MADONNA UNIVERSITY
Center for Research

APPLICATION for UMBRELLA EXEMPTION FACULTY FORM

Center for Research
Room 2107 Administration Building
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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!

- To facilitate teaching of research methods involving human subjects to students conducting class projects, the Institutional Review Board (IRB) has approved an "umbrella" policy. What this means is that an instructor may submit an application for "umbrella" approval for all students who conduct projects that meet delineated criteria.

- Procedure: The instructor completes the Umbrella Approval Application and the students complete individual Exempt applications for each project which they submit to their instructor**. Group projects would complete one Exempt application form**. The instructor submits the Umbrella Approval Application to the Center for Research for review and approval prior to initiation of student data collection. The Application may be submitted at the beginning of the semester in anticipation of the student projects.

- **Name each document as follows**:
  Year_month_day_last name_first initial_document. For example:
  11_09_07_smith_s_IRB 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 two working days. **If you do not hear from us, call 734-432-5666**.

DATE SUBMITTED:	

1. Course Number and Name	Semester

2. INSTRUCTOR

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

3. RESEARCH INTEGRITY TRAINING

A. Have you 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)	Yes		No	
B. Have the students received instruction regarding research integrity requirements for protection of human subjects' rights appropriate to the type of research being conducted?	Yes		No	

4. SINGLE-SEMESTER PROJECT CRITERIA

To be eligible for UMBRELLA-EXEMPTION, ALL projects must meet ALL the following criteria:

A. This project is part of a single semester course.	True		False		
B. Data collection procedures for class projects in this category are limited to one or more of the following (Check all that apply):			False		
1. Normal educational practices (e.g., tests, instructional strategies)					
2. Survey/questionnaire of decisionally competent adults (18+ years of age, not incarcerated) **No questions regarding illegal or socially unacceptable behavior.**					
3. Interview, individual or group, of decisionally competent adults (not incarcerated). **No questions regarding illegal or socially unacceptable behavior.**					
4. Observation of public behavior **where investigator does not participate in the activity.**					
5. Quality assurance record review where identifiable information is not collected.					
C. The sample contains at least five subjects and results are reported on groups of no fewer than five subjects.	True		False		N/A
D. If audiotape or videotape is used, the medium may be shared only with the student's instructor (not the class) and will be destroyed upon completion of the project, with faculty oversight.	True		False		
E. The project does **NOT** require or use a ***signed*** consent, electronic identification of subject, or other unique identifier (e.g. code #, name).	True		False		
F. The project does **NOT** use **identifiable** data, documents, records, pathological specimens, or diagnostic specimens.	True		False		
G. The project does **NOT** cover topics that would put the subject at risk for criminal or civil liability or be damaging to the subject's financial standing, employability, or reputation.	True		False		
H. The project does **NOT** entail deception of subjects (the subjects know exactly what you or they are doing and why).	True		False		

If you checked FALSE to ANY of the questions above, the student projects are NOT UMBRELLA-EXEMPT eligible. DO NOT COMPLETE THIS APPLICATION. Submit an IRB Application (Exempt or Expedited) for EACH PROJECT.

5. RISK ASSESSMENT

In order for your study to qualify as **EXEMPT from full IRB review**, 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. Do **ALL** the studies meet the definition of minimal risk as defined above?	Yes		No	
b. Have you discussed, with the students, risks to project participants (e.g., breach of confidentiality) and methods to minimize these risks (e.g., data collected for the study will be kept on a password protected desktop computer in a locked office)?	Yes		No	

6. OVERVIEW OF THE RESEARCH

a. List **examples** of the **types** of research studies that will be conducted, such as interviews of business managers, reviewing medical charts without recording identifying information. What guidelines have you given the students?

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

7. LOCATION OF THE RESEARCH

All research will require a signed Agency Approval form (Appendix A) to be kept in the instructor's records.

a. List the types of site(s) at which the research will be conducted. (Attach additional page if more sites than six.)

Potential Location Description	Potential Location Description

8. RESEARCH METHODS & ACTIVITIES

a. Check all research activities that apply. **Only these methods may be used for UMBRELLA-EXEMPT studies.**

☐	Existing data, not publicly available	☐	Record/chart review without identifiable private information
☐	Existing data, publicly available	☐	Specimen research (must be existing at time of application)
☐	Internet (anonymous) using software such as Qualtrics or Survey Monkey	☐	Surveys, questionnaires, or interviews (one-on-one)
☐	Observation of participants without investigator participation in the activity.	☐	Surveys, questionnaires, or interviews (group)
☐	Oral history (does not include medical history)	☐	Taste-testing
☐		☐	Other (***specify***):

9. PARTICIPANT POPULATION

a. Only decisionally competent adults (18 years old and above) will participate in the research:

Yes ☐ No ☐

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

☐ Adults

☐ Unknown (e.g., research using secondary data/specimens, non-targeted surveys, program protocols)

☐ Other **Specify:**

10. INCENTIVES TO PARTICIPATE

I confirm that participants **will not 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 ☐

11. INFORMED CONSENT PROCESS

a. Indicate the consent process(es) and document(s) to be used in the study. Check all that apply. ***See Informed Consent Guidance - Exempt Research for instructions or contact IRB for more information.***

☐ Verbal ☐ Online ☐ Unsigned form

☐ Not Applicable (e.g., existing data or specimens, observations, quality improvement)

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 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.) Course Instructor retains documentation for one year.***

☐ Identifiers permanently removed from the data and destroyed (de-identified)

☐ Identifiable/coded (linked) data are retained

☐ Identifiable data not collected

12. APPLICATION CONTENTS

All these documents must be submitted for this research project. Check all appropriate boxes.

☐ **Umbrella Application for Exemption** **REQUIRED!!**

13. ASSURANCE of COURSE INSTRUCTOR

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:

- Supervise the projects as approved to confirm they are conducted by appropriately trained and qualified personnel with adequate resources;
- Direct students not to Initiate the research until after written determination of exemption has been received;
- Direct students to obtain and document (unless waived) informed consent from human subjects (or their legally authorized representatives) prior to their involvement in the research using the final version of the consent form(s)/script(s) and process submitted for determination;
- Promptly report to IRB events that may represent unanticipated problems involving risks to subjects or others;
- Inform IRB of any proposed changes in the research or informed consent process (via a REVISED Exempt Application) before changes are implemented, and agree that no changes will be made until an exempt determination is made by IRB (except where necessary to eliminate apparent immediate hazards to participants); and
- Inform all students conducting 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 Course Instructor

Date

Printed name of Course Instructor