

BELLARMINE UNIVERSITY INSTITUTIONAL REVIEW BOARD
APPLICATION FOR RISK-BENEFIT RESEARCH REVIEW

Complete this form when the Principal Investigator judges a study to be *greater than Minimal Risk*.

STUDY TITLE: _____

PRINCIPAL INVESTIGATOR: _____

a) Describe in detail ALL RISKS to Human Subjects in the proposed Research and indicate if they are Long- or Short-term:

Physical risks-

Psychological risks-

Financial risks-

Legal risks-

Other Risks-

b) Describe Expected Benefits:

Direct subject benefit-

Value of knowledge to be gained-

c) Explain the level of Confidentiality for Data Collected and the Potential Publication of Results:

Does the investigation require the disclosure of sensitive or potentially sensitive information by the subject concerning his or her past or present behavior? Cross-reference pertinent portions of all study instruments appended to the Protocol in your submission packet. What use may be made of this information and other results obtained in the study?

By signing below, the Principal Investigator is indicating all risks have been thoroughly explained on this form and you agree to abide by the directions of the Bellarmine IRB with regards to obtaining Informed Consent, Making Amendments to the project, Promptly reporting ANY Adverse Events, and Completing all necessary paperwork including filing a Termination Report.

Principal Investigator Signature

Date

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. In this case, the proposed research involves greater than minimal risk to live human subjects. By signing below, you acknowledge having read and understand the Protocol and support this performance of this project by your faculty.

Department Chair

Date