MADONNA UNIVERSITY
Center for Research

APPLICATION for EXEMPTION

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.

- Students: after you complete the application, submit it to your research advisor/instructor for review and approval. Insert your instructor's contact information in the Principal Investigator fields.

- Students: Have your advisor/instructor sign page 8 and the Agency Permission Form(s) (Appendix A).

- Scan the signed pages.
  - 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

2. PRINCIPAL INVESTIGATOR (or STUDENT INVESTIGATOR)

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

***3.* FACULTY ADVISOR**

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

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

Name (Last, First, MI):		Department:	
E-mail:		Fax:	
Work Phone:		Mobile phone:	

Student Co-Investigator (Attach page with additional student co-investigators)

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

5. RESEARCH INTEGRITY TRAINING

Have all investigators and key personnel completed the required web-based course (UNV 3000 on MU Blackboard, CITI, or equivalent) in the protection of human research subjects? (Attach copies of certificates of completion that are **less than 36 months old**; UNV 3000 has 3 certificates)

Primary/Student Investigator (Name)		Yes		No	
Co-Investigator (Name)		Yes		No	
Co-Investigator (Name)		Yes		No	

6. FINANCIAL CONFLICT OF INTEREST

	Yes	No
Does any MU investigator (including principal or co-investigator), key personnel, or their immediate family members have a financial interest (including salary or other payments for services, equity interests, or intellectual property rights) that would reasonably appear to be affected by the research, or a financial interest in any entity whose financial interest would reasonably appear to be affected by the research?		

7. FUNDING OR OTHER SUPPORT

a. Is the research funded or has funding been requested? **(Includes TET and FPD funding)** Yes ☐ No ☐

If Yes → Specify sponsor:

Provide a copy of the grant application or funding proposal. The University is required to verify that all funding proposals and grants (new or renewals) have been reviewed before funds are awarded.

b. Is any support other than monetary (e.g., materials, equipment, etc.) being provided for the study?	Yes		No	
If Yes → Specify support and provider:				

8. 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.*"

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

b. **All research involves some risk. Describe (below)** *the 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).

9. SCREENING QUESTIONS

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?	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 prisoner research)	Yes		No	
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 decisionally impaired adults 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 decisionally impaired adults 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 (PHI)? 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.

10. OVERVIEW OF THE RESEARCH

a. List the research question(s)/hypothesis(ses)/Aims:

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

11. LOCATION OF THE RESEARCH

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

a. List the specific site(s) at which the research will be conducted, including MU sites. (Attach additional page if needed.)

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

12. RESEARCH METHODS & ACTIVITIES

a. 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)

13. 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)	☐	Other
☐	Specify:	☐	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.

14. PARTICIPANT IDENTIFICATION, RECRUITMENT, & SELECTION

a. Describe how potential participants will be identified (e.g., advertising, individuals known to investigator, record review, course instructor approval, etc.). Explain how investigator(s) will gain access to this population, as applicable.

b. Describe the recruitment process, including the setting in which recruitment will take place. Where will you approach the participants? Explain how the process respects potential participants' privacy. ***Provide copies of proposed recruitment materials (e.g., ads, flyers, website postings, recruitment letters, and oral/written scripts).***

15. INCENTIVES TO PARTICIPATE

Will participants receive compensation or other incentives (e.g., free services, cash payments, gift certificates, parking, classroom credit, travel reimbursement) to participate in the research study? Yes ☐ No ☐

Compensation plans should be pro-rated (not contingent upon study completion) and should consider participation withdrawals, as applicable.

If Yes → Describe the incentive, including the amount and timing of all payments.

16. INFORMED CONSENT PROCESS

a. Indicate the consent process(es) and document(s) to be used in the study. Check all that apply. ***Provide copies of documents, as applicable. See Informed Consent Guidance - Exempt Research for instructions or contact HSRC for more information.***

☐	Assent – Form (Children, Decisionally impaired adults)	☐	Parental Permission – Form
☐	Assent – Verbal Script/Online/Unsigned (Children. Decisionally impaired adults)	☐	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

c. Describe how you will explain the study to the participants.

17. 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.).

18. CONFIDENTIALITY OF DATA

a. Explain how information is handled, including storage, security measures (as necessary), and who will have access to the information. Include both electronic and hard copy records.

b. Indicate what will happen to the identifiable data at the end of the study. ***Research-related records should be retained for a period of at least 3 years after the research has been discontinued (i.e., no further data collection, long term follow-up, re-contact, or analysis of identifiable/coded data.)***

- Identifiers permanently removed from the data and destroyed (de-identified) (tapes destroyed after transcription)
- Identifiable/coded (linked) data are retained
- Identifiable data not collected

19. HIPAA RESEARCH AUTHORIZATION (Health Insurance Portability and Accountability Act)

Will individually identifiable Protected Health Information (PHI) subject to the HIPAA Privacy Rule requirements be accessed, used, or disclosed in the research study?

- ☐ No
- ☐ Yes → Check all that apply:
  - ☐ Written Authorization from subject or guardian → ***Provide a copy of the Authorization Form***
  - ☐ Partial Waiver (recruitment purposes only) →Complete **Appendix** B
  - ☐ Full Waiver (entire research study) → Complete **Appendix B**
  - ☐ Alteration (written documentation) → Complete **Appendix B**

20. APPLICATION CONTENTS

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

- ☐ Type of Request Checklist **REQUIRED!!**
- ☐ **Application for Exemption** **REQUIRED!!**
- ☐ Appendix B: Waiver of HIPAA Research Authorization (question 19)
- ☐ Consent form(s), Assent Form(s), Permission Form(s), and Verbal Script(s), including translated documents (question 16)
- ☐ Data Collection Form(s) involving Protected Health Information (PHI) (question 12)
- ☐ Recruitment Materials (e.g., ads, flyers, telephone or other oral script, radio/TV scripts, internet solicitations) (question 14b)
- ☐ Script(s), Instructions, or Information Sheet(s) (question 16)
- ☐ Instruments (e.g., questionnaires or surveys to be completed by participants) (question 12)
- ☐ Other Committee Approvals/Letters of Support/Agency Permission (question 11, Appendix A)
- ☐ Other supporting documentation and/or materials

21. ASSURANCE: PRINCIPAL INVESTIGATOR (or Advisor)

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 Principal Investigator (or Advisor) by appropriately trained and qualified personnel with adequate resources;
- Initiate the research after written determination of exemption has been received;
- Obtain and document (unless waived) informed consent and HIPAA or FERPA research authorization from human subjects (or their legally authorized representatives) prior to their involvement in the research using the final version of the consent form(s) and process submitted for determination;
- Promptly report to HSRC events that may represent unanticipated problems involving risks to subjects or others;
- Provide significant new findings that may relate to the subjects willingness to continue to participate;
- Inform HSRC of any proposed changes in the research or informed consent process (via a new Exempt 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;
- Retain research-related records for audit for a period of at least three years after the research has ended (or longer, according to sponsor or publication requirements) even if I leave the University;
- Contact HSRC for assistance in amending (to request a change in Principal Investigator) or terminating the research if I leave the University or am unavailable to conduct or supervise the research personally (e.g., sabbatical or extended leave); and
- Inform all Co-Investigators, research staff, employees, and students assisting in the conduct of the research of their obligations in meeting the above commitments.

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

Signature of Principal Investigator /Student Investigator | Date

Printed name of Principal Investigator/Student Investigator

Signature of Advisor | Date

Printed name of Advisor

Signature of Co- Investigator | Date

Printed name of Co- Investigator