University of Portland
Institutional Review Board for Research Involving Human Subjects

IRB Study Continuing Review/Revision Form

Completion of this form is required at least annually for all active studies[1]. Please attach any revised materials. Revision means any change to the study protocol, consent form, or any supportive materials (e.g. questionnaires, advertisements, etc.) or the addition of new materials that may have human subject implications.

Principal Investigator: _____

Phone Number: _____

Email Address: _____

Title of Study: _____

Date of Initial IRB Approval:

Current status of Study (check one):
_____ Study currently in progress
_____ Study has not yet started
_____ Study has terminated: date study completed: _____

Request for Revisions
Please describe the revision(s) to the original study protocol and/or materials and briefly explain the reason for the revision(s):

_____

_____

_____

_____

***Please attach a copy of the revised protocol and/or materials.**

Questions:
Please answer the following questions:

1. Have any revisions been made to the original study protocol or materials?

_____Yes * _____ No

* If yes, when was the revision approved by the IRB? _____

2. If the study is still active, when do you expect to complete it? _____

3. Have any subjects withdrawn from the study or complained about the study process?

_____Yes* _____ No

*If yes, please describe in detail:

_____

_____

_____

_____

4. Have there been significant developments in the field since your study began that might affect the risk/benefit ratio for subjects?

_____Yes* _____No

*If yes, how are you responding to those changes?

_____

_____

_____

_____

5. Please summarize any problems or study related injuries affecting human subjects that might have arisen since the last review. (If no problems or injuries, state none.)

_____

_____

_____

_____

_____ _____

Name of Principal Investigator Date

[1] Investigators are required to provide the information requested on this form to the IRB(s) which provided approval to the study at least annually (and more often if requested by the IRB) per the Code of Federal Regulations, Title 45 Part 46 of the Federal Register, effective July 14, 2009.