

Institutional Review Board

Modifications / Changes Review Form (IRB-3)

Institutional Review Board, Office of Academic Affairs
600 S. Michigan Avenue, Rm. 811M, Chicago, IL 60605

phone: 312-369-8795

email: IRB@colum.edu

Any amendment to an approved protocol must be reviewed and approved by the IRB before the amendment is implemented. Such amendments could include changes to the study design, procedures, enrollment, methods of recruitment, personnel, funding source or the consent form. This includes changes that appear to reduce risks to subjects.

Submission of modifications/changes to an approved study should include this form accompanied by a revised proposal packet with all modifications/changes highlighted within the document. A clean (not highlighted) version of the proposal packet should also be included so that a final document is on record and, if necessary, revised informed consent forms can be stamped and dated.

Date:

Principal Investigator:

Faculty Advisor:

Correspondent:

Protocol No.:

Study Title:

1. Describe each proposed amendment(s) and explain why it is being made.

2. For each amendment listed above, explain whether the proposed amendment increases or decreases the level of risk to participants and, if so, describe. If the level of risk remains the same, describe this as well.

Please answer the following question:

Has the funding source or the status of funding changed since initial or last re-approval review?

___ Yes or ___ No

If yes, please amend the IRB-1 accordingly and, if a new funding source was added, please provide the IRB with a complete copy of the grant for review.

Attach two (2) copies of a revised protocol and/or consent form inclusive of all amendment(s) proposed. In one copy the amendments should be identified by using the track-changes feature of Microsoft Word or by using bold text to facilitate the IRB review; the other copy should be a “clean” copy incorporating the revisions.

Original Signature of Principal Investigator	Date

Original Signature of Faculty Advisor (Only for Student-Initiated Research)	Date

Level of Original Review: Full Expedite: Exempt Full
Protocol No. [Click here to enter text.](#)

Submitted	Reviewed	Approved
STAMP	STAMP	STAMP