Lourdes University Institutional Review Board
6832 Convent Blvd.
Sylvania, OH 43560
FWA 00018892

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:**

Lourdes University Students' Perceptions Regarding Bikeability and Walkability of Campus

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

(a) Anticipated start date: 1/15/17 Anticipated end date: 5/1/17

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

3). **Principal Investigator Information:**

Name:	John Smith
Department or Affiliation:	College of Nursing
Address:	6832 Convent Blvd. Sylvania, OH 43560
Telephone:	419-123-4567

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

Email: Jsmith123@lourdes.edu

(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: Jane Doe, PhD

Phone: 419-123-4567 Email: Jdoe123@lourdes.edu

(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:

(C) Faculty or Staff from "Other Institution" 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 others involved in project:**

Name	Project Involvement
N/A	

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 DECRIBE 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 main ideas, and (3) use lay terms.

With the onset of the 21st century an emphasis has been placed on reducing environmental barriers to physical activity. This emphasis has driven researchers to examine the built environment by engaging community members in the evaluation of transportation infrastructure. Research has shown that rates of active travel correlate with environmental factors such as available pedestrian infrastructure, perceived safety, and neighborhood aesthetics (Dill, 2009; McNeill, Kreuter, & Subramanian, 2006; Wendel-Vos, Droomers, Kremers, Brug, & Van Lenthe, 2007). A growing amount of literature demonstrates that altering land use, increasing pedestrian infrastructure, and working with city planners to influence neighborhood design are effective ways to increase utilitarian transit; thereby increasing physical activity levels in Americans. Since college campus design is one way to influence pedestrian infrastructure among students, more research is needed to assess the barriers, benefits, and perceptions of reengineering the built environment to promote physical activity on campus.

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

What are the perceptions of Lourdes University students in relation to the bikeability and walkability of campus?

(C) List the Research Methods that will be used (for example: survey, experimental, quasi-experimental, action research, participant observations). Provide a general description of methods in lay terms.

This is a survey research design.

Complete the appropriate permission forms, found on the left side of the IRB main page.

- (1) Complete 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 letter from other institutions
- (3) Complete 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.

Lourdes University

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

1. Lourdes University undergraduate students provide the target demographic for this study. 2) Since the purpose is to assess the perceptions of students regarding campus aesthetics and utilitarian travel, undergraduate students living on campus are most apt to provide opinions on this subject.

(F) Number of Participants:

(a) What is the maximum number of participants for whom you are seeking approval? 200

(b) How many participants do you expect to participate? 100

(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 at X & request agency permission; Step-2 send out informed consent statement, etc):

This is a survey research design utilizing Lourdes University students. The researcher will receive approval from the registrar and obtain a list of names and addresses of all eligible students. Data will be collected using a mailed survey printed on colored paper, which research shows increases response rates (Brennan & Charbonneau, 2005). The data collection will occur with four mailings and will use several practices to also maximize response rate; these include keeping the length of the questionnaire to four pages; offering a one-dollar monetary incentive in the first mailing; and personalizing the cover letter (King, et al., 2001; Edwards, et al., 2007). Beginning February 1, 2017, the initial wave will include a personalized cover letter with an explanation of the research, a $1 bill, a copy of the survey, and a stamped return envelope all sent through first-class mail. The second wave, occurring two weeks after the first, will be a repeat of wave one, minus the $1 incentive. The third wave, occurring two weeks after the second, will be a letter to remind the participants to please fill out the survey. The fourth and final wave, occurring two weeks after the third, will be a follow-up reminder, either by phone, email, or postcard..

(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.

(a) 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):						

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

As stated above, the purpose is to assess the perceptions of students regarding campus aesthetics and utilitarian travel; thus undergraduate students living on campus are most apt to provide opinions on this subject.

8). INFORMED CONSENT:

Directions: Samples are available under "Forms" on the left hand side of the website.

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

☒	Adults who have ability to consent
☐	Adults who lack 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:

Participants will be given a cover letter with information about the study (see attached). Return of the survey will imply consent for participation.

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 to your protocol submission):

1. A survey designed by the researcher will be used to collected data.
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, birthdates, social security numbers, or even a small sample size*):

Yes ☐ No ☐ N/A ☐

i. 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 material (e.g. data instruments, interview questions/responses, computer task data) will be <u>distributed</u> and <u>collected</u> to protect the privacy of the participants:

Distributed and Collected: No personal identifiers will be collected through the use of the survey. Any surveys that might have inadvertently included names or other identifying information will be destroyed. Surveys will entered into a password protected electronic database for analysis and hard copies of the surveys will be stored in the faculty advisor's office in a locked file.

(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. Surveys will entered into a password protected electronic database for analysis and hard copies of the surveys will be stored in the faculty advisor's office in a locked file.
2. A request to waive signature was submitted along with this application, thus no informed consent documents will be collected or stored.
3. The researcher and faculty advisor will have access to these materials.
4. All study materials and data will be destroyed after 3 years.

(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 3 years

No informed consent documents are being collected, but all study materials will be housed in the faculty advisor's office in a locked file.

11). **RISK:**

A research participant is considered to be at risk if the research procedures expose 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. 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 videotaped
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:

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

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

There is no potential for deceit.

(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?

Participants will be receiving a small monetary incentive of $1, which could increase pressure of participation.

(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.

No study is without risk, however this study does not pose any risk to participants over and above the risks encountered in everyday life.

(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.

As stated above, participants will receive a $1 incentive to participate.

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

Participants will be providing information that could increase the aesthetics and walkability/bikeability of campus.

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

Although the results of the study could be published, no information that could identify participants will be included.

(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 Permission, Survey/Interview Instrument, etc…) must be typed and submitted in digital format to: irb@lourdes.edu. *Please note protocol review may be delayed if a submission is missing a document.*

1. **Application Form:**
   ☒ Submit the IRB application by sending it as an attachment to irb@lourdes.edu

2. **CITI Training:**
   ☒ Principal Investigator completed required C.I.T.I. training modules
   ☒ Faculty Advisor completed required C.I.T.I. 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, 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 format 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 which the research will be conducted. 45 CFR 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 non-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)
   ☐ Faculty Supervisor or Department Chair (for Faculty Principal Investigator protocols)

13). PRINCIPAL INVESTIGATOR ASSURANCE STATEMENTS:

(All Data must be kept for 3 years)

(A) RESEARCH PROJECTS CONDUCTED BY STUDENTS

The Student Researcher Principal Investigator agrees to the following:

As a Student Researcher 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) had my Faculty Advisor, Faculty Supervisor or Department Chair 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.

☒ Further, 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: /s/John Smith Date: 12/15/16

(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: /s/Jane Doe Date: 12/17/16

(example: /s/John S. Doe)

(B) RESEARCH PROJECTS CONDUCTED BY FACULTY, STAFF, ADMINISTRATION

The Faculty/Staff Researcher Principal Investigator agrees to the following:

As a Faculty/Staff Researcher Principal Investigator, the electronic signature below (ex: /s/John S. Doe) denotes my intent to certify that 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) had my Faculty Supervisor or Department Chair review the application and 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 IRB 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 IRB; (3) and to supply the IRB with a completed Project Closure Form at the close of the research, and all other reports/information as requested.

☐ Further, by checking this box, I certify that I have complied with the IRB Electronic Submission Policy by including my Faculty Supervisor or Department Chair on all email communications with the Lourdes University Institutional Review Board. I understand that if my Supervisor or Chair 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)

Faculty Supervisor or Department Chair agrees to the following:

As a Faculty Supervisor or Department Chair, my electronic signature (ex:/s/John S. Doe) denotes my intent to certify that I have read and understood Lourdes University's policies and procedures governing research with human participants, in particular Institutional Review Board policies. I acknowledge that I: (1) have reviewed the faculty application for research; (2) confirm that the resources required to conduct and complete this project are available; and (3) certify that, to the best of my knowledge, the IRB application that has been submitted is complete.

Name: Date:

(example: /s/John S. Doe)