Lourdes University Institutional Review Board
6832 Convent Blvd.
Sylvania, OH 43560

Verification of Exempt Research
Instructions and Application

Instructions:

All human subject research must be approved in advance by the Lourdes University IRB, or it must be found to meet the narrow criteria for exemption from IRB oversight by the IRB Committee. This form will help the investigator to determine if the project is likely to meet the criteria for exemption, to present the case for exemption, and to document the decision on the request.

NOTE: A determination of Exempt status does not release the investigator from exercise of prudent practice in protecting the interests of research subjects. Exempt or not, the project must be conducted in an ethical manner, consistent with the Ethical Principles and Guidelines for the Protection of Human Subjects (The Belmont Report). In addition, Exempt research studies that involve human subjects still require investigators to complete their CITI training.

IRB applications for exempt research protocols will be reviewed by the IRB Chair or Chair Designee to determine if the research falls into an appropriate exempt category. Exempt applications are reviewed promptly. Turn-around time largely depends on the investigator's response time to the IRB's requests for clarification or revision.

Review the Exempt Categories on page 2 and the Screening Questions on page 3. If your project appears to qualify for exemption, submit a completed Verification for Exemption application to the IRB committee.

If at any time in the process, it becomes clear to you that your human subjects research protocol does not meet the requirements for exemption, STOP and use the IRB application form for expedited and full review research.

Helpful hint, always ask:

1. Is there any type of risk to participants involved in the study?
2. Are you able to link identifiable information to a participant'?

If your answer is no to both, you will fall within the exempt category.

REMEMBER:
You may not start your research project until you receive written communication from the Lourdes IRB confirming that your research meets the exemption criteria.

Categories and Screening:

EXEMPT CATEGORY CLAIMED (please check the category that best describes your research)

1.	☐	Research conducted in established or commonly accepted educational settings, involved normal educational practices, such as (i) research on regular and special education instructional strategies; or (ii) research on the effectiveness of or the comparison among instructional techniques, curricular or classroom management methods. This category may include children.
2.	Research involving the use of **educational tests** (cognitive, diagnostic, aptitude, achievement), **survey procedures, interview procedures or observation of public behavior**, unless (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subject, and (ii) any disclosure of the human subjects responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employment, or reputation. Research which deals with sensitive aspects of the subject's own behavior such as illegal conduct, drug use, sexual behavior, or use of alcohol, cannot be exempt from review.	
	☐	(a) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement) for which subjects cannot be identified, or release of the information would not be harmful to the subject. This category may include children
	☐	(b) Research invovling the use of survey procedures, or interview procedures, or observation of public behavior for which subjects cannot be identified, or release of information would not be harmful to the subject. **This category may NOT include children.**
3.	☐	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: (A) 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; (B) 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. 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.
4.	☐	Research involving the collection or study of **existing data**[1]**,** documents, records, pathological specimens, or diagnostic specimens, if these sources are publically available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subject. This category may include children.
5.	☐	Research and demonstration projects which are conducted by or subject to the approval of **federal** department or agency heads and which are designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs; or (iv) possible changes in methods or levels of payment for benefits or services under those programs. This category may include children.
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 safe, or agriculture chemical or environmental contaminant at or below the level found to be safe by the U.S. Food

[1] Existing data means the items exist before the research was proposed or was collected prior to the research for a purpose other than the proposed research. (For purposes of a grant, this refers to data collected prior to the time the research was proposed)

		and Drug Administration or approved by the Environmental Protection Agency of the Food and Safety and Inspection Service of the U.S. Department of Agriculture. This category may include children.
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 an IRB conducts a limited IRB review.
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) An IRB conducts a limited IRB review and makes the determination that the research to be conducted is within the scope of the broad consent. 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.

EXEMPT SCREENING QUESTIONS

Please complete the following sections as applicable.

To help determine if your application is exempt, use the screening questions below. If you answer yes to any category, stop and complete the Application for Research Using Human Subjects that is found on the IRB website.

A. For research involving special populations, interventions, or manipulations:			
Yes ☐	No ☐	N/A ☐	1. Does your research involve pregnant women, fetuses, prisoners, or the mentally ill or incapacitated?
Yes ☐	No ☐	N/A ☐	2. Does your research involve using survey or interview procedures with children, minors <18 years old?
Yes ☐	No ☐	N/A ☐	3. Does your research involve the observation of children in settings where the investigator(s) will participate in the activities being observed?

B. **For research using survey procedures, interview procedures, observational procedures and questionnaires (note: exemption is not allowed in surveys or interviews with children):**			
Yes ☐	No ☐	N/A ☐	1. If data are to be recorded by audiotape or videotape, is there potential harm to subjects if the information is revealed or disclosed?
Yes ☐	No ☐	N/A ☐	2. If the subjects are to be identifiable either by name or through demographic data, is there potential harm to participants if the information is revealed?
Yes ☐	No ☐	N/A ☐	3. Will collection include sensitive data (e.g. illegal activities, or sensitive themes such as sexual orientation, sexual behavior, undesirable work behavior, or other data that may be painful or very embarrassing to reveal, such as death of a family member, memories of physical abuse)?

C. For research using existing or archived data, documents, records, or specimens only. *Please note*: Existing data means the items existed before the research was proposed or was collected prior to the research for a purpose other than the proposed research.			
Yes ☐	No ☐	N/A ☐	1. Will any data, documents, records, or specimens be collected from subjects after the submission of this application?
Yes ☐	No ☐	N/A ☐	2. If the data, documents, records, or specimens are originally labeled in such a manner that subjects can be identified, directly or indirectly through identifying links, is the investigator recording the data in such a manner that subjects can be identified, directly or indirectly through identifying links (i.e. demographic information that might reasonably lead to the identification of individual subjects – name, phone number, etc…; or any code number that can be used to link the investigator's data to the source record – medical record number or hospital admission number?

VERIFICATION OF EXEMPT RESEARCH

REMINDER: BEFORE YOU BEGIN FILLING OUT THE APPLICATION, BE SURE TO SAVE IT TO EITHER YOUR DESKTOP OR YOUR DOCUMENTS

1). **Project Title:**

2). **Project Dates:** **NOTE – Project may not start until the investigator receives IRB exemption approval letter**

(a) Anticipated start date**:** Anticipated end date**:**

(b) This project may be conducted on an annual basis: Yes: ☐ No: ☐

3). **Principal Investigator Information:**

Name:

Department or Affiliation:

Address:

Telephone:
(note: use of personal phone numbers should be avoided)

Email:

(note: students, faculty, staff at Lourdes University MUST use their Lourdes University email account)

4). **Check Box for Principal Investigator Type:**

☐ Undergraduate Student ☐ Graduate Student ☐ Lourdes University Faculty/Staff ☐ Other Institution

(A) Student Researcher as Principal Investigator:

Research Purpose: Capstone Project: ☐ Course Project: ☐ Personal Scholarship: ☐

Faculty Advisor: Name:

Phone: Email:

(B) Lourdes University Faculty or Staff as Principal Investigator:

Faculty: ☐ Staff: ☐ Administration: ☐

Research Purpose: Course Project: ☐ Personal Scholarship: ☐

Department OR Program:

Supervisor, Department Chair, or Dean:

Name:

Phone: Email:

5). Funding Information:

(a) Is this project being funded? Yes ☐ No ☐

(b) If yes, list the funding source(s):

(c) Is this project contingent upon receiving support? Yes ☐ No ☐

6). Co-investigators and other personnel involved in project:

Please list all study personnel involved in the conduct of this study. All study personnel **must** complete required training in human subject research and provide to the IRB office certification verifying completion of the requirement. The IRB will not review a study without such forms on file for all research personnel.

Name	Project Involvement

7). METHODS AND PROCEDURES (please read carefully):

This section must be written in lay terms so that it can be understood by the non-scientific members of the IRB

(a) Describe briefly the background and significance of the study:

(b) What is the objective of the study?

8). **PROTOCOL SUMMARY:**

(a) Describe the study design, including a description of the procedures (sequentially) to which human subjects will be subjected and the information to be collected:

(b) Describe the population to be studied:
(e.g. identify
1. who are the participants; and
2. why have they been chosen)?

1)

2)

(c) Number of Participants:

i. What is the maximum number of participants for whom you are seeking approval?

(d) Data Collection:

i. Will the data be collected anonymously?
(*Collected data are anonymous **if** the researcher cannot associate a participant's response to a participant and there are no collected identifiers that can connect the data to a participant*):

Yes ☐ No ☐

ii. If the answer to (i) is "no," then ask. Will the data be collected with identifiers?
(*Identifiers include, but are not limited to, names, student's numbers, email addresses, birthdates, social security numbers, or even a small sample size*):

Yes ☐ No ☐

(e) Confidentiality: Please provide a detailed description of how you will ensure that confidentiality will be maintained:

(f) Describe the risks (if any) involved for those participating in the study:

(g) Will the project require the consent of the subjects (e.g. an informed consent document or statement)? If consent is required, how will it be obtained? How and when will subjects be approached? Who will present the consent form? Remember: If you are requesting consent, please attach the form.

9). DATA COLLECTING INSTRUMENT:

Please attach a copy of the survey, questionnaire, or other instrument that you intend to use in this study.
1. Check the appropriate box directly below regarding how the data will be collected in your research study;
2. Complete the appropriate corresponding section:

(A) ☐ Survey/Questionnaire **(B)** ☐ Record/Database/Registry Review **(C)** ☐ Other

(A) Surveys/Questionnaires:

a. What type of instrument(s) will be used?

b. Describe the setting and mode of administering the instrument (e.g. by phone, one-on-one, group, etc…) and the provisions for maintaining privacy and confidentiality (e.g. anonymous). Include duration, intervals of administration, and overall length of participation.

(B) Records, Database, Registry Review:

a. Is the information publically available?

b. Will you have ongoing contact with the subjects?

c. Will you be recording identifiers (information items that could potentially identify human subjects)?

(C) Other, please briefly describe:

13). PRINCIPAL INVESTIGATOR ASSURANCE STATEMENTS:

(All Data must be kept for 3 years)

The Principal Investigator agrees to the following:

As Principal Investigator, the electronic signature below (ex: /s/John S. Doe) denotes my intent to certify that in the making of this application I have read and understood Lourdes University's policies and procedures governing research with human participants, in particular Institutional Review Board policies. I shall comply with the letter and spirit of these policies and will not undertake the research without Institutional IRB Approval. My signature indicates that I have: (1) completed all necessary paperwork required for this project; (2) for student investigators, had my Faculty Advisor review and electronically sign the application and review all supporting documentation before submission; and (3) to the best of my knowledge, submitted a complete IRB Application.

I acknowledge my obligation to: (1) obtain written Institutional Review Board approval prior to making any changes from the originally approved application; (2) report immediately all adverse events of the study on the participants to the Chairperson of the Institutional Review Board and if I am a student investigator, to my Faculty Advisor; and (3) supply the Institutional Review Board with a completed Statement of Project Completion Form at the close of the research, and all other reports/information as requested.

☐ For students: By checking this box, I certify that I have complied with the IRB Electronic Submission Policy by including my Faculty Advisor on all email communications with the Lourdes University Institutional Review Board. I understand that if my Faculty Advisor is not included on the initial protocol submission email, the protocol will be returned as "unreviewable" until I adhere to the Electronic Submission requirement.

Name: _____ Date: _____

(example: /s/John S. Doe)

The Faculty Advisor agrees to the following:

As a Faculty Advisor, the electronic signature below (ex:/s/John S. Doe) denotes my intent to certify that the student is knowledgeable about the regulations and policies governing research with human subjects and has sufficient training and experience to conduct this particular study in accordance with the research protocol. In addition, I confirm that:

- I have advised my student researcher throughout the IRB submission process.
- I have thoroughly reviewed this IRB application, including the protocol narrative and verify that it is complete and the research is appropriate in design.
- I agree to meet with the Student Researcher Principal Investigator on a regular basis to monitor study progress.
- I assure that the Investigator will promptly report adverse events, and will adhere to all requirements for continuing review.
- If I will be unavailable (e.g. sabbatical leave, vacation or resignation), I will arrange for an alternate faculty sponsor to assume responsibility during my absence, and I will advise the Lourdes University IRB, in writing, of such changes.
- If the student leaves the college, I will provide all necessary documents for terminating the study or continuing review.
- Finally, I certify that, to the best of my knowledge, the IRB application that has been submitted is complete.

Name: _____ Date: _____

(example: /s/John S. Doe)