

Form A
Institutional Review Board
Le Moyne College

APPLICATION FOR EXEMPT RESEARCH STATUS

Title of Project: _____

Name of Primary Investigator(s)/Researcher(s): _____

Type of Investigator(s):

- _____ Faculty or staff of Le Moyne College
- _____ Student of Le Moyne College
- _____ Individuals other than faculty, staff, or students of Le Moyne College
(Le Moyne researchers must identify all outside investigators / collaborators and explain their role on the Research Outline.)

Name of Student Research / Lab Assistant(s): _____

(On the Research Outline, explain the role of student research / lab assistants who will assist in data collection or analysis but will not be otherwise involved in preparing the final products.)

CITI Completion Certificates must be submitted for all primary investigators, researchers / collaborators, student research / lab assistants, and faculty sponsors.

Primary Investigator's Contact Information:

Address _____
City, State & Zip Code _____
Phone number _____
E-mail address _____

For Student Researchers only:

Degree program (e.g., BA, MS, EdD, DNP): _____
Program(s) of Study: _____
Name of faculty sponsor: _____
Email address of faculty sponsor: _____

For External Researchers only:

Name of Le Moyne sponsor: _____
Email address of Le Moyne sponsor: _____

Date Application Submitted: _____

Proposed Date to Commence Data Collection: _____

(Please allow a minimum of 6-8 weeks between the application submission date and the proposed date to commence data collection.)

Nature of Activity (check all that apply):

- _____ Faculty research project
_____ Project to be submitted for extramural funding from a federal agency (e.g., NSF, FDA)
 Agency: _____ Grant Submission Deadline: _____
_____ Pilot Study for future research project
_____ Undergraduate thesis / capstone project (including Departmental / Integral Honors)
_____ Master's thesis / capstone project
_____ Doctoral dissertation
_____ Course project (not thesis or capstone related). Course number & title: _____
_____ Staff (non-faculty) research project
_____ Other (please explain): _____

Abstract of Project (maximum 150 words):

Under which of the following categories are you claiming exemption from continuing IRB oversight after approval? (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 research participants cannot readily be ascertained, directly or through identifiers linked to the participants; (ii) Any disclosure of the participants' responses outside the research would not reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' 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 research participants can readily be ascertained, directly or through identifiers linked to the participants, and the IRB conducts a review to make the determination that there are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data.

_____ (3)(a) Research involving benign behavioral interventions in conjunction with the collection of information from an adult participant through verbal or written responses (including data entry) or audiovisual recording if the participant 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 participants cannot readily be ascertained, directly or through identifiers linked to the participants; (ii) Any disclosure of the participants' responses outside the research would not reasonably place the participants at risk of

criminal or civil liability or be damaging to the participants' 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 research participants can readily be ascertained, directly or through identifiers linked to the participants, and the IRB conducts a review to make the determination that there are adequate provisions to protect the privacy of participants 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 participants, and the investigator has no reason to think the participants will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the participants 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 participants regarding the nature or purposes of the research, this exemption is not applicable unless the participant authorizes the deception through a prospective agreement to participate in research in circumstances in which the participant 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 research participants cannot readily be ascertained directly or through identifiers linked to the participants, the investigator does not contact the participants, and the investigator will not re-identify participants; (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 participants 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 participants and to maintain the confidentiality of data; and (iv) The investigator does not include returning individual research results to participants 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 research participants. I subscribe to the standards described in the document, *Institutional Review Board Policies and Procedures*.
2. I am familiar with the published guidelines for the ethical treatment of human research participants 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 research participants.
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.
5. If changes in procedures involving research participants become necessary, I will submit these changes for review before initiating the changes.

SIGNATURE _____ DATE _____
Investigator/Researcher

SIGNATURE _____ DATE _____
Investigator/Researcher

Additional signature lines for researchers and research/lab assistants on next page.

All student-led research applications and all applicants from outside Le Moyne College must have a faculty / college sponsor whose signature is here affixed:

SIGNATURE _____ DATE _____
Sponsor

SIGNATURE _____ DATE _____
____ Investigator/Researcher ____ Research / Lab Assistant ____ Other:

SIGNATURE _____ DATE _____
____ Investigator/Researcher ____ Research / Lab Assistant ____ Other:

SIGNATURE _____ DATE _____
____ Investigator/Researcher ____ Research / Lab Assistant ____ Other:

SIGNATURE _____ DATE _____
____ Investigator/Researcher ____ Research / Lab Assistant ____ Other:

SIGNATURE _____ DATE _____
____ Investigator/Researcher ____ Research / Lab Assistant ____ Other:

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