

CO 601-H

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]

ACTION: **APPROVAL TERMINATED**
DECISION DATE: [STATUS DATE]

The Sparrow Health System IRB records indicate that the approval for this study expired on [EXPIRATION DATE]. Continued involvement of human subjects, or data collection, past this date is a violation of the federal regulations (45 CFR 46.109(s)), and IRB policies.

Effective [STATUS DATE], formal approval for this study at Sparrow Health System facilities is **officially terminated**. You must cease recruitment and data collection on subjects in this research project. Contact this office promptly for guidance if you believe it is in the best interest of some or all enrolled participants to continue participating in the research interventions or interactions.

Please note that under the federal regulations (21 CFR 56.115(7)(b)), all research records must be retained for a minimum of three years after closure 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: {MSU IRB would need to be added here for "Reliance" studies, but not all of these letters would go to them}