

Date Submitted _____

File Number _____

HARPER COLLEGE INSTITUTIONAL REVIEW BOARD

Research Amendment Form

All modifications to human subjects research must be reviewed and approved prior to implementation

Minor modifications – Minor modifications to previously approved projects include those that do not alter the risk-benefit assessment for research. Examples include changes in the investigators; minor changes in the consent form, recruiting materials, measures, or procedures; minor changes in compensation, time of participation, or subject recruitment; or the use of a new site that is not materially different from a previously approved site. Minor modifications may also include changes to other parameters, whereby the investigator provides the subjects with more accurate information as a result of additional experiences with the protocol.

Major modifications – Major modifications to previously approved projects include significant protocol changes that would cause subjects to engage in activities not previously approved; or that involve an increased level of risk to the physical, emotional, or psychological well-being of participants (including the loss of confidentiality); or that involve a decreased benefit; or that otherwise result in alienation of the risk-benefit assessment for the research. For example, adding a new subject population, adding new measures that significantly differ from those currently approved, changing inclusion or exclusion criteria, changing the informed consent process, and changing procedures affecting subject confidentiality are all potentially major modifications.

Title of Research Project

Principal Investigator

Email Address

Phone

Major or Minor Modifications

Major _____ Minor _____

Describe the Amendment

Describe the request change(s) and clearly reference materials submitted with this form. Provide a clear rationale for the proposed change(s). Explain whether the risk-benefit assessment for the research is likely to change as a result of the proposed amendments(s). Justify changes that will affect risks, benefits, informed consent, inclusion or exclusion criteria, the subject population(s), research sites, or the confidentiality of private, identifiable subject information.

Please supply the following with this research amendment form:

1. An amended Research Proposal Form showing the revisions to the project
2. Revised consent documents, protocol, and any other relevant attachments that have changed

The signature of the Principal Investigator is required before this form can be processed.

I certify that the information provided in this form, with attachments, is complete and correct, that the modified protocol has not yet been used with any human subject, and that it will not be implemented until IRB approval has been obtained.

Principal Investigator Approval

Signature

Date