Title:
Review of American Indian/ Alaska Native Research

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# 0

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Date:
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1 PURPOSE

1.1 This SOP provides guidance to the IRB/HRRC and HRPO for review of research protocols conducted at Tribal sites. The IRB/HRRC must obtain sufficient knowledge of the local research context in order to fulfill its responsibilities under its FWA to comply with applicable standards in these communities. In particular, the HRPO must be sensitive to community attitudes and be able to ascertain the acceptability of proposed research in terms of tribal regulations, applicable law and standards of professional conduct and practice. Based on these principles, appropriate HRPO policies and procedures will be applied to research conducted within American Indian/ Alaska Native (AI/AN) communities.

1.2 The process begins when the HRPO receives a study submission for research involving American Indians or Alaska Natives as the targeted study subjects within their communities.

1.3 The process ends when the study submission is reviewed by the IRB/HRRC.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 Federal and State recognized tribes are Indian tribes or consortia of tribes that are federally or state recognized and eligible to receive funding and services from the Bureau of Indian affairs (BIA). When applicable, research within AI/AN tribal communities may require concurrent review and approval of research protocols by the IRB/HRRC and an appropriate tribal entity as deemed by the Tribal Council and/or the Governor.

4 RESPONSIBILITIES

4.1 HRPO staff and IRB/HRRC members are responsible for ensuring that these guidelines are followed.

5 PROCEDURE

5.1 Documentation of tribal approval of the research protocol should be forwarded to the HRPO (for example, tribal resolution, letter of support or letter of approval to conduct the study). Documentation of IRB/HRRC approval of the research protocol must be forwarded to the appropriate tribal entity.

5.1.1 When applicable research in these communities requires review and approval by other IRBs, for example Indian Health Services, Navajo Nation.
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Human Research Protections Office

5.2 The IRB/HRRC must possess or seek sufficient knowledge of the community to ensure protection of participant rights and appropriateness of the consent process, and must be sensitive to the community laws and values.

5.2.1 The IRB/HRRC must possess or seek necessary expertise and knowledge to make determinations regarding the local research context through one or more of the following as appropriate to the level of risk and in accordance with applicable regulatory guidance:

5.2.1.1 Personal knowledge of the local research context on the part of one or more of the reviewers of the research, having been obtained through direct experience with the tribal community and its participant populations.

5.2.1.2 Review of the proposed research by one or more ad hoc or cultural consultants with knowledge of the local research context.

5.2.1.3 Appointment of an IRB member from the community.

5.2.2 As appropriate, the HRPO will seek the applicable institutional agreements with the community officials.

6 MATERIALS
6.1 None

7 REFERENCES

8 SOURCE
8.1 Revision 0: HRPO Staff