Dear Tribal Leader:

The U.S. Department of Health and Human Services (HHS) is committed to engaging in meaningful consultation with Tribes on matters that have Tribal implications. To that end, we are writing to request your advice and input regarding a Notice of Proposed Rulemaking (NPRM) to revise, modernize, strengthen, and make more effective the Federal Policy for the Protection of Human Subjects that was promulgated as a Common Rule in 1991. (Enclosed is a list of the departments and agencies that currently follow the Common Rule. It is proposed that the Department of Labor will join that list, as part of the NPRM.) The NPRM, published in the Federal Register on September 8, 2015, with comments due on January 6, 2016, may be found and commented on at https://www.federalregister.gov/. Enter the docket number “HHS–OPHS–2015–0008” into the search box.

This NPRM seeks comment on proposals to better protect human subjects involved in research, while facilitating valuable research and reducing burden, delay, and ambiguity for investigators. This proposed rule is an effort to modernize, simplify, and enhance the current system of oversight. The participating departments and agencies propose these revisions to the human subjects regulations because they believe these changes would strengthen protections for research subjects while facilitating important research.

We would like to provide you with an opportunity to learn about the provisions of the NPRM with HHS experts during a Tribal consultation call on January 5, 2016. This call, which will be recorded and transcribed for the administrative record, will be held to facilitate an understanding of the NPRM and allow you to raise questions and offer input. The call-in information is as follows:

**TRIBAL CONSULTATION**
**DATE:** Tuesday, January 5, 2015  
**TIME:** 3:00 P.M. EST  
**WEBINAR**  
**LINK:** https://www.mymeetings.com/nc/join.php?i=PW6473619&p=2035033&t=c  
**CALL-IN NUMBER: 888-769-9406**  
**PARTICIPANT PASSCODE: 2035033**

We encourage you to submit written comments before the comment period deadline, which is January 6, 2016. Written comments that are submitted during the comment period will become part of the official rulemaking record.

Please contact the Office for Human Research Protections with any questions or concerns by phone, (240) 453-6909 or via e-mail at ohrp@hhs.gov.
We look forward to obtaining your advice and feedback on the NPRM.

Sincerely,

Jerry Menikoff, M.D., J.D.
Director
Office for Human Research Protections
Agencies and Departments that follow the Common Rule

Agency for International Development
Central Intelligence Agency
Consumer Product Safety Commission
Department of Agriculture
Department of Commerce
Department of Defense
Department of Education
Department of Energy
Department of Health and Human Services
Department of Homeland Security
Department of Housing and Urban Development
Department of Justice
Department of Transportation
Department of Veterans Affairs
Environmental Protection Agency
National Aeronautics and Space Administration
National Science Foundation
Social Security Administration