ATTACHMENT A

POST-APPROVAL REVIEW NOTIFICATION LETTER

To:	Principal Investigator Study Coordinator
From:	Office for Education and Quality in Clinical Research (OEQCR)
Date:	DD Month YYYY
Subject:	Quality Assurance Program
Study to be reviewed:	**HSR # XX-XXXX:**

The Office for Education and Quality in Clinical Research (OEQCR) is committed to the quality and integrity of clinical research conducted on the Hennepin County Medical Center Campus. To support this commitment, the OEQCR oversees the quality assurance (QA) program which assesses clinical research activities conducted under the Hennepin Healthcare Research Institute Federal-wide Assurance filed with the Office for Human Research Protections.

The purpose of the QA program is to ensure proper scientific, ethical, and regulatory behavior in the conduct of approved clinical research protocols. This program is designed to be educational as well as regulatory and to enhance research subject protection.

Internal, not for cause, reviews are conducted on a risk-based assessment. Assessment criteria include, but are not limited to: Investigator or research team new to clinical research; Investigator-initiated/sponsored protocols; number of enrolled and/or consented subjects, type and complexity of the trial; level of risk to the trial subjects; and any identified problems. Your protocol, HSR #XX-XXXX, has been selected for a review. A member of the review team will contact you or your study coordinator to arrange for a mutually agreeable time to conduct the review. A list (initials or ID numbers only) of all consented subjects should be available when the reviewer contacts you. The reviewer will inform you of the subjects that are randomly chosen for review. The reviewer may request time to speak with members of the study team. Sponsor monitoring follow up letters are also requested.

Items that will be needed the day of the review include a conference room or quiet area for the reviewer, study files (source documentation) for the chosen subjects, the regulatory binder, the Investigator's Brochure and protocol, and any other study specific material. All information will be held strictly confidential.

Please feel free to contact the Office for Education and Quality in Clinical Research with any questions or concerns at 612/873-6341 or 612/873-6339.

Sincerely,
Research Review Team
HHRI Office for Education and Quality in Clinical Research