City of Hope

INSTITUTIONAL REVIEW BOARD (IRB) ACTION NOTICE

TO: **Lily Lai, M.D., Principal Investigator**
City of Hope - SURGERY PS-SURGICAL ONCOLOGY

FROM: **Diana Shycoff, BS, IRB Operations Manager** Diana Shycoff
Office of Human Research Subjects Protection

DATE: **February 17, 2015**

STUDY TITLE: **EVALUATION OF COLON/RECTAL CANCER PATTERNS AND OUTCOMES OF CARE**

IRB#/REF#: **05130 / 114855**

SUBMISSION: **Submission Correction for Continuation**

REVIEW PROCESS: **Expedite**

IRB ACTION DATE: **02/16/2015**

IRB ACTION:

APPROVAL FROM 02/16/2015 UNTIL 02/15/2016

COMMENT(S) THAT MUST BE ADDRESSED:

1. The continuation states that the NCCN no longer funds the Colon/Rectal Outcomes database study. Clarify whether this means prospective data and/or specimens will no longer be shared with NCCN. If prospective data won't be shared with NCCN, then complete the following:

   (A) The consent form must be amended to remove NCCN as the Sponor and covered entity for PHI so subjects are not given incorrect information that NCCN sponsors the research and will have access to their data.

   (B) Update the study application to remove NCCN as the Sponsor for this study.

   Note, if the intent is to share data and/or specimens with another consortium, the name of that consortium must be added to the consent form used to consent prospective participants for this study. The consent form will only be re-issued for this study once Sponsor issues have been clarified. If an amendment is required to update the consent form and study application, provide the reference number in the response to these comments that must be addressed.

NOTE: **DURING THE PERIOD COVERED BY IRB APPROVAL ANY CHANGES IN THE PROTOCOL, OR ANY UNEXPECTED PROBLEMS INVOLVING HUMAN SUBJECTS, MUST BE SUBMITTED TO THE IRB VIA iRIS FOR REVIEW. NO STUDY CHANGES CAN BE INITIATED UNTIL APPROVAL HAS BEEN OBTAINED FROM THE IRB.**

If you have questions or concerns about this submission, please contact Keith Meinking.

City of Hope

Account: Audrey Choi, M.D.
Department: City of Hope - Grad Med Ed & Clin
Navigation: Home > my studies > study mgmt.

Home Logout Help

IRB Number: 05130
PI: Lai, Lily, M.D.

Define Study Access

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Study Status: Approved

IRB Number : 05130 Study Title : EVALUATION OF COLON/RECTAL CANCER PATTERNS AND OUTCOMES OF CARE

IRB Expiration Date: 02/15/2016

Assign key study personnel(KSP) access to the study

*** The current study status does not allow for changes to the Key Personnel. If you wish to change the Key Personnel submit a change request form to the appropriate Review Board.**

***Please add a Principal Investigator for the study:**

Lily Lai, M.D.

If applicable, please select the Protocol Staff personnel:

A) Additional Investigators

Yen, Yun, M.D., Ph.D.
Co-Investigator

Niland, Joyce, Ph.D.
Co-Investigator

Koehler, Stephen, M.D.
Co-Investigator

Singh, Gagandeep, M.D.
Co-Investigator

Kim, Joseph, M.D.
Co-Investigator

Yim, John, M.D.
Co-Investigator

Morgan, Robert, M.D.
Co-Investigator

Chung, Samuel, M.D.
Co-Investigator

Yeon, Christina, M.D.
Co-Investigator

Trisal, Vijay, M.D.
Co-Investigator

Chen, Yi-Jen, M.D., Ph.D.
Co-Investigator

Lim, Dean, MD
Co-Investigator

Chao, Joseph, M.D.

Co-Investigator

Chung, Vincent, M.D.

Co-Investigator

Leong, Lucille, M.D.

Co-Investigator

Luyimbazi, David, M.D.

Participating Clinician

Schoellhammer, Hans, M.D.

Participating Clinician

Wong, Jimmie, M.D.

Participating Clinician

Cho, Won, M.D.

Participating Clinician

Goldner, Bryan

Participating Clinician

Miller, Marian, M.D.

Participating Clinician

Marcinkowski, Emily, M.D.

Participating Clinician

White, Michael, M.D.

Participating Clinician

DiPasquale, Allison

Participating Clinician

Choi, Audrey, M.D.

Participating Clinician

Merchant, Shaila

Participating Clinician

Hamner, John, M.D.

Participating Clinician

Kauffmann, Rondi, M.D.

Participating Clinician

Aimaq, Rahim, M.D.

Participating Clinician

Falor, Ann, M.D.

Participating Clinician

Lewis, Aaron, M.D.

Participating Clinician

B) Research Staff

Arbayo, Cecelia

Clinical Research Associate

Franklin, Kelly

Clinical Research Associate

Najera, Leticia

Clinical Research Associate

Cui, Kewei

Study Coordinator

Brown, Annette

Study Coordinator

Connie, Geraldine

Study Coordinator

Ko, Eunbi

Study Coordinator

Sanchez, Mireya

Study Coordinator

Luevanos, Eloise, RN

Nurse

Ituarte, Philip, Ph.D.

Biostatistician

Li, Lily

Research Associate

Hsu, Felicia

Student

Ramirez, Shirley

Student

***Please add a Study Contact:**

- [ ] Luevanos, Eloise, RN
- [ ] Najera, Leticia
- [ ] Flanagan, Bridget
- [ ] Cui, Kewei
- [ ] Brown, Annette
- [ ] Johnson, Dina
- [ ] Hmwe, Susan, MBBS, MSHS
- [ ] Herrera, Nicole
- [ ] Arbayo, Cecelia
- [ ] Franklin, Kelly
- [ ] Burroughs, Kristy
- [ ] Hernandez, Sonya
- [ ] Hsu, Felicia
- [ ] Kirschenbaum, Michele

Osmond, Dane

Choi, Audrey, M.D.

The Study Contact(s) will receive all important system notifications along with the Principal Investigator. (e.g. The study contact(s) are typically either the Study Coordinator or the Principal Investigator themselves).

If applicable, please select the Department Administrator(s)

No Department Administrators have been added.

If applicable, please select the Administrative Assistant(s)

No Administrative Assistants have been added.