## - Quick Info -

## Obtaining Ethics Clearance for Research in the United States amongst American Indians and Alaskan Natives (AI/AN)

**Note:** In the USA, an Institutional Review Board (IRB) is equivalent to a Canadian REB. The USA's national research ethics code is "45 Code of Federal Regulations 46" (also known as "45 CFR 46" or as "the Common Rule") which is roughly is equivalent to Canada's Tri-Council Policy Statement.

Link to 45 CFR 46 http://ohsr.od.nih.gov/guidelines/45cfr46.html

## **PRINT AND INTERNET RESOURCES:**

- The Ethics of Research in American Indian Communities. Murray L. Wax; American Indian Quarterly,
   Vol. 15, 1991
- Suggested Guidelines for Institutions with Scholars Who Conduct Research on American Indians American Indian Culture and Research Journal. Volume 17, Number 3 / 1993 131-139
- Recommendations for Conducting Successful Research with Native Americans Suzanne Christopher,
   Journal of Cancer Education 2005; 20:47-51.
- Conducting Research with American Indians: A Case Study of Motives, Methods, and Results Joanne
  L. Sobeck Elizabeth E. Chapleski; Charles Fisher <u>Journal of Ethnic And Cultural Diversity in Social</u>
  Work, Volume <u>12</u>, Issue <u>1</u> January 2003, pages 69 84.
- National Congress of American Indians, Research Regulation in American Indian/Alaska Native Communities: Policy and Practice Considerations. Puneet Chawla Sahota <a href="http://www.ncaiprc.org/files/Research%20Regulation%20in%20Al%20AN%20Communities%20-%20Policy%20and%20Practice.pdf">http://www.ncaiprc.org/files/Research%20Regulation%20in%20Al%20AN%20Communities%20-%20Policy%20and%20Practice.pdf</a> (The tone is quite similar to Chapter 9 of 2<sup>nd</sup> Ed. TCPS)

## **HEALTH RESEARCH WITH AMERICAN INDIANS AND ALASKA NATIVES:**

- The Indian Health Service (IHS) provides health services to American Indians and Alaskan Natives. There is a national IRB for Tribal health as well as over a dozen regional IRBs for geographic regions with a high density of Aboriginal peoples.
- See the list on this HIS website. <a href="http://www.ihs.gov/medicalprograms/research/irbTribal.cfm">http://www.ihs.gov/medicalprograms/research/irbTribal.cfm</a>
- Human Research Participant Protection in the Indian Health Service:
   http://www.ihs.gov/medicalprograms/research/irbAbout.cfm

IHS also provides decision algorithms called "Human Subject Regulation Decision Charts. These 2 charts help the researcher determine if the research is subject to ethics review by one of the IHS IRBs. These decision charts from OHRP provide graphic aids used by IHS IRBs, investigators, and others to determine if an activity is research involving human subjects that must be reviewed by an IRB under the requirements of 45 CFR 46. The charts address decisions on the following:

- Whether an activity is research that must be reviewed by an IRB,
- Whether the review may be performed by expedited procedures, and
- Whether informed consent or its documentation may be waived.

Remember that although it may seem clear to the investigator from this chart that his/her project is exempt, that decision can only be made by an IRB chair or administrator <a href="http://www.ihs.gov/medicalprograms/research/docs/OHRPdecisionFlowWcitations.pdf">http://www.ihs.gov/medicalprograms/research/docs/OHRPdecisionFlowWcitations.pdf</a>