in a non-disfiguring manner; deciduous teeth; and permanent teeth if patient care indicates a need for extraction.

_____Collection of excreta and external secretions including sweat, uncannulated saliva, placenta removed at delivery, and amniotic fluid at the time of rupture of the membrane prior to or during labor.

_____Recording of data collected from subjects 18 years of age or older in the course of noninvasive procedures routinely employed by professionally certified/licensed individuals in the clinical practice of medicine, psychology and social work. This includes the use of physical practice sensors that are applied either to the surface of the body or at a distance and do not involve input of matter or significant amounts or energy into the subject or an invasion of the subject's privacy. It also includes such procedures as weighing, testing sensory acuity, electrocardiography, electro-encephalography, thermography, detection of naturally occurring radioactivity, diagnostic echography, and electroretinography. It does not include exposure to electromagnetic radiation outside the visible range (e.g. x-rays, microwaves.)

_____Collection of blood samples by venipuncture, in amounts not exceeding 450 milliliters in an eight-week period and no more often than two times per week, from subjects 18 years of age or older and who are in good health and not pregnant

_____Collection of both supra- and subgingival dental plaque and calculus, provided the procedure is not more invasive than routing prophylastic scaling of the teeth and the process is accomplished in accordance with accepted prophylastic techniques.

Certification

1. I am familiar with the policies and procedures of Le Moyne College regarding human subjects. I subscribe to the standards described in the document, IRB Policies and Procedures for the Protection of Human Subjects.

2. I am familiar with the published guidelines for the ethical treatment of subjects associated with my particular field of inquiry (e.g. as published by the American Psychological Association, American Sociological Association.)

3. I am familiar with and will adhere to any official policies in my department concerning research with human subjects.

4. I understand that upon consideration of the nature of my project, the IRB may request a full application for review of my research at their discretion and convenience.

5. If changes in procedures involving human subjects become necessary, I will submit these changes for review before initiating the changes.

DATE_____SIGNATURE_____
Investigator(s)/Researcher(s)

DATE_____SIGNATURE_____
Investigator(s)/Researcher(s)

All applicants from outside Le Moyne College and all student applicants must have a college sponsor whose signature is here affixed.

DATE_____SIGNATURE_____
Sponsor

Attachment 3

Form C

Institutional Review Board
Le Moyne College

APPLICATION FOR REVIEW OF RESEARCH

Name of Investigator (Researcher)_____
Date Submitted_____
Address_____
City_____Zip Code_____
Phone number _____
E-mail address_____
Program of Study_____
Name of faculty/staff advisor/sponsor _____
Phone number of sponsor_____
Proposed Date to Commence Data Collection_____

Title of Project:

Type of Investigator (researcher): check as appropriate
_____ Faculty or staff of Le Moyne College
_____ Student at Le Moyne College
_____ Individual other than faculty, staff or student of Le Moyne College
(Please identify outside investigator and explain nature of research activity.)

Nature of Activity: check all that apply
_____ Project to be submitted for extramural funding:

Agency_____

_____ Project not to be submitted for extramural funding
_____ Demonstration
_____ Class project (number and title of class:)_____
_____ Master's thesis
_____ Independent study
_____ Other (please explain) _____

Note: All applications from applicants outside Le Moyne College and all student applicants must be co-signed by the faculty or administrator supervising the research activity.

Please answer the following questions with regard to the research activity proposed:

Does the research involve:	YES	NO
a. drugs or other controlled substances?	____	____
b. payment of subjects for participation?	____	____
c. access to subjects through a cooperating institution?	____	____
d. subjects taking internally or having externally applied any substance(s)?	____	____
e. removing any fluids (e.g. blood) or tissue from subjects?	____	____
f. subjects experiencing stress (psychological or physical) above a level that would be associated with their normal everyday activities?	____	____
g. misleading (deceiving) subjects about any aspect or purpose of the research?	____	____
h. subjects who would be judged to have limited freedom of consent (e.g. minors, mentally disabled or ill, aged)?	____	____
i. any procedures or activities that might place the subjects at risk (psychological, physical, or social)?	____	____
j. a written consent form (e.g. parent)?	____	____
k. data collection over a period longer than twelve (12) months?	____	____

Certification

1. I am familiar with the policies and procedures of Le Moyne College regarding human subjects. I subscribe to the standards described in the document, IRB Policies and Procedures for the Protection of Human Subjects.

2. I am familiar with the published guidelines for the ethical treatment of subjects associated with my particular field of inquiry (e.g. as published by the American Psychological Association, American Sociological Association).

3. I am familiar with and will adhere to any official policies in my department concerning research with human subjects.

4. If changes in procedures involving human subjects becomes necessary, I will submit these changes for review before initiating the changes.

DATE_____ SIGNATURE _____
Investigator(s)/Researcher(s)

DATE_____ SIGNATURE _____
Investigator(s)/Researcher(s)

All applicants from outside Le Moyne College and all student applicants must have a college sponsor whose signature is here affixed.

DATE_____ SIGNATURE_____
College Sponsor

Attachment 4

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 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.

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.

Attachment 5
Research Outline (Form RO)

The IRB requires that researchers submit a description of the planned research that adheres to the following outline. Each of the seven sections in boldface print must be addressed. You may type directly in the box below each section heading. Please see the Instructions for Form RO for detailed information on filling out each section of this form.

I. **Rationale and Aims:**

II. **Methods and Procedures:**

III. **Subject Population:**

IV. **Potential Risks:**

V. **Informed Consent Procedures:**

VI. **Safeguarding Against Risks:**

VII. **Benefits and Risks**:

Attachment 6

Guidelines for Online Surveys in Applications to the Institutional Review Board

I. Types of online surveys.

Most researchers use one the following methods for conducting online surveys:

A. The researcher uses the Le Moyne College email system in one of two ways:

1. The researcher uses the Le Moyne College email system to recruit subjects, distribute survey questionnaires to subjects, and receive surveys returned by subjects.

2. The researcher uses the Le Moyne College email system to recruit subjects and then uses a third party website (such as Survey Monkey) to post the survey. Once the survey is posted, the researcher uses the Le Moyne College email system to send an email containing a link that subjects can click on to gain access to the survey on the third party website. Once the survey period has expired, the researcher either conducts any analysis using software provided by the third party website or uses the Le Moyne College internet service to download the survey results for further analysis.

For researchers that choose one of the above methods, Le Moyne College does not make its directory of student email addresses available to students. If student researchers want to use the College's student email directory for recruiting participants and/or distributing surveys (or survey links), *the faculty research sponsor named on the IRB application must request access to the email directory and distribute the relevant email correspondence on behalf of the student researcher.* Therefore, student researchers who use this method of recruitment and distribution must state the following in the Research Outline of their IRB application: (i) their faculty sponsor will send out the recruitment email and/or survey or survey link to potential participants using an email list provided by the Registrar's Office; and (ii) the faculty sponsor will send out the email using the *bcc* feature in GMail. Please note: Before the Registrar will release the list of email addresses to the faculty sponsor, the sponsor must provide the Registrar with a copy of the official project approval letter sent by the IRB to the researcher.

B. The researcher posts survey notices on social media such as Facebook, Twitter, and Tumblr. If users click on a link that accompanies the notice, they will go to a third party website that is hosting the survey that they may want to complete.

C. After preparing the survey instrument, the researcher contracts with an external company to conduct the entire survey process. This process includes the recruiting of subjects, the hosting of the survey, and the storage of results, which are then made available to the researcher.

II. **Procedures and safeguards for online surveys**.

In all cases, the following procedures and safeguards must be followed.

A. ***Consent***:

The first page of the survey must contain the usual consent form which subjects can read before making a fully-informed decision about whether or not to participate in the research. If subjects wish to participate, they check a box that accompanies a statement in which they confirm that they have read the consent form, understand it, and consent to participate in the study. If subjects do not wish to participate, they check a box that accompanies a statement stating that they do not consent to participate. They should either be directed to an exit page from which the survey cannot be accessed or instructed to close their browser tabs associated with the survey study. In all cases, responses from subjects who did not check the consent to participate box may not be used in any of the researcher's subsequent work.

B. ***Other Procedures and Safeguards***:

1. If researchers propose to use a third party website to host the survey or an external company to conduct the entire survey process, they must include in the application to the IRB a complete assessment of the security, privacy and confidentiality practices of the service provider. If necessary, the IRB will consult with the College's IT department when assessing whether or not the service provider can be used for hosting the survey.

2. For any online survey service used, the researcher's complete assessment must provide information about the following items:

a. Secure transmission

Information sent to and from websites can either be transmitted in a text format that could be read if the information was intercepted by a third party (http protocol) or encrypted so that a third party could not read the intercepted information (https protocol). It is strongly recommended that https encryption be used. The application should include verification that this type of secure transmission is used.

b. Database security

The researcher should only have access to their data stored on a server of the online company by using a username and password.

c. Server security

The servers on which the data are stored should be located in a data center with appropriate physical security controls.

d. Access time period

The researcher should indicate how long the data will be stored on the external site and the procedures that will be used for its deletion. Alternatively, they should provide a date by which the data will be deleted from the external site.

e. Confidentiality of respondent

The subject's IP address should be masked from the researcher. If not, the researcher should explain what is done with the IP address.

3. *Voluntary participation*. Given that participation in research is voluntary, it is likewise assumed that participants may skip questions that make them uncomfortable or that they do not want to answer. Therefore, in creating and administering an online survey, the survey must be set up so as to allow respondents to skip questions. In other words, the survey may not prevent respondents from moving to the next page or submitting their responses if questions have been left unanswered. The only question that must be required is the consent statement on the consent form, where respondents either affirm their willingness to participate in the research or decline to participate. If the nature of the research design necessitates that participants answer some or all survey questions, a justified rationale for requiring responses must be provided in the *Methods and Procedures* section of the Research Outline. In all cases, however, respondents must be allowed to skip any and all questions that are not absolutely required for the purposes of the research.

III. **Selecting a third party service**.

While researchers are free to choose the method and online survey service that best suits their needs, the IRB is aware of several services that have frequently been used by academic researchers: Amazon's Mechanical Turk, Google Forms, Qualtrics and Survey Monkey. Researchers should consult the website of their chosen service to obtain the information (needed in their IRB application) to address the security and confidentiality issues raised above and also to obtain guidance on how to format their survey and select options that will comply with IRB standards at most academic institutions.

IV. **Submitting your materials to the IRB**.

The IRB requests that applicants submit their surveys and consent forms in their final form so that the committee can ensure that they are appropriate, accurate, and not confusing for subjects. In the case of online surveys, researchers must print out the consent form and survey in their final form from the web site, scan them, and submit them to the IRB as a PDF file. Researchers must also include in the text of their email to the IRB a clickable link to the consent form and survey so that the IRB may view the materials online.

Attachment 7

Adult Research Participation Consent Form

The IRB requires the researcher to provide an exact copy of the consent form that will be distributed to potential subjects. Both the researcher and subject must have a copy of the consent form signed by the researcher and subject before data can be collected from a subject. In the case of consent for online surveys, the email notifying subjects of the survey and providing the link to it must inform subjects that they should either (a) print a copy of the consent form which accompanies the survey, or (b) write down the contact information provided on the consent form for the researcher and the co-chairs of Institutional Review Board.

Under the Forms Tab on the IRB website there is a separate form for Parental Consent when potential subjects are less than 18 years of age.

Below are the sections and typical content that are required for a consent form that will enable a potential subject to make a fully informed consent decision.

Title of Project:
Researcher(s):
Sponsor: This would be a faculty mentor for student researchers, or a Le Moyne College faculty sponsor for researchers who are not affiliated with Le Moyne College and who intend to recruit Le Moyne College employees or students as research subjects.

Your consent is being sought to participate in this study. Please read the following information carefully before you decide whether or not to consent to participate.[1]

Purpose of the research: Provide a brief overview of what research issues or hypotheses will be examined with the data collected from subjects. There should also 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.

Procedure to be followed: This section must include a description of all the ways that the researcher will interact with subjects, including informed consent procedures, specific tasks the researcher will ask subjects to do, and all procedures related to data collection.

Discomforts/risks: The researcher should 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 significant risks, an explanation of why these methods were used and not others is required. What alternative methods are available?

Please note that **all** research that intends to respect the privacy, confidentiality, or anonymity of the research participants runs the risk, however remote, that there may be a breach of confidentiality. This must be identified as a risk in this section. You should also identify the level of confidentiality that will be maintained.

[1] These statements must appear in your consent form.

In addition to the general risks described in the previous paragraph, researchers who plan to use online surveys must also include the following disclaimer in this section of their consent form:

> Whenever one works with email or the internet, there is always the risk of compromising privacy, confidentiality, and/or anonymity. Your confidentiality will be maintained to the degree permitted by the technology being used. It is important for you to understand that no guarantees can be made regarding the interception of data sent via the internet by third parties.

Incentives/benefits for participation: This section must include any general benefits, such as helping to make a contribution to the knowledge of the topic under study, helping specific groups of people, or providing information that will enable the researcher to make a contribution to the general well-being of society. Specific benefits, such as receiving payment for participation or extra credit in a course, must also be included in this section.

Time duration of participation: The researcher must provide an estimate of how much time the subject can expect to spend participating in the research project. In addition, if subjects will be completing surveys, they should be told how long they will have to submit their survey responses.

Statement of confidentiality: If relevant, the researcher should 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. In studies that intend to maintain confidentiality or anonymity, this refers to an assessment of the extent to which the names and other private information and data provided by individuals will be protected by the researcher from release. Describing how the confidentiality of private information and research data will be maintained is an important component of the informed consent process.

If anonymity is being claimed, the researcher should describe the procedures by which they will obtain consent and the data from subjects without having any knowledge of the subjects' identities.

The researcher also has an obligation to inform potential subjects about the following aspects of the data collection process: (1) how their data will be presented and 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 it will be stored during the study, (4) what will become of the data after the completion of the study, and (5) what, if any, limitations exist to these confidentiality procedures. With regard to how the data will be used, you should mention how the collected data will be presented in your final product to minimize the risk of disclosing identities if that is a potential risk. Subjects should be informed of how any written, spoken, or visual responses will be presented. For example, would you use direct quotes? How would the individual subjects be referred to in the final product? Similarly, what types of statistical measures or analyses will be used with quantitative data and to what extent will quantitative data be disaggregated by subgroup according to type of subject?

In compliance with federal guidelines, all records related to research approved by either Expedited review (Form B) or Full Board review (Form C), including signed consent forms and collected data, must be retained in secure storage at Le Moyne College or on a secure Le Moyne College server for at least three years after the research project has been completed.

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 responses and/or the number and type of subjects who participate. Subjects should therefore be informed of the number of individuals who will be included in the research project and the size of any subgroups of individuals who might be identified by their responses. 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. This is especially important when subgroups defined by potentially identifying information are used and there are only a small number of potential subjects who could be classified as members of any subgroup.

The following information must be included (as relevant): (1) whether the subject's biospecimens (even if identifiers are removed) might be used for commercial profit and whether the subject will or will not share in this commercial profit; (2) whether clinically relevant research results, including individual research results, will be disclosed to subjects; if so, state how they will be disclosed; and (3) whether research involving biospecimens will (if known) or might include whole genome sequencing

If the researcher does not apply for broad consent, when the researcher collects private information or identifiable biospecimens that could be used in future studies, one of the following two statements must be included:

Identifiers might be removed and the de-identified information or biospecimens may be used for future research without additional informed consent from the participants.
OR
The participant's information or biospecimens will not be used or distributed for future research studies even if identifiers are removed.

Please note: If you include the first statement above, it means that you (or other investigators) may decide to use the de-identified information or biospecimens in future secondary research studies approved by the IRB. This is consistent with IRB policies and practices that were already in place prior to the recent revisions to federal guidelines; the statement that is now required simply makes this practice explicit for potential research participants. If you include the second statement, identifiable information or biospecimens collected for your study cannot be used in any future secondary research studies, without exception. Researchers applying for approval of secondary research studies will now need to provide confirmation for the IRB that the first statement above was included on the consent form at the time the data was initially collected (this applies only to data collected for primary research studies on or after January 21, 2019).

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

Voluntary participation: You must inform your subjects that their participation is voluntary. In addition, you must include a statement that asks them to contact the researcher if they felt coerced to participate in any way. Finally, if you will interview subjects, administer a survey, or ask them to answer questions, you must tell them that they are free to skip any question that they do not want to answer or that makes them uncomfortable. If the nature of the research design necessitates that participants answer some or all survey questions, a justified rationale for requiring responses must be provided in the *Methods and Procedures* section of the Research Outline (and you would, therefore, not be able to state on the consent form that they can skip any

question that they do not want to answer). In all cases, however, respondents must be allowed to skip any and all questions that are not absolutely required for the purposes of the research.

Termination of participation: You must tell your subjects that they may choose to withdraw from the study at any time.

Broad Consent: A researcher may apply for approval of broad consent regarding future use of collected data that contain identifiable private information and/or identifiable biospecimens. **If applicable, the application for broad consent should be included at this point in the standard adult research participation consent form.** Researchers can use de-identified information and de-identified biospecimens for secondary research without getting a subject's broad consent as long as the secondary research project has been approved by the IRB. However, if a subject is asked to provide broad consent and refuses, that subject's data may not be used for any future secondary research project that relies on broad consent, nor can the researcher apply for a waiver of informed consent for said project. Please see Attachment 9 of these Policies and Procedures for additional material on the use of broad consent and the information that must be provided to research participants on the broad consent form.

Questions regarding the research: Questions regarding the research itself should be directed to the researcher and to the college sponsor (in the case of student researchers or researchers not employed by Le Moyne College). Information such as phone numbers and/or email addresses of the researcher and sponsor should be provided.

Questions or concerns regarding a subject's rights as a research participant: Questions or concerns regarding a subject's rights as a research participant should be directed to the co-chairs of the Institutional Review Board. They can be reached at irb@lemoyne.edu or phone number 315-445-4573.

This research has been reviewed and approved by Le Moyne College's Institutional Review Board.[2]

Consent Space: For consent that is obtained on a hardcopy form, the consent form must provide a space that includes the following:

- A statement for subjects to read such as: *I have read all the information provided on this form, am at least 18 years of age, and consent to participate in this study.*
- This statement should be followed by a line on which subjects will sign their name if they consent to participate and a line for the date. Below the signature line there should be a line on which subjects can print their name.
- You should include content such as: *If you do not consent to participate, you do not need to sign this form. Simply return it to the researcher.*
- You should also provide a line on which you as the investigator will sign your name and a line on which you write the date for when you sign.

  An example of this appears below:

[2] This statement must appear on your consent form.

I have read all the information provided on this form, am at least 18 years of age, and consent to participate in this study.

_____ _____

Signature Date

_____

Please print your name here.

If you do not consent to participate, you do not need to sign this form. Simply return it to the researcher

Signature of investigator_____Date_____

Attachment 8

Adult Sample Research Participation Consent Form

Your consent form must follow the format of the sample below.

Title of Project: Involvement and Field Dependence-Independence in the Detection of Deception

Researcher(s): ___Joanie Student and Imso Smart, Ph.D. (faculty sponsor) _____

Your consent is being sought to participate in this study. Please read the following information carefully before you decide whether or not you consent to participate.

Purpose of the research: The purpose of this study is to examine the effects of cultural background on deception detection. The results will be used in my Honors thesis and may be included in an article submitted for publication in an academic journal.

Procedure to be followed: You will be asked to view pictures of strangers and rate them on a seven-point scale in terms of attractiveness, honesty, and believability. You will also be asked to give your age and gender. Finally, you will view ten 15-second videotapes and you will be asked whether the person in the video is lying or telling the truth. You will be asked to provide a brief explanation of your assessment of the person's truthfulness.

Discomforts/risks: The risks in this study are minimal (i.e., no greater than those ordinarily encountered in daily life or the performance of routine physical or psychological examinations or tests). As with all research with human subjects, there is a risk, however remote, of a breach of confidentiality in the collection and storage of information and the presentation of results.

Incentives/benefits for participation: If allowed by their professor, participants will receive extra credit in a designated course. Furthermore, all participants have the opportunity to contribute to the greater field of psychology. The research itself will benefit knowledge on deception detection and awareness of cross-cultural differences.

Time duration of participation: Participation in the study will not exceed 30 minutes.

Statement of confidentiality: Records will be kept confidential and will be available only to the researchers named above. They will be stored on the researcher's password protected computer during the course of the study. The signed consent forms and participants' responses will be securely stored for at least three years by the sponsor following the completion of the study. Participants' information will not be used or distributed for future research studies even if identifiers are removed.

If the results of this study are published, the data will be presented in some type of group form and individual participants will not be identified. The demographic data will be used to form subgroups for presenting the data and analyzing the results. Subgroups will be large enough to prevent the identification of a small group of individuals or their responses. It is expected that approximately 100 Le Moyne undergraduates will participate in this study. Descriptive statistics such as means and frequency distributions will be used, and a correlation analysis will be used to assess the relationships between the demographic variables (age and gender) and the ratings of attractiveness, honesty, and believability. Direct quotes may be used when presenting the results for the participants' assessments of truthfulness. Those being quoted will be referred to by pseudonyms.

Voluntary participation: Your participation is voluntary. If you believe you have been in any way coerced into participation, please inform the researcher. Also, you are free to skip any question that you do not want to answer or that makes you uncomfortable.

Termination of participation: You may choose to withdraw from the study at any time and still receive extra course credit.

Questions regarding the research or your participation in this research project should be directed to:

Joanie Student at Student@lemoyne.edu or phone number 315-445-#### or Dr. Imso Smart at Professor@lemoyne.edu or phone number 315-445-%%%%.

Questions or concerns regarding your rights as a research participant should be directed to: the Le Moyne College IRB co-chairs at irb@lemoyne.edu or (315) 445-4573.

This research has been reviewed and approved by Le Moyne College's Institutional Review Board.

*I have read all the information provided on this form, am at least 18 years of age, and **consent** to participate in this study.*

_____ _____

Signature *Date*

_____

Please print your name here.

If you do not consent to participate, you do not need to sign this form. Simply return it to the researcher.

Signature of Investigator _____ Date_____

Signature of Investigator _____ Date_____

Attachment 9

Broad Consent Form Instructions

In some cases, a researcher may apply for approval of broad consent regarding future use of collected data that contain identifiable private information and/or identifiable biospecimens. The application for broad consent is included as part of the Adult Consent Form that is submitted for a primary research application to the IRB. A primary research application is the set of documents submitted to the IRB when the researcher is seeking approval for a new study which involves the collection of new data from human subjects. Secondary research involves the use of identifiable private information and/or identifiable biospecimens that was previously collected during primary research.

Please note: This form applies only to research with identifiable information and identifiable specimens. Researchers can always use de-identified information and de-identified biospecimens for secondary research without getting a subject's consent as long as the secondary research project has been approved by the IRB. However, if a subject is asked to provide broad consent and refuses, that subject's data may not be used for any future secondary research project that relies on broad consent, nor can the researcher apply for a waiver of informed consent for said project.

IRB guidelines require that consent forms and data for all non-exempt research be maintained for a minimum of three years. In cases of broad consent, however, researchers must maintain a copy of all consent forms for as long as the subjects' information and/or biospecimens will be used in future research studies. In the event that a primary or secondary research project with broad consent is audited, the researcher will need to provide proof that the subjects whose data is being used gave consent for future use of their data. When providing that proof, the researcher must submit with their future application:

- the original consent form that included broad consent
- the IRB approval of the primary study that included broad consent
- a summary description of the subject pool that agreed to broad consent during the primary study
- all of the other documents required for a typical application to the IRB
- if new data is to be collected and used along with the secondary data, the future application must also include an adult consent form for use by participants from whom the new data will be collected.

When applying for Broad Consent, the information below must be included in the IRB application for the primary research study. (**Please note**: The application for Broad Consent should be placed in the Adult Research Participation Consent Form as indicated in Attachment 7.)

- **Confidentiality of records:** This section should include where the identifiable information and biospecimens will be stored, how it will be stored to prevent unauthorized access to it, and the period of time during which it will be stored, maintained, and available for future research use.

- **Potential future research:** The researcher must provide a description of the information or biospecimens that might be used for future research, the types of research that may be conducted, whether sharing of the information or biospecimens will occur, and who might

use it. If the levels or types of risks and benefits associated with future possible research are different from those associated with the primary study, the subjects must also be informed of these differences.

- **Voluntary participation:** Subjects must be informed that the decision to participate in broad consent is voluntary. This must include a statement that asks them to contact the researcher if they felt coerced to participate in any way.

- **Notification of subjects:** The researcher must state whether subjects will or will not be notified about the details of any subsequent research with the secondary data. In addition, the researcher must indicate whether or not future research results such as clinically relevant findings will or will not be disclosed to subjects. Subjects must also be provided with contact information in the broad consent form for reaching the primary researchers in the future.

- **Commercial profit:** The researcher must inform subjects whether or not their identifiable information or biospecimens will be used in future research projects that may generate commercial profit to any researcher or institution involved.

- **Whole genome sequencing:** For secondary research using identifiable biospecimens, the research must inform subjects whether or not it is possible that future research will involve whole genome sequencing.

I have read this request for broad consent and any questions have been answered. I agree to give my broad consent to the future research uses of my identifiable information and identifiable biospecimens. My participation is voluntary, and I may withdraw at any time without any penalty or loss of benefits to which I am entitled.

I agree to this request for broad consent.

_____ _____
Signature Date

_____
Please print your name here

I do not agree to this request for broad consent.

_____ _____
Signature Date

_____
Please print your name here

_____ _____
Researcher's Signature Date

Attachment 10

Parental or Guardian Permission Form for Research Involving a Minor
Psychology Department

(Please note that this is a sample. Your consent form need not be formatted exactly like this one as long as it includes the necessary elements in the guidelines.)

Title of Project: Read to Me: An Examination of Differences in Book Reading Styles

Researcher(s): Imso Smart, Ph.D (Faculty advisor) and Joanie Student

Your permission is being sought to have your child participate in this study. Please read the following information carefully before you decide whether or not to give your permission.

Purpose of the research: The purpose of this study is to help us determine whether differences in child-directed reading styles exist among college students of various majors.

Procedure to be followed: During testing, your child will be read various books by college students of different majors while being videotaped. The videotaping is for the sole purpose of examining the reading styles employed by the adult participants, and in no way will be used to examine or test the behavior of your child.

Discomforts/risks: The risks in this study are minimal (i.e., no greater than those ordinarily encountered in daily life or the performance of routine physical or psychological examinations or tests). There are no foreseeable discomforts or dangers to either you or your child in this study.

Incentives/benefits for participation: There are no direct benefits to your child, but your child will receive a small gift for participating. The results of this study, however, will increase our knowledge of the various reading techniques and strategies used by college students.

Time duration of participation: Participation in the study will not exceed 1 hour.

Statement of confidentiality: All records are kept confidential and will be available only to professional researchers and staff. If the results of this study are published, the data will be presented in group form and individual children will not be identified.

Voluntary participation: Your child's participation is voluntary. If you feel your child has in any way been coerced into participation, please inform the faculty advisor. We also ask that you read this letter to your child (if age-appropriate) and inform your child that participation is voluntary. At the time of the study, your child will once again be reminded of this by the researcher

Termination of participation: If at any point during the study you or your child wishes to terminate the session, we will do so.

Questions regarding the research should be directed to:
Dr. Imso Smart (x-XXXX)

Questions or concerns regarding your child's rights as a research participant should be directed to: the Le Moyne College IRB co-chairs at irb@lemoyne.edu or (315) 445-4573.

This research has been reviewed and approved by Le Moyne College's Institutional Review Board. If at any time before, during or after the experiment your child experiences any physical or emotional discomfort that is a result of his/her participation, or if you have any questions about the study or its outcomes, please feel free to contact us.

SIGNING THE FORM BELOW WILL ALLOW YOUR CHILD TO PARTICIPATE IN THE STUDY DURING SCHOOL HOURS WITHOUT YOUR PRESENCE. Please return by Thursday, July 29. If you do not sign and return this form, the researchers will understand that you do not wish to allow your child to participate.

Parent Signature

I, the parent or guardian of _____, a minor_____ years of age, permit his/her participation in a program of research named above and being conducted by Joanie Student and Dr. Imso Smart.

_____ _____
Signature of Parent or Guardian *Date*

_____
Please print your name here.

Student Signature

I, _____, agree to participate in the program of research named above and understand that my participation is voluntary.

_____ _____
Signature of Student *Date*

_____
Please print your name here.

Signature of Investigator_____ Date_____

Signature of Investigator_____ Date_____

Please note: *For research involving minors, child assent should be sought whenever possible. At times, this may entail creating a separate consent document for parents and children (each written in age-appropriate language) and each must be signed. At other times, parents may be required to make the decision for the child. Please be aware that participants give consent, parents give permission, and minors give assent. Your documents should contain the appropriate terms.*

Attachment 11
Le Moyne College Institutional Review Board
REQUEST TO CHANGE AN APPROVED STUDY

All human subjects-related changes to IRB approved studies must be reviewed and approved by the IRB co-chairs prior to their implementation, unless immediate steps must be taken to protect subjects from imminent grave harm or risk. The IRB must be notified as soon as possible when unforeseen events necessitate an immediate change in procedure.

Please fill out all sections of this form completely. The IRB co-chairs will review the request and make a decision regarding the proposed changes. In rare cases, the co-chairs may decide that the proposed change requires full Board review before a decision can be made. The co-chairs will notify the researcher if the proposed change will require full Board review.

Date of Change Request:

Section I: Approved Study Information

Name of Investigator(s):

Form (*A, B, or C*):

IRB Application Number:

Title of Project (*as it appears on approved application*):

Date of Approval of Application (*or latest extension or approval of Change Request*):

Section II: Nature of the proposed change

_____ 1. Change in the number of research subjects.

_____ 2. Change in location or addition of a new site for recruiting subjects or for collecting data from your subjects. (Please submit a signed copy of a letter from the appropriate administrator or director of the site that gives you permission to conduct your research there).

_____ 3. Change in procedure for recruiting subjects.

_____ 4. Change in experimental methods (Change in what you will ask subjects to do).

_____ 5. Other.

Section III: Explanation. In the space below, please provide the relevant details for the nature of the proposed change that you selected in Section II. Describe briefly the original plan, the change in plan, and your reasons for requesting the change. If subjects will be recruited or data will be collected at a conference or other public event, please provide the dates and location of the event. Use an additional page if necessary.

_____ _____

Signature Date

_____ _____

Faculty Sponsor Date

Attachment 12
Le Moyne College Institutional Review Board

APPLICATION FOR CONTINUING IRB APPROVAL

All **Form C** research projects must receive continuing approval from the IRB if the research will continue or resume after the initial one-year approval period. If your project has been completed, you should submit a *Project Closure Form* instead of this form.

Please fill out all sections of this form completely. In order to avoid any disruption in your research activities, this form must be submitted to the IRB co-chairs (at irb@lemoyne.edu) no later than **one month** prior to the expiration date of your project.

Note: If you use a paper (rather than electronic) consent form, please submit a copy of the consent form with this request so that the IRB may update the stamped approval date.

Date of Application for Continuing Approval:

Section I: Project Information

Name of Investigator(s):

IRB Application Number:

Project Title *(as it appears on approved application)*:

Approval Date of Original Application (*or latest extension or approval of Change Request*):

Section II: Information on Continuing Research Activities

1. Please check the statement below that describes the research you plan to conduct during the upcoming renewal period. If you plan to make changes to your project's methods and procedures or consent process during the next year, or if there has been a change in the assessment of your project's risk, please also submit the *Request to Change an Approved Study* Form.

____ Data from human subjects will be collected during the upcoming renewal period.

____ The research covered by this renewal will be limited to the analysis of data collected under the previously approved research application.

2. Please provide the following information:

- The total number of subjects who have participated prior to this renewal:

- The number of subjects that you intend to recruit or collect data from in the upcoming renewal period:

- Has the assessment of potential risks to subjects, as described in the previously approved application, changed? ____YES ____NO

(If there has been a change in potential risks or in your assessment of risk, please submit the *Request to Change an Approved Study* Form.)

- Have there been any unanticipated problems or adverse events involving confidentiality, safety or risk to subjects during the last year? ____YES ____NO

(If yes, please provide details below, including whether or not the IRB was notified.)

- Have there been any complaints from subjects? ____YES ____NO

(If yes, please provide details below.)

Explanations of YES responses (Use another page if necessary):

_____ _____
Signature of Principal Investigator Date

_____ _____
Signature of Faculty Sponsor Date

Attachment 13
Le Moyne College Institutional Review Board

PROJECT CLOSURE FORM

Upon completion of all **Form C** approved research projects, this Project Closure Form must be submitted to the Institutional Review Board.

Please fill out this form completely and submit it to the IRB co-chairs at irb@lemoyne.edu.

Date Project Closure Form Submitted:

Section I: Approved Study Information

Name of Investigator(s):

IRB Application Number:

Project Title *(as it appears on approved application)*:

Approval Date of Application (*or latest extension or approval of Change Request*):

Date project was completed:

Section II: Summary of Human Subjects-related Research Activities

1. Number of Subjects:

a) Number of subjects the study was approved to recruit: _____

b) Number of participants who participated: _____
c) Number of participants who withdrew: _____

2. Did you make any changes to either your project's methods and procedures or consent process during the course of your research? ____YES ____NO

3. Did your research involve any unanticipated problems involving risks to participants or others, risks to confidentiality, or other adverse events? ____YES ____NO

4. Did any participants withdraw from the research, or voice complaints about the research? ____YES ____NO

5. Have you made the proper arrangements for your research records and consent forms to be stored at Le Moyne College for the required three year time period? ____YES____NO

Section III: Explanation

If you answered YES to questions 2, 3 or 4 above, and/or if you answered NO to question 5, please explain your responses in the space below. Use an additional page if necessary.

_____ _____

Signature of Principal Investigator Date

Sources for Additions to Policies and Procedures, 2017-2020

- Internal IRB audits: Clarkson University, "IRB Audits," (December, 2007) at https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&cad=rja&uact=8&ved=0ahUKEwiltZ_r8ILQAhVF7YMKHSySAccQFggeMAA&url=https%3A%2F%2Fwww.clarkson.edu%2Fdor%2Fdocuments%2FIRB%2520Audit%2520Procedure%2520121107.doc&usg=AFQjCNGHEq85DuvW-oJOpenkA0h2ZCRcWg and Syracuse University, Office of Research Integrity & Protections, "Audit Form," (February, 2011) at http://researchintegrity.syr.edu/wp-content/uploads/2016/10/Audit-Form.doc

- Conflicts of Interest: University of Southern California, Chapter 5 of "USC Human Subject Protection Program Policies and Procedures," (2016) at https://oprs.usc.edu/files/2012/11/Chapter-5-Conflicts of Interest.pdf

- Noncompliance, project suspension, and project termination: University of Southern California, Chapter 20 of "USC Human Subject Protection Program Policies and Procedures," (2016) at https://oprs.usc.edu/files/2012/11/Chapter-20-Reportable-Events-Noncompliance-Suspensions-and-Terminations.pdf

- Unexpected problems: University of Southern California, Chapter 20 of "USC Human Subject Protection Program Policies and Procedures," (2016); and Office of Human Research Protections, Department of Health and Human Services, "Unanticipated Problems Involving Risks & Adverse Events Guidance," (2007) at http://www.hhs.gov/ohrp/regulations-and-policy/guidance/reviewing-unanticipated-problems/#Q3

- OHRP external Oversight of Le Moyne College IRB: Office of Human Research Protections, Department of Health and Human Services, "Unanticipated Problems Involving Risks & Adverse Events Guidance," (2007) at http://www.hhs.gov/ohrp/regulations-and-policy/guidance/reviewing-unanticipated-problems/#Q3