

**PROTOCOL
APPLICATION FORM**
SOCIAL, BEHAVIORAL, AND EDUCATIONAL EXPEDITED REVIEW
HUMAN SUBJECTS IN SOCIAL, BEHAVIORAL, AND EDUCATIONAL
RESEARCH
University of Massachusetts Amherst

1. Purpose of the study

a) Provide a brief lay summary of the purpose of the study.

b) What does the Investigator(s) hope to learn from the study?

2. Study Procedures

a) Describe all study procedures.

b) State if audio or video taping will occur. Describe what will become of the tapes after use, e.g., shown at scientific meetings, erased. Describe the final disposition of the tapes.

c) State if deception will be used. If so, provide a rationale and describe debriefing procedures. Include a debriefing script with this application.

3. Background

a) Describe past findings leading to the formulation of the study.

4.(a-i) Subject Population

a) State how many subjects you propose to use and state the rationale for the proposed number.

b) Describe the subject population, including the age range, gender, ethnic background, and type of subjects (e.g. students, professors, subjects with learning disabilities, mental health disorders, etc.). Please incorporate specific inclusion/exclusion criteria (e.g. physical and psychological health, demographic information, or other unique characteristics).

c) State the number and rationale for involvement of potentially vulnerable subjects to be entered into the study, including minors, pregnant women, prisoners, economically and educationally disadvantaged, decisionally challenged, and homeless people.

d) If women, minorities, or minors are not included, a clear compelling rationale must be provided. Examples for not including minors: disease does not occur in children; drug or device would interfere with normal growth and development; etc.

e) State the number, if any, of subjects who are laboratory personnel, employees, and/or students. They should be presented with the same written informed consent. If compensation is allowed, they should also receive it.

f) State the number, if any, of subjects involved in research conducted abroad and describe any unique cultural, economic or political conditions.

g) Describe your procedures for recruiting subjects, including how potential subjects will be identified for recruitment. Attach all recruitment materials (flyers, recruitment letters and/or emails, etc.) at the end of this application.

Note: Potential subjects may not be contacted before IRB approval.

h) Compensation. Explain the amount and type of compensation (payment, experimental credit, gift card, etc.), if any, that will be given for participation in the study. Include a schedule for compensation and provisions for prorating.

i) Please state: A: The total expected duration of the study, including the time expected for data analysis (e.g., This study is expected to last 1 year) AND B: How much time each subject is expected to be involved in the study (e.g., The involvement of each subject will be 1-session for a total of 90 minutes).

5. Risks

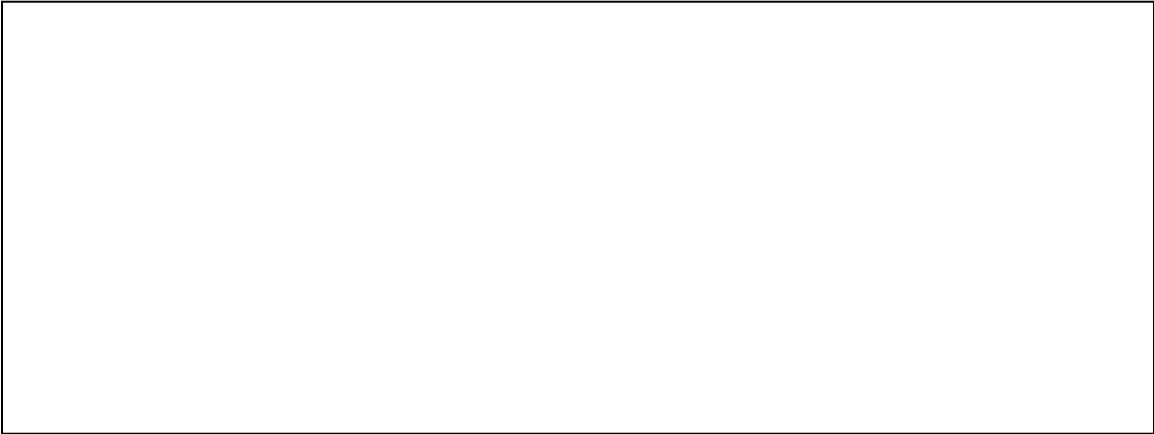
HHS Regulations define a subject at risk as follows: "...any individual who may be exposed to the possibility of injury, including physical, psychological, or social injury, as a consequence of participation as a subject in any research..." This also includes risks to subject confidentiality and any discomforts, hazards, or inconveniences. For the categories below, include a description of risks.

a) Describe the risks related to:

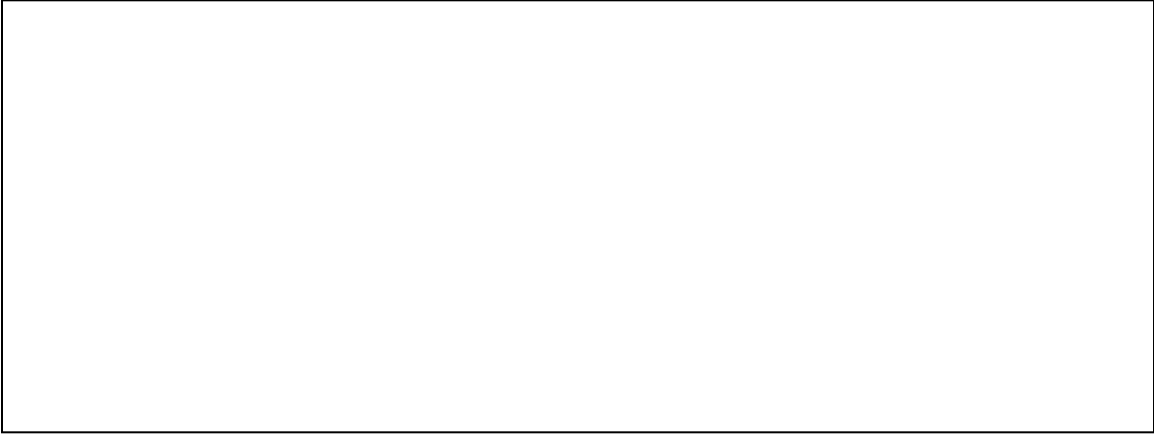
Physical well-being

Psychological well-being

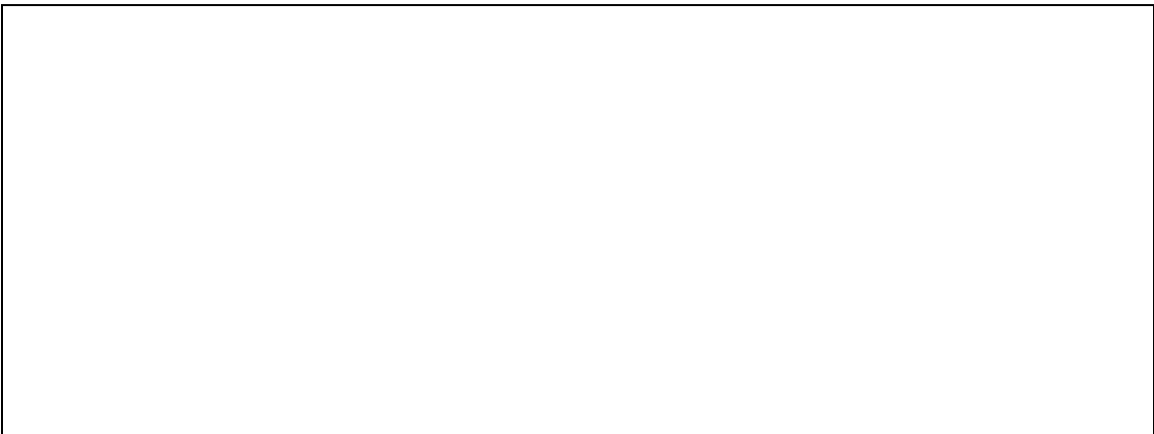
Economic well-being

A large, empty rectangular box with a thin black border, intended for text input related to the 'Economic well-being' section.

Social well-being

A large, empty rectangular box with a thin black border, intended for text input related to the 'Social well-being' section.

Breach of confidentiality (including audio/video taping)

A large, empty rectangular box with a thin black border, intended for text input related to the 'Breach of confidentiality' section.

b) For research conducted abroad, describe any risks associated with the unique cultural or political environment.

c) Discuss plans for ensuring necessary medical or professional intervention in the event of a distressed subject.

6. Benefits

a) Describe the potential benefit(s) to be gained by the subjects or by the acquisition of important knowledge which may benefit future subjects, etc. (This DOES NOT include compensation or extra credit).

7. Procedures to Maintain Confidentiality

a) Describe the procedures in place which protect the privacy of the subjects and maintain the confidentiality of the data, as required by the federal regulations, if applicable.

b) If information derived from the study will be provided to a government agency, or any other person or group, describe to whom the information will be given and the nature of the information.

c) Specify where and under what conditions study data will be kept, how specimens will be labeled and stored (if applicable), who has access to the data and specimens, and what will be available to whom.

8. Potential Conflict of Interest

a) Do any of the involved investigators or their immediate family (as described below) have consulting arrangements, management responsibilities or equity holdings in the Sponsoring company, vendor(s), provider(s) of goods, or subcontractor(s)? YES NO

b) Do any investigators or their immediate family have any financial relationship with the Sponsoring company, including the receipt of honoraria, income, or stock/stock options as payment? YES NO

c) Is any Investigator(s) a member of an advisory board with the Sponsoring company? YES NO

d) Do any investigators receive gift funds from the Sponsoring company? YES NO

e) Do any investigators or their immediate family have an ownership or royalty interest in any intellectual property utilized in this protocol? YES NO

"Immediate family" means a spouse, dependent children as defined by the IRS, or a domestic partner.

If one or more of the above relationships exist, please include a statement in the consent form to disclose this relationship. i.e., a paid consultant, a paid member of the Scientific Advisory Board, has stock or stock options, or receives payment for lectures given on behalf of the sponsor. The consent form should disclose what institution(s) or companies are involved in the study through funding, cooperative research, or by providing study drugs or equipment.

If you answer yes to any of the questions above, you must file a Conflict of Interest disclosure statement located at <http://www.umass.edu/research/ora/facon.html>.

9. Informed Consent Background

Provide consent process background information below.

Please complete the table below for each consent form and attach the consent form(s) at the end of this application.

Who is obtaining consent? The person obtaining consent must be knowledgeable about the study and authorized by the PI to consent human subjects.	
How is consent being obtained?	
What steps are you taking to determine that potential subjects are competent to participate in the decision-making process?	

If you are requesting a consent form waiver, address the following four points. A Yes/No response alone is not adequate.

1. The research involves no more than minimal risk to the subjects.

YES

NO

2. The waiver will not adversely affect the rights and welfare of the subjects.

YES

NO

3. The research could not practicably be carried out without the waiver.

YES

NO

4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

YES

NO

10. Assent Background

All minors must provide an affirmative consent to participate by signing a simplified assent form, unless the Investigator(s) provides evidence to the IRB that the minor subjects are not capable of assenting because of age, maturity, psychological state, or other factors.

Please complete the table below for each assent form and attach the assent form(s) at the end of this application.

Who is obtaining child assent and parent consent? The person obtaining consent must be knowledgeable about the study and appointed by the PI to perform this function of the research.	
How is assent being obtained?	
What steps are you taking to determine that potential subjects are competent to participate in the decision-making process?	

If you are requesting an assent form waiver, please explain the rationale for altering written assent for minors.

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11. Attachments

At the end of this application, please attach all relevant documents listed below as well as any additional materials that will be provided to subjects.

- Copies of grants (including those submitted through OGCA)
- Recruitment materials (flyer, letter, newspaper ad etc)
- Questionnaires/Surveys

Obligations

Obligations of the Principal Investigator are:

Modifications - Changes in any aspect of the study (for example, project design, procedures, consent forms, advertising materials, additional key personnel or subject population) will be submitted to the IRB for approval before instituting the changes;

Consent Forms - All subjects will be given a copy of the signed consent form. Investigators will be required to retain signed consent documents for six (6) years after close of the grant or three (3) years if unfunded;

Training - Human subject training certificates, including those for any newly added personnel, will be provided for all key personnel;

Adverse Events - All adverse events occurring in the course of the protocol will be reported to the IRB as soon as possible, but not later than ten (10) working days;

Continuing Review - IRB Protocol Report Forms will be submitted annually at least two weeks prior to expiration, six weeks for protocols that require full review;

Completion Report - The IRB will be notified when the study is complete. To do this, complete the IRB Protocol Report Form and select "Final Report."

The Principal Investigator has read and agrees to abide by the above obligations.

Protocol Director: _____ **Date:** _____

Faculty Sponsor: _____ **Date:** _____