

## Indigenous Wellness Research Institute – National Center of Excellence Data Request Process

The Indigenous Wellness Research Institute- National Center of Excellence (IWRI-NCoE) houses data for academic and community partners. Some of these data sets are available for analysis. Access to available data sets includes a standard access approval processes and may include project specific approval processes. Please note that IWRI works with many tribal communities and agencies, and as such, in addition to IWRI-NCoE access processes, tribally owned or governed data will also have tribal community/agency access processes.

### Data Request Overview:

1. Contact the PI for initial inquiry and propose preliminary purpose for accessing the data.
2. PI will notify the IWRI-NCoE data management team.
3. The IWRI-NCoE data management team will send the following documents to the party requesting the data
  - a. IWRI-NCoE data use forms
    - i. Data Analysis Plan. Requires that all persons conducting analysis on the IWRI-NCoE dataset have on file a plan for each set of analyses. This plan takes the form of a one-page abstract of work proposed.
      1. Please note that prior approval also extends to all presentations at conferences, or other public settings.
    - ii. Human Subject Approval Process Form.
      1. Requires review by an IRB for use of identifiable data or data analysis that is outside the scope of the original aims of the study.
      2. Requires review by other entities that have rights or ownership of the data i.e., tribe, health board, agency, community publication committee. This review is required regardless of identifiable or deidentifiable data.
    - iii. Data Use Agreement Form
      1. This is a signed declaration of the data use and restrictions
    - iv. Alteration to Scales or Measurements
      1. Releases IWRI-NCoE from any liability of the use of its measures.
    - v. Confidentiality Agreement
      1. All person(s) accessing individual level data must sign a confidentiality agreement.
  - b. Project specific data use forms (if applicable)
    - i. These can include agreements with Tribal community/agency or partner data sharing agreement and publication agreement.
  - c. Final or most recent stamped consent form
  - d. Grant
  - e. Frequencies/codebook (if available)

The following documents are available on the IWRI web site (subject to availability and PI's approval)

- a. Study abstract
  - b. Variable matrix
4. After you have received the project documents, fill out any applicable IWRI-NCoE data use forms and project specific data use forms to describe your proposed project. Complete and sign all forms and send to IWRI Research Core in one of the following ways: (1) fax to (206) 543-1228, attn: Cynthia Pearson; (2) electronic attachment to [iwridata@uw.edu](mailto:iwridata@uw.edu), cc:ing pearsonc@uw.edu; or (3) mail to Cynthia Pearson, Box 354900, 4101 15<sup>th</sup> Ave NE, Seattle, WA 98105-6299.
  5. After initial approval, you and the PI (or their designate) will shepherd the proposal through any additional approval processes i.e., tribal or agency partner, health board, community or academic IRB. The time it takes for PI approval and, if necessary, tribal or other IRB approval to be processed varies by project. A discussion with the investigator should yield a better idea of the time it will take to complete this step.

6. Once IWRI data is obtained, a paper must be under review within a year or a new request must be submitted. If a paper is not under review within the second renewal period you will forfeit your right to the use of the data.
7. Only person(s) who have received approval may access and run analysis off the dataset.
8. Dataset must be destroyed and removed from all computers upon request from IWRI-NCoE.

**Indigenous Wellness Research Institute National Center of Excellence  
Data Analysis Plan Form**

Name of Data Set:

Type of Data Set:     Focus groups    In-depth interviews    Survey    Intervention

Principal Investigator of Data:

**Proposed Work Plan** (delete sections that do not apply)

Working Title:

Primary Author:

Project Author (must list an author from the project, preferably the PI):

Other Authors:

**Statement of the Problem**

1. What are the major issues and concepts?
2. What is the primary relevance, significance, or motivation for analysis?
3. What are the specific objectives-questions, hypotheses, etc?

**Analysis Plan**

1. What are the specific group or subgroups of focus (i.e., women, men, etc.)?
2. What are the primary questionnaire items to be used which are necessary to answer your proposed hypothesis? (Include questionnaire item number and description)
3. What is the analysis plan and specific statistical techniques to be employed?
  - a. Dependent Variable(s)
  - b. Independent Variables
  - c. Control Variables

**Dissemination Plan**

What are the plans for dissemination? Check all that apply. ("To be determined" is an insufficient response.)

Publication

- Journal - Name of journal:
- Book chapter  
Title, Author, Book Editor(s), Publisher:  
Expected Publication Date:
- Master's Thesis: Expected completion date:
- PhD Dissertation - Expected completion date:
- Other, please explain:

Presentation

- Conference:  
Abstract Due Date, Organization, Conference Dates, and Location:
- Community Event:  
Abstract Due Date, Organization, Conference Dates, and Location:
- Other, please explain:

**Grant proposal**

All proposals using any IWRI related data must first be approved by the Principle Investigator (or designate) of each study. No new research projects (e.g. R mechanisms), applications or competitive supplements proposing to use any IWRI data will be accepted by NIH until the data set has been publicly released. Any such applications will be returned to the applicant prior to review.

**Indigenous Wellness Research Institute – National Center of Excellence  
Human Subject Approval Process**

- 1) Are the data in the form received identifiable or de-identified?
- 2) Is the person with whom the data will be shared an agent (faculty, staff, and student) of the UW, an agent of some other institution, or functioning as an independent researcher?
- 3) How closely does the use of the shared data match the aims/purpose of the original study? Please justify your response.
- 4) What did the consent process or data sharing/use agreement say about using the data, and in what form?
- 5) Is the study federally funded?
- 6) Do any of the following entities claim ownership of or control over the data? If so please name the entity below. Note: If any other entities have claim or right to review over the data, approval from said entities must be received prior to release of the data.
  - Tribe(s):
  - Health board
  - Tribal agency
  - Community oversight or publication committee
  - Other agency
  - Other IRB
- 7) Depending on the specific situation, a given instance of sharing study data might require one or more of the following:
  - a) If the data is de-identified and in line with the aims of the original project, no human subject approval is required.
  - b) A modification to add to the study the person with whom the data will be shared (the modification might include an IRB Authorization Agreement or Individual Investigator agreement if the study is federally funded and the person receiving the data is not an agent of the UW). (see Section I. “researchers and research staff” on the modification form at <http://www.washington.edu/research/hspd/> )
  - c) A modification to the study to inform subjects that their data will be shared, and how
  - d) A new UW Human Subjects application

Please note: if the person receiving the data is not an agent of the UW, responsibility for determining whether IRB review is needed might rest with that person and his/her institution.

Does your institute require a secondary review?     Yes    No

If yes, please provide Human Subject certificate approval number for secondary analysis:

\_\_\_\_\_

**Indigenous Wellness Research Institute – National Center of Excellence  
Data Use Agreement**

(Each person who will have access to the data set must sign and return.)

1. I will not disseminate or make copies of the dataset (including for unrestricted public use or for other unrestricted uses) for anyone else without the express permission of the study Principle Investigator and the IWRI-NCoE.
2. I will notify the PI and the IWRI-NCoE data management team if I conduct additional analyses other than those proposed in this request via written documentation.
3. I will offer the PI of the data set a co-author position of any paper submitted for publication. I will discuss this with the PIs and come to agreement about appropriate PI co-authorship before I write the first draft of my paper.
4. I will acknowledge that the original collector of the data and the relevant funding agency bears no responsibility for my use of the data or for interpretations or inferences based upon such uses.
5. I will forward to the study PI and the IWRI-NCoE data management team all documentation of new variables of major study constructs (e.g., combination of more than two variables, complex logic statement or factor analyses) that I create accompanied by the relevant syntax.
6. I will destroy the data set after the purposed analysis has been accepted for publication or upon request from IWRI-NCoE. Confirmation of the removal of the dataset will be sent to IWRI-NCoE.
7. I understand that if the data use is for a publication I must have a paper under-review within one year of receipt of the data, otherwise I will request a one year extension and provide an updated data use proposal.
8. I understand that if I fail to produce a product within two years of receipt of the data I forfeit my rights to the purposed data use.

I agree that compliance with this pledge and the underlying policy is a condition of continuing collaboration and association with the IWRI-NCoE.

---

Name (printed), Date

---

Signature, Role in Project

---

Email

---

Mailing Address

---

Core Faculty/Faculty Mentor Signature (if applicable)

**Indigenous Wellness Research Institute – National Center of Excellence  
Alteration to Scales or Measurements**

The Indigenous Wellness Research Institute hereby grants permission to use (name of data set) in accordance with the following conditions, which shall be assumed by all to have been agreed to as a consequence of accepting and using this document:

1. Changes to the (measure) may be made without the written permission of IWRI-NCoE. However, all such changes shall be clearly identified as having been made by the recipient.
2. The user of this (measure) accepts full responsibility, and agrees to indemnify and hold IWRI-NCoE harmless, for the accuracy of any translations of the (measure) into another language and for any errors, omissions, misinterpretations, or consequences thereof.
3. The user of this (measure) accepts full responsibility, and agrees to indemnify and hold IWRI-NCoE harmless, for any consequences resulting from the use of the (measure).
4. The user of the (measure) will provide a credit line when printing and distributing this document acknowledging that it was developed at IWRI.
5. No further written permission is needed for use of this (measure).

---

Sign and date here confirming you agree to the measurement use policy

**Indigenous Wellness Research Institute – National Center of Excellence  
Confidentiality Agreement**

(Each person who will have access to the data set must sign and return.)

As a Researcher, you will be exposed to many personal statements, data, and other information made by respondents who participate in the study. The participants' sign a consent form to participate that indicates his/her willingness to divulge information to us. However, on that same form, we state that all information will be kept confidential. We have instituted a Research Confidentiality Policy statement to assure that the participant's confidentiality will be secured.

The Research Confidentiality Policy requires that persons accessing study materials and data sign this agreement before reviewing any data with the understanding that any breaches of confidentiality will be grounds for immediate removal from the project.

The Research Policy on Confidentiality reflects the Project's commitment and assurance to the participants that you comply with the confidentiality policy of the study and respect the confidences of all participants.

By signing this form, you agree to:

Not divulge any material/information about the respondent or the tribal community obtained in the course of working with the data to anyone.

Not divulge names of participants or tribal community to any other staff or anyone else other than the Project Investigators and the research team.

Ensure that project materials with any identifying information will always be secured in your possession and not looked at by any person other than study personnel

Take responsibility for securing the confidentiality of all materials during or after any use.

I agree to comply with the Research Confidentiality Policy and keep in confidence any information about participants in this project that I might encounter in data collection, analysis and/or dissemination.

---

Please type or print name

---

SIGNATURE

---

Date