MADONNA UNIVERSITY
Graduate School

APPLICATION FOR EXPEDITED OR FULL REVIEW

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 Faculty advisor/instructor for review and approval.
- Students: Have your Faculty advisor/instructor sign page 10 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
  11_09_07_smith_s_signature pages (one document)
  11_09_07_smith_s_training certificates (one document)
- 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/INSTRUCTOR

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 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 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? 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 EXPEDITED REVIEW

Are you requesting **Expedited Review**? Yes ☐ No ☐

9. 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. (Attach additional page if more sites than two.)

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

10. OVERVIEW OF THE RESEARCH

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

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

11. SCIENTIFIC BACKGROUND & LITERATURE REVIEW

Summarize existing knowledge and previous work that support the expectation of obtaining useful results without undue risk to human subjects. ***Use complete sentences (limit 300 words).***

12. RESEARCH METHODS & ACTIVITIES

a. Identify and describe all interventions and interactions that are to be performed solely for the research study. Distinguish research (i.e., experimental) activities from non-research activities. ***Provide data collection forms to be used.***

b. Check all research activities that apply:

- ☐ Audio, video, digital, or image recordings
- ☐ Biological sampling (other than blood)
- ☐ Blood drawing
- ☐ Data, not publicly available
- ☐ Data, publicly available
- ☐ Deception → Complete **Appendix C** & **Appendix D1**
- ☐ Diet, exercise, or sleep modifications
- ☐ Focus groups
- ☐ Observation of participants (including field notes)
- ☐ Oral history (does not include medical history)
- ☐ Placebo
- ☐ Pregnancy testing
- ☐ Randomization
- ☐ Record review (which may include PHI)
- ☐ Specimen research
- ☐ Surveys, questionnaires, or interviews (one-on-one)

☐	Food supplements	☐	Surveys, questionnaires, or interviews (group)
☐	Internet or e-mail data collection	☐	Other **Specify**:
☐	Materials that may be considered sensitive, offensive, threatening, or degrading		
☐	Non-invasive medical procedures (e.g., EKG, Doppler)		

c. Describe your data collection instrument. **(Attach a copy)**

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

13. NUMBER OF PARTICIPANTS

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. The total number of research participants may be increased only with prior HSRC approval.

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

b. Explain how this number was derived (e.g., statistical rationale, attrition rate, etc.).

c. Is this a multi-site study?	☐	Yes → Indicate the total number of participants to be enrolled across all sites:	
	☐	No	

14. PARTICIPANT POPULATION

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

Age(s): _____

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

☐	Adults	☐	Pregnant Women/Fetuses → Complete **Appendix F**
☐	Decisionally Impaired Adults → Complete **Appendix E**	☐	Non-English Speaking → Complete **Appendix G**
☐	Children (< 18 years) → Complete **Appendix H**	☐	Students from Participant Pools (e.g., REP)
☐	Healthy Volunteers		Specify:
☐	Neonates (uncertain viability/nonviable) → Complete **Appendix F**	☐	Unknown (e.g., research using secondary data/specimens, non-targeted surveys, program protocols)

c. Describe the characteristics of the population(s) and explain how the nature of the research requires/justifies inclusion of the proposed population(s).

d. Are any of the participants likely to be vulnerable to coercion or undue influence? Yes ☐ No ☐

If Yes → Describe additional safeguards to protect participants' rights and welfare.

e. Will pregnant women be excluded from participation in the research? Yes ☐ No ☐

If Yes→ Explain how the nature of the research requires/justifies their exclusion. Address means of pregnancy screening, if excluded.

15. PARTICIPANT IDENTIFICATION, RECRUITMENT, & SELECTION

a. Provide evidence that you will be able to recruit the necessary number of participants to complete the study.

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

c. List the names of investigator(s) and/or key personnel who will recruit participants and what process will be used to determine participant eligibility.

d. Describe the recruitment process; including the setting in which recruitment will take place. 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).***

16. 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 participant withdrawals, as applicable.

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

17. ALTERNATIVES TO STUDY PARTICIPATION

Other than choosing not to participate, list any specific alternatives, including available procedures or treatments that may be advantageous to the subject.

18. 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 and/or complete relevant appendices, as needed. See Consent for Research for templates or contact HSRC for more***

information.

☐	Assent – Form	☐	Parental Permission – Form
☐	Assent – Verbal Script	☐	Parental Permission – Verbal Script → Complete **Appendix D2**
☐	Informed Consent – Form	☐	Translated Consent/Assent – Form(s) → Complete **Appendix G**
☐	Informed Consent – Verbal Script → Complete **Appendix D2**	☐	Waiver or Alteration of Consent Process → Complete **Appendix D1**
☐	Informed Consent – Addendum	☐	Waiver of Consent Documentation → Complete **Appendix D2**

b. List the names of investigator(s) and/or key personnel who will obtain consent from participants or their legally authorized representatives. ☐ N/A

c. Who will provide consent or permission (i.e. participant, legally authorized representative, parent and/or guardian)? ☐ N/A

d. 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

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

f. Explain how the possibility of coercion or undue influence will be minimized in the consent process. ☐ N/A

g. Will any other tools (e.g., quizzes, visual aids, information sheets) be used during the consent process to assist participant comprehension? ☐ Yes → ***Provide copies of these tools*** ☐ No

19. 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.).

20. 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. Explain if any personal or sensitive information that could be potentially damaging to participants (e.g., relating to illegal behaviors, alcohol or drug use, sexual attitudes, mental health, etc.) will be collected. ☐ N/A

c. Explain any circumstances (ethical or legal) where it would be necessary to break confidentiality. ☐ N/A

d. Indicate what will happen to identifiable data at the end of the study. ***Research-related records should be retained for a period of at least three 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)
- ☐ Identifiable/coded (linked) data are retained
- ☐ Identifiable data not collected

21. HIPAA RESEARCH AUTHORIZATION

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

- ☐ No
- ☐ Yes → Check all that apply:
  - ☐ Written Authorization → ***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**

22. REASONABLY ANTICIPATED BENEFITS

a. List the potential benefits that participants may expect as a result of this research study. State if there are no direct benefits to individual participants. ***Compensation is not to be considered a benefit.***

b. List the potential benefits that society and/or others may expect as a result of this research study.

23. RISKS, HARMS, & DISCOMFORTS

a. Describe all reasonably expected risks, harms, and/or discomforts that may apply to the research. Consider the range of risks, including physical, psychological, social, legal, and economic. As applicable, discuss severity and likelihood of occurrence.

b. Describe how risks, harms, and/or discomforts will be minimized.

24. MONITORING

Does the research involve greater than minimal risk (i.e., are the harms or discomforts described in Question #29 beyond what is ordinarily encountered in daily life or during the performance of routine physical or psychological tests)? Yes ☐ No ☐

If Yes → Describe the plan to oversee and monitor data collected to ensure participant safety and data integrity. Include the following:

- The information that will be evaluated (e.g., incidence and severity of actual harm compared to that expected);
- Who will perform the monitoring (e.g., investigator, sponsor, or independent monitoring committee);
- Timing of monitoring (e.g., at specific points in time, after a specific number of participants have been enrolled); and
- Decisions to be made as a result of the monitoring process (e.g., provisions to stop the study early for unanticipated problems).

25. ASSESSMENT OF RISKS & BENEFITS

Discuss how risks to participants are reasonable when compared to the anticipated benefits to participants (if any) and the importance of the knowledge that may reasonably be expected to result.

26. PARTICIPANT COSTS/REIMBURSEMENTS

a. List any potential costs subjects (or their insurers) will incur as a result of study participation (e.g., parking, study drugs, diagnostic tests, etc.).

b. List any costs to participants that will be covered by the research study.

27. APPLICATION CONTENTS

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

- ☐ Type of Request Checklist **REQUIRED!!**
- ☐ **Human Subjects Research Application** **REQUIRED!!**
- ☐ Appendix A: Agency Permission
- ☐ Appendix B: HIPPAA Waiver (question 21)
- ☐ Appendix C: Deception (question 12b)
- ☐ Appendix D1: Waiver or Alteration of Consent Process (questions 12b & 18a)

	Appendix D2: Waiver of Consent Documentation (question 18a)
	Appendix E: Decisionally Impaired Adults (question 14b)
	Appendix F: Pregnant Women/Fetuses/Neonates (question 14b)
	Appendix G: Non-English Speaking Participants (questions 14b and 18a)
	Appendix H: Children (question 14b)
	Consent form(s), Assent Form(s), Permission Form(s), and Verbal Script(s), including translated documents (question 18a)
	Data Collection Form(s) (question 12a)
	Data Collection Form(s) involving protected health information (Appendix B)
	Recruitment Materials (e.g., ads, flyers, telephone or other oral script, radio/TV scripts, internet solicitations) (question 15d)
	Script(s) or Information Sheet(s), including Debriefing Materials (question 19)
	Instruments (e.g., questionnaires or surveys to be completed by participants) (question 12b)
	Other Committee Approvals/Letters of Support (Appendix A)
	Research Protocol
	Complete Grant Application or Funding Proposal
	Other supporting documentation and/or materials

28**. 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 research as approved by the HSRC under the direction of the Principal Investigator (or Advisor) by appropriately trained and qualified personnel with adequate resources;
- Initiate the research after written notification of HSRC approval has been received;
- Obtain and document (unless waived) informed consent and HIPAA research authorization from human subjects (or their legally authorized representatives) prior to their involvement in the research using the currently HSRC-approved consent form(s) and process;
- Promptly report to the 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 the HSRC of any proposed changes in the research or informed consent process before changes are implemented, and agree that no changes will be made until approved by the MU HSRC (except where necessary to eliminate apparent immediate hazards to participants);
- Complete and submit a Continuing Review of Human Subjects Research application before the deadline for review at intervals determined by the HSRC to be appropriate to the degree of risk (but not less than once per year) to avoid expiration of HSRC approval and cessation of all research activities;
- 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 the Center for Research 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 Review of Human Subjects Research application is accurate and complete.

Signature of Principal Investigator/Student Investigator	Date
Printed name of Principal Investigator/Student Investigator	
Signature of Advisor/Instructor	Date
Printed name of Advisor/Instructor	
Signature of Co- Investigator	Date
Printed name of Co- Investigator	