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Research Protection Office
Office of Research Administration
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One Hoppin Street
Providence, RI 02903
Tel 401 444-6246, Fax 401 444-7960

E. P. Bradley Hospital
Rhode Island Hospital
The Miriam Hospital
Newport Hospital
Gateway Healthcare

DATE: February 22, 2016

TO: Thomas Miner, MD

FROM: Janice Muratori, MSN, FNP-BC
Director, Research Protection Office

SUBJECT: **HUMAN SUBJECTS PROTECTION of Continuing Review/Progress Report AS PER EXPEDITED REVIEW/Includes Revision**
FWA-Rhode Island Hospital (RIH) 00001230, The Miriam Hospital (TMH) 00003538
IRB Registration #s: RIH IRB 1 - 00000396, RIH IRB 2 - 00004624, TMH IRB - 00000482

CMTT/PROJ: 008209 45 CFR 46.110(5)

TITLE: [211035-11&12] Retrospective Review of Gastric Cancer and Esophageal Cancer

Your research project was reviewed and approved on February 18, 2016. This research has been approved as meeting the expedited criteria for the protection of humans per 45 CFR 46.110 (5) by the Lifespan - Rhode Island Hospital IRB 1. This institution is in compliance with the ICH GCP as they correspond to the FDA/DHHS regulations. This review and approval are applicable for RIH.

It is the responsibility of the principal investigator to ensure that the study is conducted as approved by the IRB. All protocol modifications/changes must be approved by the IRB before any changes are implemented except when necessary to eliminate immediate hazards to subjects.

You are required by Federal regulations and Hospital policy to immediately report any unanticipated problems, untoward effects or reactions, serious side effects and/or deaths of subjects involved and related to this project to the IRB through the Research Protection Office.

IRB approval for this project expires on February 17, 2017. If you wish to continue your research after this date you are required to submit a continuation report (CR) prior to expiration of approval. A reminder notice will be sent approximately 30 days before the continuation report is due. The CR must be reviewed by the IRB no later than the date of expiration in order for the study to be in compliance with federal regulations. Federal regulations do not allow for ANY grace period for renewal.

Please provide a termination report to the IRB when the research is completed and IRB approval may be terminated.

REMINDER: RESEARCH DATA SHOULD ONLY BE STORED ON LIFESPAN MANAGED DEVICES AND AUTHORIZED ENCRYPTED THUMB DRIVES. In no circumstances should this data be stored on personally owned and managed devices. Obtaining consent and research authorization does

not remove the requirements and restrictions of the HIPAA Security Rule. For more information contact Janice Muratori at (401)444-6897, JMuratori@lifespan.org.

This document has been electronically signed in accordance with all applicable regulations, and a copy is retained within our records.