

Privacy Concerns for American Indian/Alaska Native Individuals and/or Populations

Please provide any feedback regarding this scenario in the comment form below or by clicking [here](#).

Max Researcher wants to study treatments for heart disease at the population-level for American Indians and Alaska Native sub-populations, who have a high prevalence of this disease. Max will require electronic health record data from the Indian Health Service (IHS), a Covered Entity, to conduct her research.

The research protocol must be approved by the IHS IRB,^[1] as well as Max's own research institution. Additionally, the proposed research study must first obtain the formal, written approval from the appropriate Tribal governments, which Max will submit with the application to the IHS IRB. Max must also provide evidence of support from the IHS facility's Chief Executive Officer (CEO) to document that the project will not use IHS resources in a manner that would adversely impact the health care provided at the facility.

Max will set up a DUA with the IHS in order to obtain access to their data and provide a set of eligibility criteria for inclusion of participants in the study. Due to the nature of the study (i.e., that Max is studying a very small sub-population) re-identification is a risk. Consequently, IHS will deidentify the data before sending to Max and IHS will abide by the HIPAA minimum necessary standard to disclose data.

Questions:

- Are there special considerations with regard to the risk of re-identification due to the small population size?
 - Specifically, what provisions should be in place in the protocol to prevent such a situation?
- Are there any other alternative protections to de-identification?
- What are the implications of the research participation or research findings that might negatively impact/stigmatize the population of interest? How can these risks be mitigated effectively?
- Are AN/AI excluded from research due to the burdens of research study approval? How can these issues be resolved/eased (e.g., better clarity for researchers on what tribal governments may require)?

Title	Response
Description	Max Researcher is conducting research on the American Indian/Alaska Native subpopulations, where risk for re-identification is high due to the small population size.
Primary actor /participant	Covered Entity, Researcher
Support actor /participant	IHS Information System, and Research Information System
Preconditions	<ul style="list-style-type: none">• All parties obtain all legally required authorizations for data transfer (DUA).• Both the IHS IRB and Max's research institution's IRB must approve the study protocol.• The Tribal governments must also approve the research protocol.• The IRB approved research protocol specifies terms of data release.• Data will be de-identified by IHS before sharing it with Max Researcher.
Postconditions	The Covered Entity continues to transmit the healthcare records to the researcher in a standardized format consistent with policy and protocol.
Alternative	<ul style="list-style-type: none">• The study population is too small and thus additional protections must be put in place to reduce the risk of re-identification. Or, the researcher shows the study will provide adequate benefit, in spite of the reidentification risks.• Study participants are willing to consent to the study given benefits of research findings for these populations.
Considerations	It is ethical to avoid the creation or exacerbation of stigmas among these individuals/populations when publishing study results
Data Elements Considered	Healthcare records, Study Data
Purpose of the Data Collection	Clinical care, administrative purposes, research
Purpose of Data Use	Research
Terms of Transfer to the Data Holders	DUA
Terms of Transfer to Researchers	IRB approval

[i] <https://www.ihs.gov/dper/research/hsrp/>



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[1] <https://www.ihs.gov/dper/research/hsrp/>