

CO 601-A

09/01/07

DATE: [CURRENT DATE]

TO: [PI NAME]
FROM: Sparrow Health System IRB

STUDY TITLE: [ID AND TITLE]
IRB REFERENCE #: [LOCAL IRB REFERENCE NUMBER]
SUBMISSION TYPE: [SUBMISSION TYPE]

ACTION: **APPROVED**
APPROVAL DATE: [STATUS DATE]
EXPIRATION DATE: [EXPIRATION DATE]
REVIEW TYPE: [REVIEW TYPE]

Thank you for your submission of [SUBMISSION TYPE] materials for this research study. The Sparrow Health System IRB has **APPROVED** your submission. This approval is based on an appropriate risk/benefit ratio and a study design wherein the risks have been minimized. All research must be conducted in accordance with this approved submission.

- *(indicate whether the approval is for Initial review, Continuing review, Amendment with detailed reference info such as Amendment # and date)*

This study has received [REVIEW TYPE] based on the applicable federal regulation.

Please remember that **informed consent** is a process beginning with a description of the study and insurance of participant understanding followed by a signed consent form. Informed consent must continue throughout the study via a dialogue between the researcher and research participant. Federal regulations require each participant receive a copy of the signed consent document.

Please note that any **revision** to previously approved materials must be approved by this office prior to initiation. Please use the appropriate revision forms for this procedure.

All **SERIOUS** and **UNEXPECTED** and/or **UNANTICIPATED adverse events** must be reported to this office. Please use the approved adverse event forms for this procedure. All FDA and sponsor reporting requirement should also be followed.

Please report all **NON-COMPLIANCE** issues or **COMPLAINTS** regarding this study to this office.

Based on the risks, this project requires **Continuing Review** by this office on an annual basis. Please use the appropriate renewal forms for this procedure.

Please note that this office expects you to promptly inform the IRB upon **completion** of this research study. Please use the appropriate closure form for this procedure. Please note that all research records must be retained for a minimum of three years after completion of the study.

If you have any questions, please contact us at 517.364.2150 or via Email: irrc@sparrow.org. Please include your study title and IRB reference number in all correspondence with this office.

George S. Abela, MD, IRB Chairperson
Institutional Research Review Committee
Sparrow Health System

This letter has been electronically signed in accordance with all applicable regulations, and a copy is retained within our records.

cc: