UNIVERSITY OF ILLINOIS
AT CHICAGO

Office for the Protection of Research Subjects (OPRS)
Office of the Vice Chancellor for Research (MC 672)
203 Administrative Office Building
1737 West Polk Street
Chicago, Illinois 60612-7227

**Approval Notice**
**Initial Review (Response To Modifications)**

December 9, 2016

Lawrence Feldman, MD
Hematology Oncology
Section of Hematology-Oncology
840 S. Wood St., 820-E C.S.B., M/C 713
Chicago, IL 60612
Phone: (312) 996-1588 / Fax: (312) 413-4131

RE: Protocol # 2016-1085: "BTCRC-LUN15-017: A Phase Ib/II Study of Anti-PD-1 Antibody Pembrolizumab and Imprime PGG for Patients with Metastatic Non-small Cell Lung Cancer After Progression on First-Line Chemotherapy"

Dear Dr. Feldman:

Your Initial Review (Response To Modifications) was reviewed and approved by the Expedited review process on December 6, 2016. You may now begin your research

Please note the following information about your approved research protocol:

**Protocol Approval Period:** December 6, 2016 - December 6, 2017
**Approved Subject Enrollment #:** 8
**Additional Determinations for Research Involving Minors:** These determinations have not been made for this study since it has not been approved for enrollment of minors.
**Performance Sites:** UIC
**Sponsor:** Merck Oncology
**PAF#:** Not available
**Grant/Contract No:** Not available
**Grant/Contract Title:** Big Ten Cancer Research Consortium BTCRC-LUN15-017: A Phase Ib/II Study of Anti-PD-1 Antibody Pembrolizumab and Imprime PGG for Patients with Metastatic Non-small Cell Lung Cancer After Progression on First-Line Chemotherapy

**Research Protocol:**

a) A Phase Ib/II Study of Anti-PD-1 Antibody Pembrolizumab and Imprime PGG for Patients with Metastatic Non-small Cell Lung Cancer After Progression on First-Line Chemotherapy: Version Date: 20SEP2016

**Informed Consents:**

a) Protocol BTCRC-LUN15-017 UIC Consent Phase Ib V1.1 dated 11/15/2016
b) Waiver of informed consent granted [45 CFR 46.116(d)] for the identification of potential

subjects in the recruitment phase of the research.

c) Protocol BTCRC-LUN15-017 UIC Consent Phase II V1.1 dated 11/15/2016

**HIPAA Authorization:**

a) Review Preparatory to Research acknowledged [45 CFR 164.512(i)(1)(ii)]

**Please note the Review History of this submission:**

| Receipt Date | Submission Type | Review Process | Review Date | Review Action |
|---|---|---|---|---|
| 10/27/2016 | Initial Review | Convened | 11/08/2016 | Modifications Required |
| 11/23/2016 | Response To Modifications | Expedited | 12/06/2016 | Approved |

Please remember to:

→ Use your **research protocol number** (2016-1085) on any documents or correspondence with the IRB concerning your research protocol.

→ Review and comply with all requirements as explained in the following, which are posted on the OPRS website *(http://tigger.uic.edu/depts/ovcr/research/protocolreview/irb/index.shtml)*: "**UIC Investigator Responsibilities, Protection of Human Research Subjects**" *(http://tigger.uic.edu/depts/ovcr/research/protocolreview/irb/policies/0924.pdf)*

**Please note that the UIC IRB has the prerogative and authority to ask further questions, seek additional information, require further modifications, or monitor the conduct of your research and the consent process.**

**Please be aware that if the scope of work in the grant/project changes, the protocol must be amended and approved by the UIC IRB before the initiation of the change.**

We wish you the best as you conduct your research. If you have any questions or need further help, please contact OPRS at (312) 996-1711 or me at (312) 413-2053. Please send any correspondence about this protocol to OPRS at 203 AOB, M/C 672.

Sincerely,

Laura Litman
IRB Coordinator, IRB # 3
Office for the Protection of Research Subjects

Enclosures:

1. **Informed Consent Documents:**
   a) Protocol BTCRC-LUN15-017 UIC Consent Phase II V1.1 dated 11/15/2016
   b) Protocol BTCRC-LUN15-017 UIC Consent Phase Ib V1.1 dated 11/15/2016

cc: Damiano Rondelli, Hematology Oncology, M/C 713
OVCR Administration, M/C 672
IDS, Pharmacy Practice, M/C 883