MADONNA UNIVERSITY
Graduate School

APPLICATION FOR EXEMPTION
Single-Semester Project – Student Form

Center for Research
Room 2107 Administration Building
36600 Schoolcraft Rd, Livonia, MI 48150
Phone: (734) 432-5666 Fax: (734) 432-5862 CenterForResearch@madonna.edu

ELECTRONIC SUBMISSION REQUIRED

INSTRUCTIONS FOR SUBMISSION OF HUMAN SUBJECTS REVIEW APPLICATION

THIS APPLICATION MUST BE SUBMITTED ELECTRONICALLY. READ AND FOLLOW ALL INSTRUCTIONS OR YOU WILL DELAY YOUR APPLICATION!

- **Students:** after you complete this application, submit it to your course instructor for review and approval. Insert your instructor's contact information in the Course Instructor fields.

- **Students:** Have your instructor verify Research Integrity Training and sign page 6. (REQUIRED!)

If your instructor determines that your project does not meet the criteria for Umbrella-Exemption category, you must submit this to the Center for Research for review. Follow the instructions below.

- Scan the signed pages and submit in a separate file. **DO NOT SCAN THE WHOLE APPLICATION. IT MAY BE TOO BIG TO GO VIA EMAIL.**

  - The computer lab contains scanners and technicians who can help you with this process. (Take this instruction sheet.)

- **Name each document as follows**:
  Year_month_day_last name_first initial_document. For example:
  11_09_07_smith_s_HSRC application (DO NOT SCAN. You may save as PDF, if desired)
  11_09_07_smith_s_signature pages (one document SCANNED)
  11_09_07_smith_s_training certificates (one document SCANNED)
  DO NOT SCAN THE WHOLE APPLICATION. IT MAY BE TOO LARGE TO GO VIA EMAIL.

- Submit the completed application and scanned documents to CenterForResearch@madonna.edu. You will receive a confirmation within a working day or two. **If you do not hear from us, call 734-432-5666.**

DATE SUBMITTED:	

1. PROJECT TITLE (REQUIRED)

2. COURSE INSTRUCTOR

Name (Last, First, MI)		Department	
Street Address		City, State, Zip	
E-mail		FAX	
Work Phone		Mobile phone	

3. STUDENT

Name (Last, First, MI)		Program	
Street Address		City, State, Zip	
MU E-mail		Alternate E-mail	
Work Phone		Mobile phone	

4. Student Co-Investigator(s) (Attach page with additional co-investigators)

Name (Last, First, MI)		Department:	
Street Address		City, State, Zip	
MU E-mail		Alternate E-mail	
Work Phone		Mobile phone	
Name (Last, First, MI)		Program	
Street Address		City, State, Zip	
MU E-mail		Alternate E-mail	
Work Phone		Mobile phone	

5. RISK ASSESSMENT

In order for your study to qualify as **EXEMPT**, it may involve only minimal risk to human subjects. By Federal Regulations at 45CFR46.102(i), "*Minimal risk means that the probability 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.*"

Does your study meet the definition of minimal risk as defined above? Yes ☐ No ☐

Describe t*he risks to project participants (e.g., breach of confidentiality) and explain how they will be minimized, this should include a description regarding* how participants' confidentiality will be protected (e.g., data collected for the study will be kept on a password protected desktop computer in a locked office).

6. SCREENING QUESTIONS (Refer to Addendum as needed for Categories)

a. Will the research expose participants to discomfort or distress beyond that normally encountered in daily life? Yes ☐ No ☐

b. Could disclosure of participants' responses outside the research reasonably place participants at risk of criminal or civil liability or be damaging to participants' financial standing, employability, or reputation? (This means surveying illegal behavior such as texting while driving or other "minor" infractions!) Yes ☐ No ☐

c. Does any part of the research require deception or incomplete disclosure of information to participants? Yes ☐ No ☐

d. Will prisoners (or their data and/or specimens) be participants in the research? (MU does not permit Yes ☐ No ☐

	prisoner research)				
e.	For research involving normal educational practices, will the research be conducted outside of commonly accepted educational settings or deviate from normal educational practices?	Yes		No or N/A	
f.	For research involving use of educational tests, will the research involve surveys or interview procedures with anyone who is decisionally incompetent or under the age of 18 years?	Yes		No or N/A	
g.	For research involving use of educational tests, will the research involve observations of the public behavior of anyone who is decisionally incompetent or under the age of 18 years, during which an investigator participates in the activities being observed?	Yes		No or N/A	
h.	For research involving the collection or study of **publicly** available existing data, documents, records, pathological specimens, or diagnostic specimens or data recorded such that subjects cannot be identified directly or through identifiers, will any of the data, documents, records, or biological specimens be collected or created after the date of this application for exemption?	Yes		No or N/A	
i.	For research involving the collection or study of **publicly** available existing data, documents, records, pathological specimens, or diagnostic specimens or data recorded such that subjects cannot be identified directly or through identifiers, will any of the information obtained from private sources of data, documents, records, or biological specimens be recorded by the investigator in such a manner that participants could be identified directly or through identifiers linked to the participants?	Yes		No or N/A	
j.	Is the research subject to FDA regulations?	Yes		No or N/A	
k.	Will data collection include Protected Health Information?	Yes		No	

If you checked YES to ANY of the questions above, your research is NOT EXEMPT. DO NOT COMPLETE THIS APPLICATION. Submit an HSRC Application B for Expedited or Full Review.

7. OVERVIEW OF THE RESEARCH

a. Research Question(s)/hypothesis(ses)/Aims:

b. Provide the estimated beginning and ending dates of the project.

8. LOCATION OF THE RESEARCH

All research will require a signed Agency Approval form. Appendix A

a. List the specific site(s) at which the MU research will be conducted. (Attach additional page if more sites than two.)

Location Name (or description)	Address (street, city and state, or country)

9. RESEARCH METHODS & ACTIVITIES

Check all research activities that apply. ***Attach a copy of materials to be used (e.g., interview/focus group questions, instruments, data collection forms, etc.)***.

☐	Audio, video, digital, or image recordings (*highlight one)*	☐	Record/chart review
☐	Existing data, not publicly available	☐	Specimen research (must be existing at time of application)
☐	Existing data, publicly available	☐	Surveys, questionnaires, or interviews (one-on-one)
☐	Focus groups	☐	Surveys, questionnaires, or interviews (group)
☐	Internet (anonymous) or e-mail data collection *(highlight one)*	☐	Taste-testing
☐	Observation of participants (including field notes)	☐	Other (**specify)**:
☐	Oral history (does not include medical history)		

b. Describe your data collection instrument. (Attach a copy)

c. Describe procedures for data collection and how data will be protected (include location, length of time and disposition of data)

10. PARTICIPANT POPULATION

a. Describe your subjects: Who or what (records. database) are they?

b. Specify the age(s) of the individuals who may participate in the research:

Age(s):

c. Specify the participant population(s) to be included (check all that apply):

☐	Adults	☐	Non-English Speaking
☐	Children (< 18 years)	☐	Unknown (e.g., research using secondary data/specimens, non-targeted surveys, program protocols)
☐	Students from Participant Pools (e.g., REP)	☐	Adults who are decisionally incompetent
	Specify:	☐	Other **Specify:**

d. Provide the total number of participants (or number of participant records, specimens, etc.) for whom you are seeking MU approval.

NOTE: The number of participants is defined as the number of individuals who agree to participate (i.e., those who provide consent or whose records are accessed, etc.) even if all do not prove eligible or complete the study.

11. INFORMED CONSENT PROCESS

Describe how participants will be informed about the project and their consent obtained. ***See Informed Consent Guidance - Exempt Research for instructions or contact HSRC for more information.***

☐	Assent – Form (Children)	☐	Parental Permission – Form
☐	Assent – Verbal Script/Online/Unsigned (Children)	☐	Parental Permission – Verbal Script/Online/Unsigned

☐	Informed Consent – Form signed	☐	Translated Consent/Assent – Form(s), Script(s), etc.
☐	Informed Consent – Verbal/Online/Unsigned form	☐	Other (Specify):
☐	Not Applicable (existing data or specimens)	☐	FERPA authorization

b. Describe the consent process. Explain when and where consent will be obtained and how subjects and/or their legally authorized representatives will be provided sufficient opportunity (e.g., waiting period, if any) to consider participation. N/A ☐

12. PRIVACY OF PARTICIPANTS

a. Describe the provisions to protect the privacy interests of the participants.

b. Does the research require access to personally identifiable private information? Yes ☐ No ☐

If Yes → Describe the personally identifiable private information involved in the research. List the information source(s) (e.g., educational records, surveys, medical records, etc.).

13. APPLICATION CONTENTS

Indicate the documents being submitted for this research project. Check all appropriate boxes.

- ☐ Type of Request Checklist **REQUIRED!!**
- ☐ **Application for Single-Semester Project approval** **REQUIRED!!**
- ☐ Consent form(s), Assent Form(s), Permission Form(s), and Verbal Script(s), including translated documents
- ☐ Data Collection Form(s) involving Protected Health Information (PHI)
- ☐ Recruitment Materials (e.g., ads, flyers, telephone or other oral script, radio/TV scripts, internet solicitations)
- ☐ Script(s), Instructions, or Information Sheet(s)
- ☐ Instruments (e.g., questionnaires or surveys to be completed by participants)
- ☐ Other Committee Approvals/Letters of Support/Agency Permission/FPD Approval (question 8, Appendix A)

14. ASSURANCE: PRINCIPAL INVESTIGATOR

I agree to follow all applicable policies and procedures of Madonna University and federal, state, and local laws and guidance regarding the protection of human subjects in research, as well as professional practice standards and generally accepted good research practice guidelines for investigators, including, but not limited to, the following:

- Perform the project as approved under the direction of the Course Instructor by appropriately trained and qualified personnel with adequate resources;
- Promptly report to course instructor events that may represent unanticipated problems involving risks to subjects or others;
- Inform course instructor of any proposed changes in the research or informed consent process (via a new In-Class-Only Project Application) before changes are implemented, and agree that no changes will be made until an exempt determination is made by HSRC (except where necessary to eliminate apparent immediate hazards to participants);
- Maintain research-related records (and source documents) in a manner that documents the validity of the research and integrity of the data collected, while protecting the confidentiality of the data and privacy of participants;

I verify that the information provided in this application is accurate and complete.

Signature of Student Investigator | Date

Printed name of Student Investigator

Signature of Student Investigator | Date

Printed name of Student Investigator

Signature of Course Instructor (REQUIRED) | Date

Printed name of Course Instructor

15. RESEARCH INTEGRITY TRAINING – Course Instructor Completes

I (course Instructor) have completed the required web-based course (UNV 3000, CITI, or equivalent) in the protection of human research subjects. (Submit copies of certificates of completion that are **less than 36 months old** **if not on record in the Center for Research**; UNV 3000 has 3 certificates)

Course Instructor (Name) | Yes ☐ | No ☐

Signature of Course Instructor | Date