MOUNT CARMEL
Institutional Review Board, Office of Research Affairs
6150 East Broad Street • Columbus, Ohio 43213-1574
mountcarmelhealth.com/research

April 6, 2015

Ming Zeng, PhD, MD
192 Remington Road
Columbus, Ohio 43209

IRB Study #150325-5
Research Review for Upper GI cancer in Multidisciplinary Team (MT) Approach

Dear Dr. Zeng:

The above titled research protocol has been approved by expedited review. The IRB was able to provide expedited approval under 45 CFR 46.110 (5) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).

Items receiving expedited review and approval:
- Protocol
- Data Collection Sheet
- HIPAA Waiver of Authorization

The research sites approved for this research protocol:

- Mount Carmel East
- Mount Carmel West
- Mount Carmel St. Ann's
- The Mark H. Zangmeister Center

This approval will appear on the agenda at the next convened meeting of the IRB. If any issues are raised, you will be notified in writing.

Date of Initial approval: 04/06/15 **Date of Expiration: 04/05/16**

This approval period is for one year. A continuing review must be accomplished before this study can proceed beyond the date of expiration. As part of our continuing review process, we may randomly audit your study to ensure compliance with regulations.

Protocol title and the assigned IRB number, **150325-5** must identify all correspondence regarding this study. Upon completion of the study, you will be required to submit a protocol termination report.

As Principal Investigator, your responsibilities with regard to this research protocol are:

- to conduct the research study in an ethical manner,
- to obtain prior review from the IRB before implementing any protocol amendments and changes to approved research except where necessary to eliminate apparent immediate hazards to the study subjects,
- to immediately report to the IRB any serious adverse reactions and/or unanticipated effects on subjects which may have occurred as a result of this study,

- to report any significant changes to the study site and significant deviations from the research protocol,
- to report all deaths of enrolled subjects at the approved site,
- to submit a termination report upon completion,
- to train study personnel in the proper conduct of human subject research and the protection of human subjects,
- to prepare and maintain adequate and accurate case histories that record all observations and other data pertinent to the investigation on each individual administered the investigational drug/device or employed as a control in the investigation. Case histories include the case report forms and supporting data/source documents (e.g., signed and dated consent forms and medical records, progress notes of the physician, the individual's hospital chart(s), and the nurses' notes). The case history for each individual shall document that informed consent was obtained prior to participation in the study.

The Mount Carmel Institutional Review Board is duly constituted fulfilling FDA requirements for diversity. Only those IRB/IEC members who are independent of the investigator and the sponsor of the trial are allowed to vote/provide opinion on the trial. The IRB has written procedures for initial and continuing review of clinical trials, prepares written minutes of convened meetings, and retains records pertaining to the review and approval process; all in compliance with requirements defined in 21 CFR (Code of Federal Regulations) Parts 50, 56 and ICH (International Conference on Harmonization) guidance relating to GCPs (Good Clinical Practice).

If you have any questions regarding your protocol or this letter, please contact the IRB office at 614/546-4325 or e-mail irb@mchs.com.

Sincerely,

James Sinard/KW

James Sinard, MD
IRB Chairperson
Mount Carmel Institutional Review Board

cc: IRB File