HUMAN SUBJECTS RESEARCH PROPOSAL

Researcher(s):

Advising faculty member(s): (if applicable)

Proposed starting date:

I. TITLE OF RESEARCH PROJECT

II. PURPOSE AND OBJECTIVES OF THE RESEARCH

III. DESCRIPTION OF SUBJECT POPULATION(S)

A. Who are the subject groups and how are they being recruited?

B. Approximate number of subjects in each group to be used:_____

C. If advertising for subjects, include a copy of the proposed advertisement.

D. What are the criteria for selection and/or exclusion of subjects?

E. If special populations are being used, please justify.

IV. ACTIVITIES INVOLVING HUMAN SUBJECTS

A. Describe the activities involving each subject group as described in III.A. Include the expected amount of time subjects will be involved in each activity and where the activities will be conducted.

B. How will the data be collected (check):

☐ questionnaires (submit a copy)

☐ interviews (submit interview questions)

☐ observations (briefly describe)

☐ standardized tests (if yes, identify test(s)

☐ other? (describe)

V. DATA

A. How will the data be recorded (notes, tapes, computer files, completed questionnaires or tests, etc.)?

B. Who will have access to the gathered data and how will confidentiality be maintained during the study, after the study, and in reporting of results?

C. What are the plans for the data after completion of this study and how and when will the data be maintained or destroyed?

VI. BENEFITS, RISKS, COSTS

A. What are the potential benefits to humanity?

B. What are the potential benefits to the subjects?

C. What compensation, if any, will be offered to the subjects and how will compensation be scheduled throughout the study?

D. Which risks to the subjects are most likely to be encountered, and at what level?

	None	Minimal	More than minimal	Not sure
physical	☐	☐	☐	☐
psychological (emotional, behavioral, etc.)	☐	☐	☐	☐
loss of confidentiality	☐	☐	☐	☐
deception	☐	☐	☐	☐
other (explain)	☐	☐	☐	☐

E. Describe any risks identified in D above.

F. What safeguards will be used to eliminate or minimize these risks?

G. If subjects experience adverse reactions, how will they be managed?

H. What are the costs, if any, to the subjects (monetary, time, etc.)?

VII. INFORMED CONSENT

A. How will the study be explained to the subjects and by whom?

B. Attach informed consent form(s) you will use in the study.

C. Indicate rationale for any special conditions relating to informed consent (deception or withholding information, for example).