Concordia University
Saint Paul, MN
Protocol Form
Research Involving Human Subjects

Reviewed Classification Requested: _____ Exempt ____ Expedited
_____ Full Review

1. Project Title:
2. Principal Investigator: Name _____
   first *middle* *last*
   Phone # _____ College/Department _____
   Investigator's Address _____
   _____
3. Please list co-investigators: _____
4. Duration of the Study: _____ to _____
   start conclusion
   [Protocol must be renewed annually]
5. Type of Submission: _____ New _____ Renewal* ____ Modification
   *Renewal refers to projects which are ongoing i.e. class related project which are conducted each semester or annually. The principal investigator must inform the Human Subjects Review Committee regarding the projects being implemented on an annual basis.
6. Will this research be conducted at a location other than CSP?

   ____ No ____ Yes: If yes, attach approval documentation if appropriate.

   Identify location of the study: _____
7. Subjects (please estimate numbers):
   ____ patients as experimental subjects
   ____ patients as controls
   ____ minors (under 18)
   ____ CSP students/faculty/staff
   ____ pregnant women, unborn children
   ____ mentally disabled respondents
   ____ prisoners
   ____ normal adult volunteers
   ____ persons whose 1st language is not English
   ____ physically challenged
   ____ other _____
8. Procedures: [Attach relevant materials such as questionnaires, interview schedules, written instruments, etc.]
   ____ survey questionnaire
   ____ interview, phone - in person
   ____ medical or other personal records
   ____ filming, taping, recording
   ____ participant observation
   ____ psychological intervention
   ____ blood, tissue, secretia samples
   ____ investigational device
   ____ placebo
   ____ payment of subjects
   ____ observation
   ____ anthropological fieldwork
   ____ incomplete disclosure of purpose
   ____ other _____

9. Check one:

____ faculty/staff research
____ fellow/post-doctoral research
____ student research (undergraduate)
____ student research (graduate)

If the principal investigator is a student, please complete the following:

Advisor's Name _____
please print
Address _____
_____

Telephone _____

Advisor's Signature _____

10. In lay terms please describe your research. Include your research questions and methods to be used. Describe the purpose of the research and a description of the tasks subjects will be asked to complete (i.e. what will the subject need to do).

_____ _____
Principal Investigator's Signature Date

To be completed by Human Subjects Review Committee: One copy to the principal investigator, one copy to files of Human Subjects Review Committee.

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Declined _____ Reasons:

Approved with modifications: _____ [See attached]

Approved _____ _____
Signature, Chair Human Subjects Review Committee Date

_____ _____
Signature, Second Reviewer - expedited review only Date

Copies to: Principal Investigator Human Subjects Review Committee file