

CO 601-G

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: **CLOSURE ACCEPTED**
DECISION DATE: [STATUS DATE]

Thank you for your submission of the Application for Closure for this research study. On [STATUS DATE] the Sparrow Health System IRB officially **ACCEPTED** the permanent closure of this study. We will place a copy of these materials in the research study file in our office.

Please note that official closure indicates that all research activities (including data collection and analysis) are complete and have stopped. **Under the federal regulations (21 CFR 56.115(7)(b), all research records must be retained for a minimum of three years after completion of the study.**

Storage of Archived Data: The confidentiality of identifiable information must be maintained even after the research is complete. If you are maintaining data with identifiers, it is your responsibility to continue to protect the privacy and confidentiality of the subjects and to store and protect the data in accordance with the IRB and federal regulations.

If your data is completely de-identified, you can continue to perform data analysis, as research no longer meets the definition of human subject research. Guidance regarding Security Guidelines and de-identified data can be found at http://www.sparrow.org/irrc/irrc_securityguidelines.asp

Future Use of Archived Data: If the data is de-identified, further use of this data by students or colleagues does not require IRB approval. If your stored data contains personal identifiers, future use may require IRB approval – please contact this office for advice when needed.

Problems: While your research is complete and closed, you may still encounter unanticipated problems, adverse events, or other problems that may increase the risk to the human subjects. In this event, please notify this office promptly. You will be directed on the best way to report these events to the IRB.

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: