Application for Human Subjects Research Approval

**RESEARCH APPROVAL APPLICATION**

**Directions:**

* Answer each question with sufficient detail for someone unfamiliar with your topic to understand and reach a conclusion.
* Type your responses in the boxes provided and upload the requested documents (PDF or Word format only).
* Fully answer only the question asked or enter “N/A” if it is not applicable.
* Only attach documents containing the specific information requested. Do NOT attach an actual research proposal.
* Do NOT copy material from a research proposal without explaining its meaning and significance.
* Do not use abbreviations or discipline-specific jargon without first defining its meaning.
* Failure to follow these directions will result in delays in reviewing/processing the application.

**Principal Investigator and Co-Investigator(s) Information:**

* E-mail
* Phone number
* IRB training certificate number

**Faculty Research Advisor’s Information:**

* Name
* Phone number
* E-mail address
1. **INTRODUCTION**
2. Is this research being funded by a source external to Utica University or the researcher(s), or is a proposal for external support being submitted?

 YES NO

 [POPS UP IF YES] List the funding source(s) and upload the external funding proposal (proposal budget not required).

 Upload funding proposals here:

1. Please give a brief summary in non-technical, lay language of the proposed research. Be sure to include a statement of the research problem, how your project will address it, and why the research is important.
2. **SUBJECT POPULATION**
3. How many subjects will be involved in the research? Estimates or ranges are acceptable. Please be aware that if you recruit over 10% more participants than originally requested, you will need to submit a request to modify your recruitment numbers.
4. List specific eligibility requirements for subjects (or describe screening procedures), including those criteria that would exclude otherwise acceptable subjects.
5. Describe how subjects will be recruited. List recruitment materials (e.g., flyer, e-mail, letter) AND attach the actual document(s) for any recruitment materials that will be used. All recruitment materials should contain a brief description of the study and what types of information you are seeking.

Upload recruitment materials here:

1. Check any vulnerable populations you specifically intend to recruit for the study:

[ ]  minors (under age 18) - if so, have you included a line on the consent form for the parent/guardian signature

[ ]  neonates (newborn child)

[ ]  human fetuses

[ ]  pregnant women

[ ]  prisoners

[ ]  persons with mental, psychiatric or emotional disabilities

[ ]  persons with physical disabilities

[ ]  economically or educationally disadvantaged

[ ]  elderly

[ ]  students from a class taught by principal investigator

[ ]  non-English speaking persons

[ ]  persons in a sensitive support program such as Alcoholics Anonymous, Incest Survivors Support Group, etc. (specify program below)

[ ]  other vulnerable population.

5. If any of the above vulnerable populations is used, state the necessity for doing so. Please indicate the approximate age range of any minors.

6. Indicate and justify the race/ethnicity of the research subjects intended to be enrolled in this study. Justify any exclusions based on age, sex, race or ethnicity.

**III. PROCEDURES TO BE FOLLOWED**

***After you have recruited subjects,*** *the IRB needs to completely understand the experience of the subjects in your research in order to assess potential risks to them as human subjects. Please answer the questions below precisely and succinctly.*

1. In lay language, describe completely (step-by-step) all the procedures the subjects in your research will follow during the course of the research activities (after recruitment). Be specific and provide sufficient detail so that the Committee can understand the experience of all the subjects in your research and assess potential risks to human subjects. If the research involves more than one group of subjects (e.g. teachers and students, employees and supervisors), please make sure to provide descriptions for each subject group.
2. How will you inform subjects about your research and then obtain their consent? (Please see the Informed Consent Checklist for elements that must be included).
3. Copy and paste any text OR upload any materials you will use to elicit informed consent from your subjects.

 Upload any consent forms to be used here:

1. How many times will observations, tests, etc. be conducted? How long will each subject’s participation take?
2. Describe the tools/materials/tests/instruments to be used and upload them below.

 Upload the tools/materials/tests/instruments to be used here:

1. If you are working with another outside agency, such as a school or private organization, please provide documentation that the agency has approved your research procedures. If that other agency has an IRB, please submit their approval of your research.

 Upload any supporting documents from outside agencies here:

**IV. POTENTIAL RISKS**

1. Estimated Risk Category

Considering your education, training, experience and professional judgment, categorize the risk of this research into one of the following (Note, as required by federal regulations and/or state law, the IRB will make an independent risk/benefit determination in its review of this research.):

[ ]  Research does not involve greater than minimal risk. Minimal risk is defined as: “….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.”

[ ]  Research involves greater than minimal risk but holds out the prospect of a direct benefit to the subjects.

[ ]  Research involves greater than minimal risk and there is no prospect of direct benefit to the individual subjects, but the research is likely to yield generalizable knowledge.

1. Describe the potential immediate and long-range risks or discomforts (psychological, social, physical, financial, legal or other) connected with the proposed procedures and explain the steps taken to minimize these risks.
2. If there are any risks, why are they necessary? Is there any other way to conduct the research that would reduce the risk to subjects, and, if so, why have you not chosen that alternative?
3. Will there be a request for information that subjects might consider to be personal or sensitive (e.g. private behavior, economic status, sexual issues, religious beliefs, or other matters that if made public might impair their self-esteem or reputation or could reasonably place the subjects at risk of criminal or civil liability)?

 YES NO

 [POPS UP IF YES] Describe and explain the steps taken to minimize these risks.

1. Could any of the study procedures produce stress or anxiety or be considered offensive, threatening, or degrading?

 YES NO

[POPS UP IF YES] Describe why they are important and what arrangements have been made for handling an emotional reaction from the subject.

1. Is there any deception of the human subjects involved in this study?

 YES NO

[POPS UP IF YES] Please describe why it is necessary, and describe the debriefing procedures that have been arranged.

##### V. POTENTIAL BENEFITS

*This does not include any form of compensation for participation.*

1. What, if any, direct benefit is to be gained by the subject? If no direct benefit is expected but indirect benefit may be expected (e.g., knowledge may be gained that could help others), please explain.
2. The IRB must find that the benefits adequately offset the potential risk to research subjects. Please assess the importance of the expected knowledge to be gained (e.g., by your professional field, by society) and provide an explanation of why you think the benefits of this research outweigh the risks.
3. **COMPENSATION OR INCENTIVE**

*Please keep in mind that the logistics of providing compensation to your subjects may compromise anonymity or complicate confidentiality protections (e.g., if your business office requires names of subjects who received compensation). If, while arranging for subject compensation, you must make changes to the anonymity or confidentiality provisions for your research, you must contact the IRB office prior to implementing those changes.*

1. Describe any compensation or incentive being offered to subjects for their participation in the study.
2. Explain compensation or incentive provisions if the subject withdraws prior to completion of the study.

# VII. CONFIDENTIALITY

*Confidentiality within research has a number of aspects such as not asking unnecessary information, protecting the identity of subjects, safeguarding records, and the way in which data is disseminated. All aspects of confidentiality should be taken into consideration when planning and conducting research.*

1. Identify ALL persons who will have access to the data from the moment they are collected until they are destroyed (including yourself).
2. Describe how confidentiality and/or anonymity of research subjects will be assured. How will identifiers be used in study notes and other materials? Will identifiers be removed from the data? If so, at what point, and if not, please explain why identifiers must be retained.
3. Will reports be written in aggregate terms, or will individual responses be described?
4. Please describe your data retention/destruction plans, including timeframes. How will research data be recorded and stored during and after the study? If there is a key code connecting subjects’ data to their identity, when will the link be destroyed?

**VIII. CONFLICT OF INTEREST**

1. Disclose any relationship between researcher and subjects - such as teacher/student, employer/employee, employee/client, classmate, teammate, or friend.

2. Do you and/or any other investigators associated with the project described in this application have, or appear to have, any actual or potential conflict of interest with respect to this research? Do you stand to gain financially or otherwise from this research or its results?

 YES NO

 [POPS UP IF YES] If yes, please explain:

**IX. ADDITIONAL INFORMATION**

1. Please describe or provide any additional information that may aid the IRB in making its decision. Do not upload an actual research proposal – it will not be reviewed.

Upload files if needed:

**NOTE:**

If you need to modify your application after submitting it for review, you must select the "Withdraw to Edit" option under "Actions" within the online application system. If the Application Status has already changed to "Under Review," please email irb@utica.edu regarding your desire to make edits. Do NOT submit changes to your application via e-mail or paper copy.

**BEFORE SUBMITTING THIS IRB APPLICATION, please acknowledge the following information:**

As the Researcher submitting this application, I understand Utica University’s policies concerning the protection of human subjects in research. I am familiar with scientific and ethical principles of conducting human subjects research studies as stated in the Belmont Report as well as regulatory requirements of current governing federal and state laws and regulations. I agree to:

* as the Principal Investigator, accept these conditions on behalf of any co-investigators listed in this application.
* accept full responsibility for the scientific and ethical conduct of this research study.
* obtain IRB approval of any changes amending or altering the protocol or informed consent document prior to implementing such changes except in cases where a change in the protocol would constitute an emergency measure.
* immediately report to the IRB any research-related adverse event or unanticipated problem involving risks to subjects or others in a form and manner as required by the IRB.
* comply with all institutional and IRB requirements of submitting timely reports required in the conduct, continuing review, and completion of this study.

I AGREE I DO NOT AGREE