Introduction

The Center for Alaska Native Health Research (CANHR) was established in 2001 with the aim of conducting research with and for Alaska Native populations that focuses on the advancement of the health and wellness of this diverse group. Doing health-related research in Alaska Native communities requires researchers to establish and foster genuine, professional and personal relationships based on trust and collaboration with individual participants, as well as with the overall community. Development of these relationships begins with a well-conceived research plan, the merits of which can be clearly communicated to participants, and are deemed practical and worthwhile by the targeted population. Conducting the research/gathering the data/specimens in the culturally sensitive manner noted in the research plan is the next step in this very important process, and allows for the most growth as researchers and participants interact and share first-hand experiences in the field setting. The strength and durability of the relationships are put to the test as the data are analyzed and findings are reported. This period can last for many years and it tests the researchers’ resolve to (1) follow through on the plan and the promises made to participants and communities, (2) maintain the collaborative process by including community representatives in the interpretation and reporting of data, and (3) maintain clear communication and high ethical standards to secure appropriate approval for deviations and/or additions to the original research plan.

CANHR staff and researchers have worked hard to enjoy the relationships and reputation that they have established in Alaska Native communities and this can be observed in the quality of data, publications, and presentations that they have amassed. In order to continue this level of research, it is imperative that we execute safeguards to ensure that not only CANHR and its affiliates adhere to these high standards, but also any researcher or graduate student who accesses and utilizes CANHR data. Therefore, ALL researchers – CANHR affiliated as well as those outside the CANHR family – must complete and submit a Data Request Form to the Experimental Design, Biostatistics, and Data Services Core (EBD Core) (skbias@alaska.edu) or to the CANHR Program Coordinator (madondanville@alaska.edu). Based on CANHR’s familiarity and past professional experience with the requestor, as well as the nature of the research plan, a more or less thorough description of the data analyses and their proposed use are required. These guidelines provide instructions for those interested in utilizing CANHR data. In general, all requests will be reviewed by acting head of the EBD Core and by the Director of CANHR for the following content:

1. Is the proposed use of the data of scientific value to the field, as well as deemed to be of practical benefit to the participants (worthwhile) providing the data?

2. Does the person requesting the data have a well-defined research question and an appropriate procedure to answer this question, or does he/she have a specified plan to accurately utilize the data to support or refute a policy stand, or as a part of a funding application?

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3. Does the person requesting the data have the capacity to accurately execute the planned use of the data in a timely fashion, as well as report the findings accurately?

4. How will the person requesting the data ensure that the anonymity and confidentiality of the research subjects and their communities will be maintained?

5. How will the person requesting the data share his/her findings with the research subjects, communities, and CANHR?

6. What assurances will the requestor provide to see to it that the data are not used in a naive manner to represent Alaska Native individuals, their communities, or tribes in a negative light?

**Submitting a Data Request Application**

The CANHR Data Request Form must be completed and accompany all applications for data. The purpose of this procedure is to allow the requestor to demonstrate the following:

- The proposed use of the data will promote Alaska Native health and/or wellness by enhancing detection, diagnosis, treatment, or prevention practices, or by contributing to the general knowledge base of these issues. In instances where the proposed use of previously gathered data is beyond the scope of that authorized by the original informed consent process, the requestor should clearly indicate the practical risks and benefits of participation.

- In all analytical proposals, the purpose and specific methodologies that will be used are described in enough detail so that the reviewers can determine their efficacy, given the design of the study that the data were derived from. If the proposed methodology is unusual or was chosen from among several viable alternatives for specific reasons, it should be described in sufficient detail so that the reviewers can understand and follow your reasoning.

- The description of the proposed data use includes the timeframe of the project as well as staff involvement in sufficient detail that the reviewers can determine whether the goals of the proposed data use are realistic and feasible in light of the available resources. Unless otherwise specified, use of CANHR datasets that come from another investigator’s project will be for a maximum of three years. Before or at the end of three years, all data files should be destroyed.

- The proposed use of the data will not harm Alaska Native individuals, communities, or CANHR. Specifically, what assurance is the requestor prepared to make to adhere to anonymity and confidentiality commitments previously made by CANHR during the collection of these data/specimens?

The completed Data Request Form, all supporting documentation, as well as a signed CANHR Confidentiality Agreement and current Collaborative IRB Training Initiative (CITI) Human Subjects

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Research Educational Program Certification (http://www6.miami.edu/citireg) should be submitted to the EBD Core (skbias@alaska.edu) or to the CANHR Program Coordinator (madondanville@alaska.edu). Documents can also be faxed to 907-474-5700 or mailed to CANHR, attn: CANHR Data Request, P.O. Box 757000, University of Alaska Fairbanks, Fairbanks, AK, 99775-7000. Questions regarding data request procedures can be emailed to the EBD Core, or call 907-474-7277.

Agreement to adhere to the CANHR Publication Policy is required of not only the researcher requesting the data, but also ANY and ALL staff, including students, lab technicians, consultants or collaborators who will be involved in processing, analyzing, managing or interpreting the data. Likewise, these individuals are also required to hold, and to submit to CANHR proof of current CITI certification (renewable every 2 years). The Collaborative IRB Training Initiative was founded in March 2000 as a collaboration between the University of Miami and the Fred Hutchinson Cancer Research Center to develop a web-based training program in basic ethical human research subjects protections. Current CITI certification is required of all individuals who will interact with CANHR data or specimens regardless of level of education, area of specialty, or experience. CITI equivalency certification will be accepted upon approval of the IRB. In addition to having CITI certification on file with CANHR, the UAF IRB also requires a copy of the CITI certification for its file. To assure that they have a copy, when taking the CITI online course please register as being affiliated with UAF; by doing so, the UAF IRB automatically receives a copy of your certificate. If you choose to register in a different manner or you already hold a current CITI certificate you can email a copy of the certificate to the UAF IRB at fyori@uaf.edu or fax to 907-474-5444.

As proponents of community-based participatory research practices, CANHR has worked with the UAF IRB to develop a version of this training program that is adapted for our rural field staff who have no exposure to, or formal college training, in human subjects research. If your proposed use of CANHR data involves individuals to whom this situation applies, please contact the CANHR Program Coordinator about accessing these materials. Remember, data requests will NOT be fulfilled until evidence of full compliance by ALL individuals who will interact with the data is on file with the EBD Core.

Requests of data for analysis performed by consultants should originate from the Project PI and the consultant must be added to the data users (page 4). This Data Request Form guideline also applies to the Project PI's staff submitting requests for the Project PI. This helps provide CANHR with a complete record of all data dissemination. Please note that the consultant or his/her staff or colleagues who will be involved with the data need to submit or have a signed CANHR Confidentiality Agreement, as well as current CITI certification on file with CANHR.

Process:

Completing the Data Request Form

• Page 1: Identifying information – ‘Name’, is the person requesting the data or the person responsible for use of the data.
• Page 2: Indicate relationship with CANHR and the purpose of the data request. Briefly, yet sufficiently, describe what you are looking at and why this is important and worthwhile. Describe the research question and the planned procedure to analyze
the data and answer the question. Include a proposed timeline. Check the type of electronic file you would prefer.

- Page 3: Check the project the data you are requesting comes from. If the data comes from a project other than your own, you will need signature approval from the project PI. List the variables you are requesting.
- Page 4: List ALL individuals that will be involved with the data, and attach signed CANHR Confidentiality Agreement as well as current CITI certification for each (or note established compliance). Obtain appropriate Project PI signature(s) and send form to EBD Core or to the CANHR Program Coordinator.

**Review of Data Request Applications and Approval Conditions**

The EBD Core and CANHR Director will meet as needed to review Data Request applications. When necessary, adjunct reviewers who provide particular expertise relative to a specific application may be added to the process. In the case of denial of the request, concerns and reasons for the decision will be explained. When appropriate, the reviewers will encourage resubmission once the outlined concerns have been sufficiently addressed and/or amended.

Upon approval of a request, a timeline will be negotiated for the completion of that specific project, as well as a schedule of intermediate progress and final reports. In general, use of data will be for a three-year time period. If the agreed upon timeline is exceeded or other requirements are not met, following written notification, CANHR approval for use of the data may be rescinded and other qualified researchers given the opportunity to follow through on the plan.

The requestor will also be required to acknowledge CANHR for providing the data, as well as the grant that supported the collection of the specific data/specimens utilized. Upon approval of the Data Request, the requestor will receive a copy of the data as quickly as possible.

**Three Year Data Expiration or Renewal**

To protect the data provided to CANHR by research participants, CANHR has a policy that after three years all distributed data files should be destroyed or new Data Request can be submitted if there is justification for continuing the analysis.

If, after three years, you are no longer working on the data, you will be required to fill out and submit a *Finished with Dataset Form*, regarding the disposition of the file sent to you and any copies that you made. In addition to the form, please provide us with a progress report on your work.

If you wish to maintain the file and continue your analysis, you will be required to fill out and submit a *Data Renewal Form*, which addresses any delays you have encountered, how they have been resolved, and the justification for your continuation. In addition, please provide us with a progress report on your work to date and submit a new *Data Request Form*.

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