Non-BU Institutional Review Board Submission Summary Form

STUDY TITLE: ___________________________________________________________________

PRINCIPAL INVESTIGATOR: _________________________________ Phone__________________
(Must Be a Bellarmine Faculty Member)

CO-INVESTIGATORS:_____________________________________________________________
(Might be Student, Staff, BU Faculty, Non-BU Faculty, Hospital Admin, etc.)

SITE(S) WHERE THE STUDY WILL BE CONDUCTED: _________________________________________

Estimate the # of subjects to be studied _______ Dates you plan to collect data __________________

In the box below, briefly describe the portion of your study that will involve live human subjects.

RISK ANALYSIS:
Consider the following: A Minimal Risk Study is one where the probability and magnitude of harm or discomfort is not greater than that ordinarily encountered in daily life or during performance of routine physical or psychological examinations or tests. Human subjects may be exposed to the following short-term and long-term risks by participation in the study: physical risks; psychological risks; financial risks or legal risks.

In your opinion, does the study involve more than Minimal Risk? YES □ NO □
(If YES, please explain): _____________________________________________________________________

_______________________________________________________________________________________

COERCION AND AT-RISK STUDY POPULATIONS:
As a faculty member, the Principal Investigator holds a special trust and may not exert undue influence when recruiting students and university employees as potential research subjects. Full Review by the IRB may or may not be required in this event. Other potential research subjects are considered at-risk, including minors, prisoners, or the cognitively impaired. These individuals may not be entered into studies without prior Full Review by the IRB.

Is any potential subject in the proposed study either a student or employee under your supervision at Bellarmine University? YES □ NO □

Will any minors be involved in this study (less than 18 years of age)? YES □ NO □

Are any of the subjects in the proposed study cognitively impaired? YES □ NO □
(If the answer is YES to any question above, please explain in detail): _____________________________

_______________________________________________________________________________________

Will subjects be paid for their participation in this study? YES □ NO □
(If YES, explain the amount to be paid, how the amount will be pro-rated if the subject withdraws before study completion, and/or if there is any other type of compensation for participation, (e.g., coupons, raffles, etc.): __________

_______________________________________________________________________________________

Do you intend to publish or present the results of this study? YES □ NO □
(If YES, please describe where/when you anticipate publishing or presenting this work): _____________________________

_______________________________________________________________________________________
I, as Chairperson of the PI’s department, have reviewed the study protocol submitted to the non-BU IRB. Department Chairs, through appropriate procedures established within their respective departments, are responsible for reviewing research proposals/protocols for ethical considerations as well as scientific merit.

_______________________________________________                _________________
Department Chair Signature                   Date

This study will be conducted in a manner consistent with how it has been represented to the IRB and following any alterations in the procedures that may result from the IRB review process.

______________________________________________     _________________
Principal Investigator Signature                                  Date
(Bellarmine faculty member overseeing student work at non-BU site)

______________________________________________      _________________
Co-Investigator Signature                                   Date
(main person running the study at the non-BU site)

Have the Approval forms from the non-BU Institutional Review Board been submitted along with this form?  YES □   NO □

Name non-BU IRB Institution  ____________________________________________________________

Date of non-BU IRB approval  __________________________