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

Application for Research Using Human Subjects

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 investigator receives IRB 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/Affiliation:

Address:

Telephone:

(Note: Personal phone numbers should be avoided.)

Email:

(Note: Students, faculty, and staff at Lourdes 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 a 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 Project:

Supervisor, Department Chair, or Dean:

Name:

Phone: Email:

(c) Faculty or Staff from "Other Institution" as Principal Investigator

Faculty ☐ Staff ☐ Administration ☐

Research Purpose: Course Project ☐ Personal Scholarship ☐

Department OR Project:

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 others involved in the project

Name	Project Involvement

7) Overview of Project

Directions:

It is the IRB's responsibility to determine that your study is designed so as to protect the rights and welfare of human subjects. In order to fulfill this responsibility, the IRB must have a good understanding of the theoretical background, purpose, and methodology of your project. Remember that the IRB includes members from a variety of academic areas as well as community representatives. Respond to the following questions/statements as completely and**concisely** as possible, and**include enough information**for the IRB to understand your study procedures.

PLEASE DESCRIBE YOUR PROJECT IN NARRATIVE FORM

(a) In brief, what is the theoretical background of your research? Include enough information to orient IRB members to the general area of your study. It is helpful to:
(1) provide key references/citations of literature,
(2) write a concise summary of the main ideas, and
(3) use lay terms.

(b) What is the Research Question or Research Problem that you plan to study? (Please present in question form if/when applicable.)

(c) List the Research Methods that will be used (e.g., survey, experimental, quasi-experimental, action research participant observation). Provide a general description of methods in lay terms.

Complete the appropriate permission forms, found under "Forms" on the IRB page.

(1) Complete the Agency Permission form for data collection at each facility where research will be conducted.

> *The Agency Permission Form MUST be signed by an authorized person(s) for each agency/organization.*

(2) Submit any/all IRB Approval Letters from other institutions.
(3) Complete the Request for Access Data form at Lourdes University.

(d) Research Setting: Please list all of the organizations where this research project has been or will be conducted.

(e) (1) Who are the people or groups that you plan to include in your research and (2) why are they appropriate subjects for your study? Please be specific.

1)

2)

(f) Number of Participants

(1) What is the maximum number of participants for whom you are seeking approval?
(2) How many participants do you expect to participate?

(g) What means of communication will you use to approach potential research participants? Check all that apply. (Note: You may have multiple ways you are going to be contacting participants—all must be checked.)

- ☐ Advertisements
- ☐ Letters
- ☐ Random Calls
- ☐ Telephone Lists
- ☐ Notices
- ☐ Direct Solicitation
- ☐ Lourdes University email lists—specify:
- ☐ Other—specify:

(h) Describe the location where the communication is to take place and the chronological order of the research project. Please be specific.
(Example: Step 1 - Contact business owner of X and request agency permission. Step 2 - send out informed consent statement. Etc.)

(i) Because research may pose additional and/or unknown risks to vulnerable populations, Federal Regulations require additional safeguards for the protection of pregnant women, children, human fetuses, neonates, prisoners, persons at risk of suicide, and persons with impaired decisional capacity (45 CFR 46, Subpart B, C, D). Other groups, while not specifically mentioned in the Regulations, may also be vulnerable under some circumstances.

(1) Indicate which, if any, of the following groups will be research participants (check all that apply).

- ☐ Students
- ☐ Employees
- ☐ Non-English Speakers
- ☐ Pregnant Women
- ☐ Cognitively Impaired
- ☐ Senior Citizens (65+)
- ☐ Prisoners
- ☐ Institutional Residents
- ☐ Minors (under 18)—attach Research on Children Form
- ☐ Adults who lack the capacity to consent
- ☐ Mentally/Physically Challenged
- ☐ Single Subject Populations (by Ethnicity, Race, Sex, or Religion)
- ☐ Other (please specify):

(2) If one or more of the above groups is selected, state the rationale for using special groups:

8) Informed Consent

Directions:
Samples are available under "Forms" on the IRB page.

(a) How to determine which forms of consent will be used in your study (check all that apply):

- ☐ Adults who have the ability to consent
- ☐ Adults who lack the ability to consent

(b) If your study will include children (under 18 years of age), please indicate the following:

- ☐ Parent/Guardian Permission
- ☐ Child/Minor Oral Assent Script
  (non-readers: Not able to read or not proficient at reading)
- ☐ Child/Minor Written Assent to be signed by the child or minor
  (proficient readers: Can read and understand a simple assent form)

(c) Describe in detail your plan to obtain informed consent, parent/guardian permission, and/or child assent:

9) Data Collection

(a) Data collection methods (please check all methods that apply to your study):

- ☐ Observation
- ☐ Video or Audio Taping
- ☐ Instruction/Curriculum
- ☐ Physical Tasks
- ☐ Web or Internet
- ☐ Focus Groups
- ☐ Questionnaire or Survey
- ☐ Interview
- ☐ Computer Collected Task Data
- ☐ Testing/Evaluation
- ☐ Intervention
- ☐ Archival Data, Data Banks, Medical Banks
- ☐ Other (please specify):

(b) (1) What are the origins of the instrument(s) you plan to use? (e.g., are you using an instrument that you created, or are you using an already established survey, questionnaire, interview, etc.?) Please specify.
(2) If you did not design your own instrument, do you have permission of the author to use the instrument?
(Note: Please attach the permission form to your protocol submission.)

1)

2)

(c) 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

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

☐ Yes ☐ No ☐ N/A

(1) If the answer to (d) is "yes," then ask:

i) Will identifiers be removed for analysis? ☐ Yes ☐ No

ii) Will identifiers be removed for reporting? ☐ Yes ☐ No

10) Security of Data and Consent Forms

(a) Describe how the consent forms and other study materials (e.g., data instruments, interview questions/responses, computer task data) will be distributed and collected to protect the privacy of the participants.

Distributed:

Collected:

(b) (1) Describe the security of the data.
(2) Where will the consent forms and other study materials be stored?
(3) Who will have access to the materials?
(4) How and when will study data be destroyed?

1)

2)

3)

4)

(c) Signed Consent Forms must be retained for three years after the end of the study. (Note: For student projects, faculty/staff advisors should retain the original or a copy of the signed Consent Forms for three years.)
Name of the person who will retain the Consent Forms for the specified three years:

11) Risk

A research participant is considered to be at risk if the research procedure exposes the participant to possible physical or mental harm, coercion, deceit, or loss of privacy. The most obvious examples of placing participants at risk of harm include administration of unusual physical exertion, deceit, and public embarrassment or humiliation. Coercion may be present when the potential participants are not able to exercise their right to decline participation, particularly when the researcher is in a relationship of greater power over the participants. [From The Public Health Service Act 301(d), 42 U.S.C. 241(d), Office for Human Research Protections (OHRP) Department of Health and Human Services (HHS).]

(a) Risk Criteria

☐ Yes ☐ No Concern about employment and/or work

☐ Yes ☐ No Deceit, coercion, or pressure

☐ Yes ☐ No Loss of privacy or possible embarrassment/humiliation

☐ Yes ☐ No Participants will be tape recorded, photographed, or video taped

☐ Yes ☐ No Participants may experience mental discomfort

☐ Yes ☐ No Participants may experience physical discomfort

☐ Yes ☐ No Peer issues at school

☐ Yes ☐ No Experimental drugs will be used (from H.R.S.A.)

☐ Yes ☐ No Other (please describe):

(b) What is the likelihood of any deceit, coercion, or pressure? ☐ Low ☐ Moderate ☐ High

(c) Explain and describe any potential for deceit in this research study. If this study cannot be carried out without deceit, what follow-up information will be provided to the subject?

(d) Explain and describe any potential for coercion or pressure. In addition, what steps will be taken to minimize any coercion or pressure that might be experienced by research subjects?

(e) Explain the likelihood and seriousness of any other risks to the participants (physical, mental, or other). Describe alternative methods that would not entail comparable risks and why these were not used.

(f) If the research participants will be compensated or rewarded, indicate the type and amount of compensation. Indicate whether students are receiving course credit (regular or extra credit) and, if so, what alternatives are offered to those students who do not wish to participate in the research.

(g) Describe any anticipated benefits to participants. Describe any contributions to general knowledge in the field of inquiry.

(h) Explain any foreseeable circumstances under which the investigator might be required to give information about the subjects to third parties.

(i) Upon considering all previous Risk questions, please indicate the category that accurately describes this research study.

Not greater than minimal risk

Greater than minimal risk, but presenting the prospect of direct benefit to individual subjects

Greater than minimal risk, no prospect of direct benefit to individual subjects,
but likely to yield generalizable knowledge about the subject's disorder or condition

Research not otherwise approvable which presents an opportunity to understand, prevent,
or alleviate a serious problem affecting the health or welfare of subjects

12) SUBMISSION CHECKLIST

Use this checklist to ensure that your protocol submission includes all required documentation. All documents (e.g., IRB Application, Informed Consent, Agency Permissions, Survey/Interview Instrument, Investigator CITI Training, etc.) must be typed and submitted in digital format to irb@lourdes.edu.
Please note that protocol review may be delayed if a submission is missing one or more documents.

1. Application Form:

- ☐ Submit the IRB application by sending it as an attachment to irb@lourdes.edu.

2. CITI Training:

- ☐ Principal Investigator completed required CITI training modules
- ☐ Faculty Advisor completed required CITI training modules

3. Institutional Permissions (if applicable):

- ☐ Agency Permission Form signed by authorized agency representative
- ☐ IRB Approval Letter from other institutions
- ☐ Request to Access Lourdes University information form

4. Data Collection Instruments—submit in final format as participants will see them:

- ☐ Survey instruments, email survey, interview questions, etc.
- ☐ If an instrument is copyrighted, include permission from the author

5. Materials used to recruit research participants—submit in final format as participants will see them:

- ☐ Written flyer, announcement, brochure, letter, etc.
- ☐ Invitation email
- ☐ Script for telephone calls or in-person approach

6. Informed Consent Documents—submit in final form as participants will see them:

- ☐ Adult Consent Form
- ☐ Vulnerable adults with impaired consent capacity
- ☐ Request to waive signatures on Informed Consent document

7. Documents to submit if research subjects are children:

By regulatory definition, children are persons who have not attained the legal age (18 years) for consent to treatments or procedures involved in research, under applicable law of the jurisdiction in which the research will be conducted. [45 CFS 46 Subpart A, Office of Human Research Protections (OHRP) Department of Health and Human Services (DHHS).]

- ☐ Parent/Guardian Permission Form
- ☐ Child/Minor Assent Script (non-readers: Not able to read or not proficient at reading)
- ☐ Child/Minor Written Assent Form to be signed by child/minor (proficient readers: Can read and understand a simple assent form)

8. Protocol Assurance Statement is signed and dated by appropriate personnel:

- ☐ Principal Investigator
- ☐ Faculty Advisor (for Student Principal Investigator protocols)

13. Principal Investigator Assurance Statements

(All Data must be kept for three 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)