

Application for
REVISION and/or AMENDMENT
 Of a Project Involving Human Subjects

Sparrow Health System's Institutional Research Review Board (IRB)
Institutional Research Review Committee

The IRB must review any changes an investigator makes to an approved research project involving human subjects before implementation of the proposed changes. Please note that revisions may only be processed on protocols with **current** IRB approval.

IRB Contact Information

Chair:	George S. Abela, MD	Phone:	517.364.2150
Address:	Sparrow Health System IRRC/Research Compliance & Oversight 1215 E Michigan Avenue PO Box 30480 Lansing MI 48909-7980	Fax:	517.364.2763
		Email:	irrc@sparrow.org
		Office Hours:	Mon – Fri (7:30 am – 5:00 pm)
		Location:	Medical Education Bldg, 910 Jerome Street
IRB Web Site:	http://www.sparrow.org/irrc/research.asp		

DIRECTIONS: Complete all questions and attach any new or revised documents; be sure to include a copy of the currently approved consent form. Investigators may contact the IRB staff with any questions.

IRRC#:		IRB Approval Expiration Date:		Today's Date:	
Title:					
Principal Investigator:					
Address:					
Phone:		E-mail:			

A. **Categories.** Check all categories of proposed changes.

<u>Administrative Changes</u>		<u>Study Revisions / Amendments</u>		
<input type="checkbox"/>	Funding	<input type="checkbox"/>	Advertisement/Recruitment	<input type="checkbox"/> Protocol
<input type="checkbox"/>	Project Title	<input type="checkbox"/>	Consent	<input type="checkbox"/> Research Design/Analysis
<input type="checkbox"/>	Study Investigator(s)	<input type="checkbox"/>	Eligibility Criteria	<input type="checkbox"/> Subject Incentive
<input type="checkbox"/>	Data Analysis Only	<input type="checkbox"/>	Instrument(s)	<input type="checkbox"/> Target Population
				<input type="checkbox"/> Other

B. **Description.** Briefly describe the proposed revision(s) and rationale; continue on separate sheet if necessary.

C. No Yes **Risk.** Does the proposed revision(s) **increase** the level of risk for harm or privacy protection for subjects? If **yes**, please describe on an attached page.

D. No Yes **Consent.** Does the proposed revision(s) require changes in the consent process? If revising your consent document(s), enclose a copy highlighting any changes as well as a non-highlighted copy.

The new consent document(s) is an addition to the current one(s).
 The new consent document(s) is to replace the current one(s).

E. No Yes **Status.** Is the study open to accrual of new subjects or data collection? If **yes**, provide number of subjects currently enrolled _____
If **no**, provide a brief explanation (e.g. study remains open to subject follow-up, data analysis on-going, etc.)

F. No Yes **Funding.** Have any new funding source(s) been added to the project? If **yes**, please describe on an attached page (i.e. indicate source, length of funding, agency grant #) and include relevant information regarding possible Conflict of Interest.

This submission indicates that, as the responsible principal investigator, 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 the IRB has reviewed and approved the changes.

PRINCIPAL INVESTIGATOR:	
DATE:	

Reformatted 1/27/06; 8/2/2007

Approved: Institutional Research Review Committee, October 10, 2005

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