

Michigan State University
University Committee on Research Involving Human Subjects (UCRIHS)

Revision Form for UCRIHS Approved Study

USE THIS AS A COVER PAGE AND ATTACH APPROPRIATE PAGES/DOCUMENTS

Return this form to UCRIHS, 246 Administrative Building, East Lansing, MI 48824-1046;
or the PI may e-mail us this form as an attachment from his/her MSU Pilot account to: ucrihs@msu.edu.

NOTE TO INVESTIGATORS: **UCRIHS must review any changes** in procedures involving human subjects **before** the implementation of the change. Only the responsible project investigator may request study revisions by letter or e-mail (from his/her MSU Pilot account) with this cover page to the UCRIHS Chair. Revision requests are not accepted from study Co-Investigators. Attach, if applicable, any requested changes or revised documents.

CORRECT NUMBER OF COPIES: A single copy is sufficient for revisions involving no more than minor changes or posing no more than minimal risk; otherwise, please enclose three collated copies of this revision request cover sheet with applicable documents.

IRB # _____ Review Category: _____ Today's Date: _____

TITLE OF PROJECT _____

PRINCIPAL INVESTIGATOR _____

Email: _____ Phone: _____ Campus Address: _____

PLEASE MARK ALL QUESTIONS 1-6

1. Describe the proposed revision(s) and rationale for the changes on an attached page. If submitting a revised document (instrument/ methodology(s), consent, etc.) please include a copy(s) with a brief summary of changes. Where applicable, mark all categories of proposed changes below.

Administrative Changes

Study Investigators
 Project Title
 Funding (See Q4 below)
 PI address information
 Other

Study Changes

Eligibility Criteria
 Target Population
 Instrument(s)
 Data Analysis
 Consent (See Q3 below)

Other

Advertisement/Recruitment
 Investigator Brochure (attach 3 copies)
 Permanent Closure (See Q6 below)
 Other

If applicable, provide below any special name/number/language that should appear this revision's approval memo (e.g. Revision X, Version Y, Study Phase Z, etc.): _____

2. Yes No Does the proposed revision(s) alter the level of risk and/or privacy protections for subjects?. If **yes**, please describe on an attached page.

3. Yes No Does the proposed revision(s) require changes in the Consent Statement? If the answer is **yes**, check the appropriate line below and enclose a copy.

The new Consent Document is an addition to the current one.

The new Consent Document is to replace the current one.

4. Yes No Has new project funding source(s) been added?

If **yes**, please describe (be sure to indicate source, length of funding, agency grant#) and include any relevant information regarding possible Conflicts of Interest (See UCRIHS Instructions, p.6, Question 19.). FULL Review protocols should submit a copy of any grant applications/research funding contracts.

5. Yes No Are you closing the project to new enrollment but continuing human subject contact and/or tracking?

6. Yes No Are you permanently closing the project for enrollment including ending all contact with subjects?

Staff Use Only:

Approval _____

Date: _____

Agenda: _____

IRR Review _____

PLEASE CONTINUE FORM ON REVERSE SIDE

ADDITIONAL QUESTIONS FOR MEDICAL PROTOCOLS ONLY. Mark all questions, 7-11.

Adverse Reactions

7. _____ Number of **adverse events included in this mailing**. Attach 3 copies.
8. _____ **Total** number of **adverse events** reported on this protocol.
9. Yes No Do any of these new reported adverse events **involve MSU subjects**.
10. Yes No Are there **adverse events** included here that are not listed in the consent form?
11. Yes No The information in these documents requires that the **study be closed**.

For all revision requests, the Responsible Primary Investigator should sign and date below. If submitting by hard copy, this revision request cannot be processed without the PI's signature. An emailed submission from the Responsible PI's Pilot email account may serve in lieu of a signature.

As the responsible investigator, my signature below indicates that I have reviewed the proposed revisions, and that the information provided is complete and accurate. Furthermore, I acknowledge that these proposed revisions will not be implemented until after UCRIHS has reviewed and approved of the changes. (e-mail from the Principal Investigator's MSU pilot account will substitute for signature.)

Primary Investigator's Signature

(date)