

CO 601-M

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: **DETERMINATION OF EXEMPT STATUS**
DECISION DATE: [STATUS DATE]

Thank you for your submission of [SUBMISSION TYPE] materials for this research study. The Sparrow Health System IRB has determined that this project is **EXEMPT FROM IRB REVIEW** according to federal regulations.

By accepting this determination, the Principal Investigator assures that he/she will abide by the following terms and the IRB Exempt policy:

As an exempt project, the IRB will not be further involved with the review or continued review of the project, as long as the project maintains the properties that make it exempt.

- Since the IRB is no longer involved in the review and continued review of this project, it is the Principal Investigator who assumes the responsibilities for the protection of human subjects in this project and ensures that the project is performed with integrity and within accepted ethical standards, particularly as outlined by the Belmont Report. (See Belmont Report: <http://hhs.gov/ohrp/humansubjects/guidance/belmont.htm> and Exempt Policy: <http://www.sparrow.org/irrc/IRRPColicies/exempt~2.pdf>)
- The Principal Investigator assumes the responsibility for ensuring that research subjects be informed of the research through a documented or undocumented consent process, if appropriate.
- The Principal Investigator assumes the responsibility to maintain confidentiality of the subjects and the data, and maintain the privacy of the subjects and protection of the data through appropriate means. If data is anonymous, the investigators will make no attempt to identify any individuals. (See Security Guidelines: http://www.sparrow.org/irrc/irrc_securityguidelines.asp)
- The Principal Investigator assumes responsibility for assuring that human subjects will be selected equitably, so that risks and benefits of research are justly distributed.
- The Principal Investigator assumes the responsibility that co-investigators and other members of the research team adhere to the appropriate policies for the protection of human subjects, maintain confidentiality and privacy, and adhere to accepted ethical standards.
- If the Principal Investigator adds additional investigators to an exempt project, he/she may inform the IRB of the additions. This may be of particular importance to residents, fellows, and/or graduate students if their programs require proof of IRB approval.

Principal Investigator: [PI NAME]
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- Any complaints from participants regarding the risks and benefits of the project must be reported to the IRB. Any information, unexpected or adverse events that would increase the risk to human subjects and cause the category of review to be upgraded to Expedited or Full Review must also be reported to the IRB.
(See Expedited policy: <http://www.sparrow.org/irrc/IRRCPolicies/expedited~2.pdf>)
- Since the Principal Investigator and co-investigators are charged with human subject protection and adhering to ethical principles in exempt research, it is appropriate that investigators be trained in human subject principles. The Principal Investigator and all members of the research team are required to complete one of the three Human Subject Training Tutorials offered and submit verification of completion to the IRB.
(See News & Events: http://www.sparrow.org/irrc/irrc_newsevents.asp)
- Any change in the project that may raise the project from exempt to an expedited or full review category must be presented to the IRB. If there is any question about a change in the project, the Principal Investigator should consult the Chair of the IRRC. Failure to submit changes that raise the project out of the exempt category will be considered non-compliance and will be subject to investigation and action by IRB.
- When the project is completed, the Principal Investigator must notify the IRB (see Closure Procedure: <http://www.sparrow.org/irrc/irrcpolicies/closureform.doc>)

We will place a copy of this correspondence on file in our office.

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: