Department of Veterans Affairs

Memorandum

Date: February 6, 2013

From: Chair, Institutional Review Board (151)

Subj: Approval, #13-025, Epidemiology and Mortality in Pancreatic Cancer

To: Zeeshan Ramzan, M.D.

1. The Institutional Review Board met on Monday, February 4, 2013 to review the research proposal reference above.

2. The IRB **Approved** for 12 months. The study will be subject to Continuing Review before February 3, 2014. The IRB has approved a waiver of Informed Consent and a Waiver of HIPAA. The use of a consent form is waived in accordance with 45 CFR 46.116(d). **All data to be reviewed must have originated prior to this approval date.**

3. The study will now be forwarded to the Research and Development Committee for consideration on February 25, 2013. **The study may not begin until the Information Security Officer, Privacy Officer, and R&D Committee approve.**

4. Please note that the requested waiver of informed consent has been Approved, however the study is not exempt from the requirement for Annual Review by the IRB and the R&D Committee. In accordance with federal regulatory law, you must inform the IRB of deviations from the approved protocol or any loss of, or compromise to, PHI associated with this study. Should you require a change to the research, including Research Data Security Plan and waiver of HIPAA Authorization, per federal regulatory law, you must receive prospective review and approval of the IRB prior to implementing such changes.

5. You will be notified via email by the IRB Administrator when this approval of the study is nearing expiration.

6. Thank you for your submission.

Jonathan Dowell, MD
Chair, Institutional Review Board

Department of Veterans Affairs

Memorandum

Date: February 25, 2013

From: ACOS, Research & Development Committee

Subj: Notification of Action of the R&D, #13-025, Epidemiology and Mortality in Pancreatic Cancer

To: Zeeshan Ramzan, M.D.

1. The Research & Development Committee met on Monday, February 25, 2013 to review the application for approval of your study, referenced above.

2. The study has been **Approved** by the R&D Committee for a 12-month period.

3. During this approval period, you should inform the IRB of any adverse events associated with this study, deviations from the approved protocol, requested changes to the consent form, or any other events that might affect the patient's perception of the risks and benefits associated with the study.

4. The study will be subject to Continuing Review by the IRB on or before February 3, 2014.

5. Thank you for your submission.

James P. LePage, Ph. D.
ACOS, Research & Development Committee

Department of Veterans Affairs

Memorandum

Date: November 23, 2015

From: ACOS for Research (151)

Subj: RDC Notification of Action, #13-025, Epidemiology and Mortality in Pancreatic Cancer

To: Zeeshan Ramzan, M.D.

1. Your research Protocol reference above was **Approved** for 12 month continuation by the IRB on November 2, 2015. The Research and Development Committee met on Monday, November 23, 2015 and concurred with this approval.

2. The study will be subject to further review by the IRB on or before November 1, 2016.

3. Any and all conditions of Approval set forth by the IRB must be complied with. The R&D committee is satisfied with the compliance of the requirements of the IRB during the last approval period.

4. Thank you for your cooperation with this inspection and for your support of our efforts to protect human subjects.

James P. LePage, Ph.D.