

*****Sample Protocol Submission Letter to the Portland Area IHS IRB*****

March 28, 2002

Francine C. Romero, PhD, MPH, Chair
Portland Area Indian Health Service Institutional Review Board
c/o Northwest Portland Area Indian Health Board
527 SW Hall St, Suite 300
Portland, OR 97201

Dear Dr. Romero:

Enclosed please find the protocol and consent form for the study, "*Name of Study*." I have also enclosed a copy of the State University Institutional Review Board's approval, dated January 12, 2002, and the Tribal Council's approval, dated December 15, 2001.

We propose to conduct a population-based study of all tribal members age 60 and greater on the Tribe Reservation. Individuals participating in the project will receive both a comprehensive medical evaluation at the Tribal Health and Wellness Center and a safety and functional evaluation in their home performed by a tribal member. While providing researchers at State University data regarding the prevalence of dementia and other chronic disabilities, the study also offers valuable information to both individual tribal members and the Tribal community.

We have met with both staff and tribal members on the reservation on several occasions to discuss this project. We have received official approval of the project from both the Tribal Council and the Health and Welfare Committee.

We have scheduled a trip to the reservation on June 3, 2002, to begin this project. We would appreciate your informed review and approval of the enclosed material. If you have any questions or concerns, please contact me at (503) 555-5555, extension 555. I will serve as the contact person for this project. We look forward to your comments and approval.

Sincerely,

Jane Doe, MD, Principal Investigator

John Doe, RN, MN, Co-Principal Investigator

State University Memorandum

Research Support Office

Eliot Hall, Room 426

(503) 555-5555, extension 555

Date: January 12, 2000
To: Jane Doe, MD
From: Jim Brown, MD, PhD, Chair, Institutional Review Board
Subject: Protocol #1234 “Aging and Health in Native Americans of the Tribe”

Protocol and Consent Form Approval

We have received your response to the IRB recommendations on 1/3/02.

Your protocol and consent forms is approved for One Year effective 1/12/02.

The IRB protocol number and the date of this approval should be placed at the top right corner of the first page of the consent form.

Investigators must provide subjects with a copy of the consent form, keep a copy of the signed consent form with the research records, and place a signed copy in the patient’s hospital and clinical medical record (if applicable).

If this project involves the use of an Investigational New Drug, a copy of the approved protocol must be forwarded to the Pharmacy and Therapeutics Committee (Pharmacy Services – Investigational Drugs, OP-16A).

If this is a cancer study, we will notify the Oregon Cancer Center (OCC) of the IRB approval. As the principal investigator, you are responsible for providing OCC with copies of the final approved protocol and consent form.

If other levels of review and approval are required, the project should not be started until all required approvals have been obtained. In addition, studies funded by external sources must be covered by an agreement signed by the sponsor and the State University. Principal investigators are not authorized to sign on behalf of the University.

Thank you.

*****Sample IHS Service Unit Letter of Support*****

December 15, 2001

Jane Doe, MD
State University
PO Box 12
Anycity, Northwest State, 99999

Dear Dr. Doe:

This letter is to inform you that the Service Unit has reviewed and supports your research study titled, "*Name of Study*." It is our understanding the project will begin on June 3, 2002. We are very interested in your efforts that may help improve our understanding of health in our elderly population.

If you have any questions or need further assistance, please contact me at (503) 555-5555.

Sincerely,

Jane or John Doe, Service Unit Director
Name of Service Unit
Anycity, Northwest State

*****Sample Tribal Business Council Resolution*****

WHEREAS, the Tribe is a federally recognized National pursuant to the Treaty of 1855 (12 Stat. 951); and

WHEREAS, the Tribal Council is the governing body of the Tribe, by authority delegated by Resolution ABCD-1234; and

WHEREAS, the Health, Employment, and Welfare Committee of the Tribal Council has been delegated the responsibility for providing the leadership, guidance, and oversight to all of the health, employment, and welfare programs and services; and

WHEREAS, nationwide statistical data has indicated that an increase in the number of elderly Native Americans has been observed in recent decades; and

WHEREAS, a National Indian Council on Aging study has shown that the life expectancy for Native Americans has increased by 19% since 1955; and

WHEREAS, the prevalence, causes, and risk factors for chronic disabilities including dementia in Native Americans are as yet completely unknown; and

WHEREAS, a study has been designed to determine the general health status and prevalence of major disabling conditions in elderly Native Americans, the functional status of elderly Native Americans, and the effectiveness of interventions that are currently used to maintain function; and

WHEREAS, the study was designed with input from tribal council members and health staff; and

WHEREAS, in implementing the study, the researchers will follow the protocol contained in the study design; and

WHEREAS, the researchers will work closely with tribal health staff to have a clear understanding of culturally sensitive issues and to ensure that the dignity of all people contacted is maintained; and

WHEREAS, the title of the study will be “*Name of Study*,” and

WHEREAS, permission from the Executive Board of the Tribal Council is sought by Dr. Jane Doe to implement the study; and

WHEREAS, there is to be no publication of the data collected in the study without the express permission of the Tribe.

NOW THEREFORE, BE IT RESOLVED, by the Executive Board of the Tribal Council, acting under authority delegated by Section IV-A of the Rules or Procedures, approved by the Tribal Council Resolution AAAB-0001, dated January 31, 1969, and meeting at the Governmental Headquarters of the Tribe, Anycity, Northwest State, that approval to initiate the study in question be signed.

BE IT FURTHER RESOLVED, that the Tribe does not waive, alter, or otherwise diminish their Sovereign Immunity whether expressed or implied by virtue of this contract, for any and all administrative or legal action, which may arise directly or indirectly from the same. Nor does the Tribe waive, alter, or otherwise diminish their rights, privileges, remedies, or services guaranteed by the Treaty of 1855.

DONE AND DATED on this 15th day of December, 2001, by the undersigned members of the Executive Board of the Tribal Council.

Name, Chairman
Tribal Council

Name, Assistant Secretary
Tribal Council

Name, Sergeant-At-Arms
Tribal Council