

DATE: January 24, 2018

TO: Matthew Olnes, MD, PhD, FACP  
Principal Investigator  
Alaska Native Tribal Health Consortium  
3900 Ambassador Drive  
Anchorage, AK 99508

FROM: Alaska Area Institutional Review Board (IHS IRB #2)

STUDY TITLE: [665612-28] Molecular Characterization of Gastric Cancer in Alaska Native People

IRB REFERENCE #: 2015-02-012

SUBMISSION TYPE: Continuing Review/Progress Report

ACTION: APPROVED

APPROVAL DATE: January 16, 2018

EXPIRATION DATE: December 28, 2018

REVIEW TYPE: Expedited Review

REVIEW CATEGORY: Expedited Research

Dear Dr. Olnes:

The Alaska Area Institutional Review Board has given approval through Expedited Review to the protocol 2015-02-012 Molecular Characterization of Gastric Cancer in Alaska Native People. Tribal approval is required in addition to IRB approval. The protocol was approved on January 16, 2018 and has an **expiration date of December 28, 2018**.

As a reminder, the protocol and all accompanying documents **may not have modifications** for this decision to remain valid. It is your responsibility as Principal Investigator (PI) to maintain the status of your project by tracking and monitoring all activities related to the protocol. All research approved by the Alaska Area IRB is subject to 45 CFR 46 "Protection of Human Subjects" regulations, the US Food and Drug Administration regulations and the principles of the Belmont Report. Investigators are expected to be familiar with these provisions and adhere strictly to all requirements. You are required to have all personnel involved in the research complete the training at [www.citiprogram.org](http://www.citiprogram.org), once every 36 months with a 75% proficiency in all modules. Retain your completion certificates from the Collaborative Institutional Training Initiative (CITI).

Prior to making any changes to the protocol you must receive approval from the Alaska Area IRB. The IRB does not accept modifications and the Status Report and Renewal Application at the same time. Please ensure that project information is complete and submitted to the IRB using the electronic submission process at IRBNet at least four weeks prior to the expiration date of the project. In addition remember that the IRB agenda is closed on the first day of each month; all complete submissions received after the first day of each month will be placed in the IRB queue for the next IRB meeting.

The Alaska Area IRB has moved to an electronic submission process using IRBNet. To submit to the IRB proceed to IRBNet ([www.irbnet.org](http://www.irbnet.org)) and log in to your existing project. The continuing review information must include but not be limited to the Alaska Area IRB Status Report and Renewal Application forms, the current IRB approved protocol, a short abstract of the protocol, a current copy of the consent/

assent forms, and a cover letter to the IRB signed by the principal investigator. Submit to the Alaska Area Institutional Review Board (I.H.S. IRB #2) by uploading into IRBNet and add each item to the project. Inform the IRB by letter when the protocol is complete/closed.

As a reminder, the IRB must review and approve all human subjects' research protocols at intervals appropriate to the degree of risk, but not less than once per year. Per 45 CFR 46.109(e), there is no grace period beyond one year from the last IRB approval date unless the protocol approval period is shorter than one year.

It is your responsibility as Principal Investigator (PI) to maintain approval status for your project by tracking, renewing and obtaining IRB approval for all modifications to the protocol and the consent form. Keep this approval in your protocol file as proof of IRB approval and as a reminder of the expiration date. To avoid lapses in approval of your research which will result in suspension of participant enrollment and/or termination of the protocol submit the protocol continuation request at least 4 weeks prior to the **expiration date of December 28, 2018.**

All research involving staff, patients, or resources at the Alaska Native Medical Center (ANMC) must be reviewed and approved by ANMC's parent organizations after the Alaska Area Institutional Review Board approval is obtained. The parent organizations of ANMC are the Alaska Native Tribal Health Consortium (ANTHC) and the Southcentral Foundation (SCF). Tribal review and approval is required for all research protocols prior to initiation. Any manuscripts or abstracts for publication or presentations involving ANMC staff, patients, or resources must also be reviewed and receive tribal approval prior to submission. To initiate tribal review with ANTHC please contact [rampreview@anthc.org](mailto:rampreview@anthc.org) and with SCF contact [scfresearchreview@scf.cc](mailto:scfresearchreview@scf.cc). Please allow at least 8 weeks for tribal review and approval.

If you have further questions for the Alaska Area IRB you may contact us at [akaalaskaarealrb@anthc.org](mailto:akaalaskaarealrb@anthc.org) or call (907) 729-3924.

Sincerely,

Terry J. M. Powell  
Alaska Area Institutional Review Board  
IRB Administrator