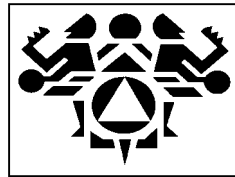


Northwest  
Tribal  
BRFSS  
Project

Model Data  
Sharing  
Agreement



Northwest Portland Area Indian Health Board  
527 SW Hall Street, Suite 300  
Portland, OR 97201

Project Telephone Number 1-877-664-0604

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# NORTHWEST TRIBAL BEHAVIORAL RISK FACTOR SURVEILLANCE SYSTEM (BRFSS) PROJECT

## Model Data Sharing Agreement

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### Table of Contents

<b>PART I: GENERAL INFORMATION .....</b>	<b>3</b>
A. Why is a data sharing agreement important? .....	3
B. Role of the Researcher or Investigator .....	4
C. Role of the BRFSS Tribe.....	5
<b>PART II: CONTENTS OF DATA SHARING AGREEMENTS.....</b>	<b>7</b>
A. Introduction and Background.....	7
B. Study Design.....	7
C. Risks and Benefits .....	7
D. Adverse Events.....	7
E. Confidentiality of Research Data.....	8
F. Analyses .....	8
G. Reporting .....	8
<b>PART III: MODEL DATA SHARING AGREEMENT .....</b>	<b>9</b>
A. Generic Tribal Data Sharing Agreement.....	9
B. Confidentiality Agreement, Use and Disclosure of Client Information .	14

**PART I: GENERAL INFORMATION****A. Why is a data sharing agreement important?**

A data sharing agreement is important because it specifically outlines the terms of understanding and agreement between the tribe and the entity that has requested use or access to the tribe-specific BRFSS data.

The data sharing agreement should discuss in detail the plans for the BRFSS data. The following questions, at minimum, should be answered:

- For what purpose will the data be used?
- Is this purpose important to the tribe?
- Who wants the data? What are their credentials and qualifications?
- What is the expected outcome of the project?
- How much of the data do they want?
- Is the request only for specific variables?
- Are they asking for information that could identify individuals?
- Who will have access to the data?
- How long do they want to keep the data for?
- Where will the data be stored?
- How will the data be stored?
- How will the data be secured?
- Frequency of data exchange?
- How will the data be analyzed? What software? What tests?
- Are there any limitations in reporting (i.e., small cell size)?
- Where will the analyses take place?
- How long will the analyses take?
- How will the data be destroyed? or what are the procedures to return the data to the tribe?
- Will the data be stored or handled according to any governmental regulations? For example, HIPAA?

- What are the plans for the dissemination of the results?
- Will the tribe receive copies of the results?
- Will oral presentations be done?
- Will reports be written? Who will receive copies?
- How will the reports be written?
- Does this request require Tribal Health Board approval?
- Does this request require Tribal Council approval?

Remember, the data sharing agreement makes sure the BRFSS tribe and the researcher understand and agree on all aspects of the use of the data.

## **B. Role of the Researcher or Investigator**

Researchers must be sensitive to the local culture, traditions, research priorities, and lifestyle of American Indian and Alaska Native (AI/AN) communities. Furthermore, researchers must be responsible and accountable to the tribal government where the research is being conducted. Tribal communities are sovereign nations.

Listed below are suggestions for improving research sensitivity and responsibility to tribal governments and communities:

### **Researcher Sensitivity**

- ◆ Ensure understanding and good communication
- ◆ Respect tribal culture and traditions
- ◆ Respect tribal sovereignty and self-determination
- ◆ Respect concerns and opinions of community
- ◆ Respect local research priorities and needs
- ◆ Respect individuals, families, and communities
- ◆ Respect human participants' rights and dignity
- ◆ Recognizing and respecting tribal concerns about participant confidentiality?
- ◆ Exclude over-studied populations from participation
- ◆ Demystify research
- ◆ Be accessible
- ◆ Provide technical assistance

- ◆ Provide feed-back and findings in a timely manner
- ◆ Respect a tribe's right to decline participation
- ◆ Respect the autonomy and decisions of the tribe

### ***Researcher Responsibility***

- ◆ Communicate and coordinate with tribal leaders
- ◆ Negotiate tribal and community consent to participate
- ◆ Maximize benefits and minimize risks
- ◆ Protect human participants and sensitive data
- ◆ Comply with informed consent process
- ◆ Obtain tribal health director; tribal health committee; tribal council; Indian Health Service (IHS) service unit director, and IHS Institutional Review Board (IRB) approval
- ◆ Do not begin research until all approvals are obtained
- ◆ Share results of the research with the tribes
- ◆ Protect participant and tribal identity
- ◆ Build capacity within the community
- ◆ Comply with the agreed-upon protocol specifications
- ◆ Comply with tribal and IHS publication clearance

### **C. Role of the BRFSS Tribe**

- ◆ As owners and keepers of the tribe-specific BRFSS data, the tribe should know and approve where the BRFSS data physically resides.
- ◆ The BRFSS tribe should designate an overseer to the data, i.e., assign a contact person.
- ◆ The BRFSS tribe should be prepared when programs and projects within the tribe request use or access to the tribe-specific BRFSS data.
- ◆ The BRFSS tribe should be prepared when programs and projects external to the tribe request use or access to the tribe-specific BRFSS data.
- ◆ The BRFSS tribe should designate a contact person to review the submitted requests.
- ◆ The BRFSS tribe should designate a contact person to oversee the request from the beginning to completion.
- ◆ The BRFSS tribe should make sure it understands any collaborator requirements or responsibilities, i.e., is the investigator seeking a degree or needing to publish?
- ◆ The BRFSS tribe should communicate its research priorities to interested investigators.
- ◆ The BRFSS tribe should take an active role in ensuring that confidentiality steps and procedures are in place and are being met.

- ◆ The BRFSS tribe should be able and willing to have regular and timely consultations with the investigators.
- ◆ The BRFSS tribe should request community capacity building activities.
- ◆ The BRFSS tribe should stipulate how it wants to be identified in oral presentations and written reports, including publications.
- ◆ The BRFSS tribe should know where and to whom the final results are being disseminated.

**PART II: CONTENTS OF DATA SHARING AGREEMENTS**

- ◆ Cover letter with a list of all investigators and a contact person and telephone number.

**A. Introduction and Background**

- ◆ Provide relevant research background and explain why this activity is necessary or important.
- ◆ Explain why it is necessary to involve the BRFSS tribe and its data in this activity.
- ◆ Explain the burdens and benefits of the research.
- ◆ Describe the potential impact of the proposed research or data analyses on the BRFSS tribe.
- ◆ Explain if the BRFSS tribe will receive compensation.

**B. Study Design**

- ◆ Provide a complete description of the study design, sequence, and timing of all procedures that will be performed. Include all materials that will be used in the procedures. Attach flow sheets if they will help the reader understand the procedures.
- ◆ Describe where the study or procedures will take place

**C. Risks and Benefits**

- ◆ Describe the nature and amount of risk of disclosure or other side effects from all study procedures or analyses.
- ◆ Describe the expected benefits for the tribal community.
- ◆ Describe how due care will be used to minimize risks and maximize benefits.
- ◆ Describe the provisions for a continuing reassessment of the balance between risks and benefits.
- ◆ Describe the data and safety monitoring committee, if any.

**D. Adverse Events**

- ◆ Describe how adverse events will be handled.
- ◆ Discuss if facilities are adequate to handle possible adverse events.
- ◆ Explain who will be financially responsible for injuries resulting from study procedures or reports (e.g., study sponsor, institution, etc.).

**E. Confidentiality of Research Data**

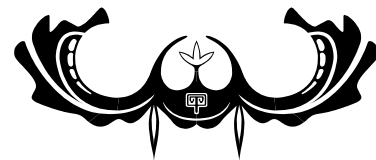
- ◆ Explain if data will be anonymous (no possible link to identifiers).
- ◆ Explain if the data will include identifiable variables.
- ◆ Explain if identifiable data will be coded and if the key to the code will be kept separate from the data.
- ◆ Explain if any other individual will have access to the identifiable data.
- ◆ Explain how data will be protected (e.g., computer with restricted access, password protected computer files, locked file cabinet, etc.).
- ◆ Will the data be stored according to any governmental regulations, for example HIPAA?

**F. Analyses**

- ◆ Explain which software programs will be used to analyze the data.
- ◆ Explain the proficiency and experience of individuals who will be responsible for analyzing the BRFSS data.
- ◆ Explain what tests will be performed.
- ◆ Explain the criteria for inclusion or exclusion of results based on sample cell sizes.
- ◆ Explain any procedures for quality assurance or for checking of results.
- ◆ Explain where the analyses will be performed.
- ◆ Explain the disposition of BRFSS data, data files, syntax files, and any output files after analyses are completed.

**G. Reporting**

- ◆ Explain how the results will be disseminated.
- ◆ Explain how the BRFSS tribe will be identified and acknowledged in any oral presentation.
- ◆ Explain how the BRFSS tribe will be identified and acknowledged in any written reports.
- ◆ Explain to whom the results will be disseminated to.
- ◆ Explain how often the results will be disseminated.



**PART III: MODEL DATA SHARING AGREEMENT**

**A. Generic Tribal Data Sharing Agreement**

**DATA SHARING AGREEMENT**  
**between**  
**(NAME OF TRIBE)**  
**and**  
**THE NORTHWEST PORTLAND AREA INDIAN HEALTH BOARD, *for example***

**I. ENTITIES RECEIVING AND PROVIDING DATA**

ENTITY RECEIVING DATA:

OFFICE:

CONTACT PERSON:

TITLE:

ADDRESS:

PHONE NUMBER:

EMAIL:

FAX NUMBER:

ENTITY PROVIDING DATA:

OFFICE:

CONTACT PERSON:

TITLE:

ADDRESS:

PHONE NUMBER:

EMAIL:

FAX NUMBER:

**II. PURPOSE, AUTHORITY AND TERM OF AGREEMENT**

**A. PURPOSE**

To facilitate the health of Indian tribes and individual American Indians and Alaska Natives in the Northwest, the Northwest Portland Area Indian Health Board (NPAIHB) requests access to tribe-specific Northwest Tribal Behavioral Risk Factor Surveillance System (BRFSS) data maintained by the {NAME OF TRIBE}. Because NPAIHB work contributes to the overall tribal mission of

improving the quality of health care for the tribe, the tribe agrees to make its tribe-specific Northwest Tribal Behavioral Risk Factor Surveillance System (BRFSS) data available to NPAIHB.

B. LEGAL AUTHORITY

1. The {NAME OF TRIBE} is a federally-recognized tribe under ....
2. NPAIHB is an Indian Organization as defined by federal law in the Indian Self-determination and Education Assistance Act, 25 U.S.C. §450b(1). NPAIHB has established *The EpiCenter*, whose mission is, in part, to provide timely and accurate health status information to Northwest tribes.

C. PERIOD OF PERFORMANCE

This agreement shall be effective when signed by both parties and shall continue until terminated pursuant to the termination clause contained herein.

**III. DESCRIPTION OF DATA/DATA WORKPLAN**

The following data will be provided under this agreement:

1. BRFSS data including *list of variables*.

Records in the BRFSS data will be ..... Information will be reported back to the tribe on..... Using the complete BRFSS data set, NPAIHB will be able to characterize the health status of AI/AN in Idaho, Oregon, and Washington. This will facilitate development of a better understanding of the magnitude and distribution of various diseases and conditions among Northwest AI/AN. This information will be especially useful for targeting effective public health interventions, for evaluating the efficacy and cost-effectiveness of those interventions, and for monitoring health trends in Northwest AI/AN.

**IV. ACCESS TO DATA**

A. METHOD OF ACCESS AND TRANSFER

Unless otherwise agreed by the parties, the data will be provided by compatible computer diskette (1.44 mb standard diskette or 100 mb Iomega Zip disk)

B. PERSONS HAVING ACCESS TO DATA

Only members of NPAIHB staff who specifically require access to such data in the

performance of their assigned duties shall have access to these data. Prior to any data transfer under this Agreement, all staff members who will have access to the information will be notified of the use and disclosure requirements. Also prior to the transfer of any data, staff members who will have access to the data shall sign the use and disclosure of client information (Attachment A) which signed copies immediately shall be provided to {NAME OF TRIBE}.

C. FREQUENCY OF DATA EXCHANGE

Annually, if updated data is available and {NAME OF TRIBE} has adequate resources to prepare the data.

D. OTHER PROVISIONS REGARDING DATA

None.

V. **SECURITY OF DATA**

The BRFSS data will be password-protected. This dataset will not be encrypted.

All reasonable precautions shall be taken to secure the data from other individuals who are not specifically authorized access. Data shall be kept on a password-protected file server located in a secure environment. They will be kept in a separate directory on the server which is also password-protected and will be accessible only by the Principal Investigator or staff members specifically authorized access as provided in this Agreement.

VI. **CONFIDENTIALITY**

A. REGULATIONS COVERING CONFIDENTIALITY OF DATA

The use and disclosure of information obtained under this contract shall be subject to 42CFR Subpart 476. NPAIHB shall maintain the confidentiality of any information which may, in any manner, identify individuals.

Further, NPAIHB shall not link the data with individually identifiable data from any other source unless specifically authorized in this Agreement.

B. NON-DISCLOSURE OF DATA

NPAIHB staff shall not disclose, in whole or in part, the data described in this agreement to any individual or agency not specifically authorized by this agreement,

except in aggregate without personal identifiers. Aggregate data also shall not be released where the cell size is less than 5.

NPAIHB will document uses and users of the data and will report this information routinely back to the contact.

**VII. PAYMENT**

No compensation will be required by either party.

**VIII. RIGHTS IN DATA**

NPAIHB agrees to provide copies of any research papers or reports prepared as a result of access to {NAME OF TRIBE} data under this Agreement, and to allow {NAME OF TRIBE} to reprint or distribute same without charge, to the extent permitted under copyright protection laws and any applicable agreements as to copyright or related intellectual property rights.

When appropriate, {NAME OF TRIBE} shall be cited as the source of the BRFSS data in all tables, reports, presentations, and scientific papers, and “NPAIHB” shall be cited as the source of interpretations, calculations, and/or manipulations of the data.

**IX. SEVERABILITY**

If any provision of this Agreement or any provision of any document incorporated by reference shall be held invalid, such invalidity shall not affect the other provisions of this Agreement which can be given effect without the invalid provision, if such remainder conforms to the requirements of applicable law and the fundamental purpose of this agreement, and to this end the provisions of this Agreement are declared to be severable.

**X. TERMINATION**

Either party may terminate this Agreement upon 30 days prior written notification to the other party. If this Agreement is so terminated, the parties shall be liable only for performance rendered or costs incurred in accordance with the terms of this Agreement prior to the effective date of termination.

**XI. WAIVER OF DEFAULT**

Waiver of any default shall not be deemed to be a waiver of any subsequent default. Waiver of a breach of any provision of the Agreement shall not be deemed to be a waiver of any other or subsequent breach and shall not be construed to be a modification of the

terms of the Agreement unless stated to be such in writing, signed by the Contracting Officer, or Executive Director of NPAIHB and attached to the original Agreement.

**XII. HOLD HARMLESS**

NPAIHB shall defend, protect and hold harmless {NAME OF TRIBE} or any employees thereof, from and against all claims, suits or action arising from any intentional or negligent act or omission of NPAIHB or its employees in the use or disclosure of any data or material provided to NPAIHB by {NAME OF TRIBE} under this Agreement. Claims shall include, but not be limited to, assertions that the use or transfer of any software, book, document, report, film, tape or sound reproduction or material of any kind, delivered hereunder, constitutes an infringement of any copyright, patent, trademark, trade name, or otherwise results in an unfair trade practice.

**XIII. RIGHT OF INSPECTION**

NPAIHB shall provide the department and other authorized entities the right of access to its facilities at all reasonable times, in order to monitor and evaluate performance, compliance, and/or quality assurance under this contract on behalf of {NAME OF TRIBE}.

**XIV. ALL WRITINGS CONTAINED HEREIN**

This Agreement contains all the terms and conditions agreed upon by the parties. No other understandings, oral or otherwise, regarding the subject matter of this Agreement shall be deemed to exist or to bind any of the parties hereto.

**IN WITNESS WHEREOF, the parties have executed this Agreement.**

\_\_\_\_\_  
{NAME OF TRIBE}

\_\_\_\_\_  
Northwest Portland Area  
Indian Health Board

\_\_\_\_\_  
DESIGNEE

\_\_\_\_\_  
Ed Fox, Executive Director

\_\_\_\_\_  
Date

\_\_\_\_\_  
Date

## B. Confidentiality Agreement, Use and Disclosure of Client Information



Northwest Portland Area Indian Health Board  
527 SW Hall, Suite 300  
Portland, OR 97211  
Phone: (503) 228-4185

### Northwest Tribal BRFSS Project **Confidentiality Agreement**

This agreement verifies by signature that \_\_\_\_\_ agrees that he or she will abide by the provisions of the Northwest Portland Area Indian Health Board's Program Operational Manual, Section C, Personal Policies and Procedures, titled, Release of Confidential Information.

#### USE AND DISCLOSURE OF CLIENT INFORMATION

Staff members with access to confidential client information are responsible for understanding rules for use and disclosure of the information. All individuals with access to confidential data need to be briefed on the confidentiality agreement and have a signed copy on file. Outlined below are key elements for staff members to follow and remember:

##### 1. CONFIDENTIALITY OF CLIENT DATA

- Individually identifiable client data is confidential and is protected by various state and federal laws.
- Tribally identifiable data is confidential and is protected by various federal laws.
- Confidential client information includes all personal information (e.g., name, birth date, social security number, diagnosis, treatment, etc.) which may, in any manner, identify the individual.
- Confidential tribal information includes any information the tribes consider confidential (e.g., name, location, names of tribal leaders, or names of tribal representatives, etc.) which may, in any manner, identify the tribe.

##### 2. USE OF CLIENT DATA

- Client data may be used only for purposes directly described in agreements between the participating tribes and NPAIHB and CDC.
- Any personal use of client information is strictly prohibited.
- Access to data must be limited to those staff whose duties specifically require

access to such data in the performance of their assigned duties.

3. DISCLOSURE OF INFORMATION

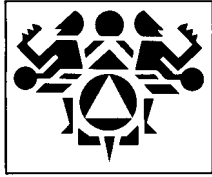
- Identified client information may not be disclosed to other individuals or agencies.
- Questions related to disclosure are to be directed to Francine C. Romero, Principal Investigator, 2001 Northwest Tribal BRFSS Project.
- Any disclosure of information contrary to 1 above is unauthorized and is subject to penalties identified in law.
- All elements remain in effect even after termination of involvement and/or employment with the Northwest Portland Area Indian Health Board.

.....  
Name : \_\_\_\_\_

Signature : \_\_\_\_\_ Date: \_\_\_\_\_

Approved By : \_\_\_\_\_  
Principal Investigator, 2001 Northwest Tribal BRFSS Project

Signature : \_\_\_\_\_ Date: \_\_\_\_\_



Northwest Portland Area Indian Health Board  
527 SW Hall, Suite 300  
Portland, OR 97211  
Phone: (503) 228-4185

Northwest Portland Area Indian Health Board  
Program Operation Manual, Section C  
RELEASE OF CONFIDENTIAL INFORMATION

The provisions of this policy state:

**Employees or Contractors may not disclose privileged information without authorization by the Executive Director or Board Chairperson. Confidential client information is subject to the Federal Privacy Act.**

**The release of confidential records maintained by the NPAIHB is violation of the Privacy Act of 1974 (Title US Code), Privacy Act Regulations (45CFR, Part 5b), and NPAIHB policy is prohibited and subject to disciplinary action.**

**It is the policy of the NPAIHB that requests from NPAIHB staff for tribal data necessary to complete NPAIHB Projects are to be made in writing to the tribal council. The request must include a statement of how the data is to be used, a list of users, a description of how the confidentiality will be maintained, and a sample resolution authorizing the release of data. All requests must be approved by the Executive Director. Records obtained for NPAIHB Projects that contain personal or tribal specific information are to be protected from uses other than those for which they were collected and be accessible only to those assigned to the project. Personal and tribal specific information is not to be disclosed without the individual's or tribal government's prior written consent. Confidentiality must be maintained by NPAIHB staff so that the relationship and reputation of NPAIHB with its member tribes and with other agencies is not jeopardized, and the reliability of data is not questioned.**

I, \_\_\_\_\_, an employee or contractor of the Northwest Portland Area Indian Health Board (NPAIHB), hereby acknowledges that I understand and will abide by the provisions of the Confidentiality Policy.

Signed: \_\_\_\_\_ Date: \_\_\_\_\_

Witness: \_\_\_\_\_ Date: \_\_\_\_\_

**NOTES**

