



<Tribal Logo>

<Tribal Nation Legal Name>

<Tribal Research or Legal Office Name>

<Address line 1>

<Address line 2>

<(000) 555-1234>

Data-Sharing Agreement

For the

<Protocol Title>

between the

<Tribal Nation Legal Name>

and

<Institution or Researcher [Institution]>

1. Project Purpose and Scope

- 1.1 Project Purpose: <Tribal Nation Legal Name> and <Institution or Researcher> are collaborating to plan, develop, and implement a research study about <topic of research> within the <Tribal Nation Legal Name> or properties owned by <Tribal Nation >.
- 1.2 Principal Investigator(s): The Lead Principal Investigator for this research is <Researcher Name>. The Co-PI's for this research are: <Co-PI Name(s)>.
- 1.3 Title and ID: The title for this research is: <Protocol Title> with <Tribal Nation IRB> - assigned ID#<IRBID>.
- 1.4 Project Scope: The research project, named <protocol title>, with IRB ID# <Tribal Nation IRB ID>, is <brief description of project including sample size, eligibility criteria, and measures>. This project shall be conducted in accordance with <applicable Tribal Code #, Tribal Resolution #, Tribal Policy and Procedure>, and 45 C.F.R. 46 et al., along with any and all other applicable federal standards governing research on human subjects.
- 1.5 Project Period: This Agreement will be in effect from the date of signature until up to <end date>, or until terminated in writing by either organization.

2. Definitions

- 2.1 “Data” shall mean any and all information obtained from **<Tribal Nation Legal Name>**, tribal members, material analysis, and results of data processing. Data does not include “Traditional Indigenous Intellectual Property”, defined in section 2.8.
- 2.2 “IRB” refers to the **<Tribal Nation>** Institutional Review Board (IRB) established by **<Tribal Code #, Tribal Resolution #>**.
- 2.3 “IRB approval” means a determination made by **<Tribal Nation IRB>** to approve of the research, contingent upon final determination by the **<Tribal Nation Governing Body>**.
- 2.4 “Material” means all physical materials gathered related to the research. **Includes: <describe physical materials to be gathered, or delete this>**
- 2.5 “Products of Research” means publications (including but not limited to reports, studies, articles, theses, books, manuscripts, sound recordings, film and video, media interviews, and computer databases), field notes, illustrations, photographs, sound recordings, collected material artifacts, replicas, and specimens, including any derivative forms they may take such as translations, communications through the electronic media, and including the internet and world wide web.
- 2.6 “Researcher” means the Lead Principal Investigator and all co-Principal Investigators listed on the Research Agreement, and any person or persons who undertake research as defined herein on the **<Tribal Nation>** or **<Tribal Nation>**-owned or -operated properties.
- 2.7 **<“Tribal acronym/abbreviation”>** means **<Tribal Nation Legal Name>**, also known as **<“Other name for Tribal Nation”>**.
- 2.8 “Traditional Indigenous Intellectual Property” means the indigenous cultural information, knowledge, stories, uses, and practices unique to the Tribe's ways of life maintained and established over Tribal homelands and aboriginal areas. This knowledge is based upon millennia of observation, habitation, and experience, and is a communal right held by the Tribe and in some instances by individuals.
- 2.9 “The Tribe” means **<Tribal Nation Legal Name>**, which may also be referred to as **<“Other name for Tribal Nation”>**.

3. Data to Be Collected

This research project will collect materials and data required to fulfill the following tasks:

- 3.1 Task 1 **<Insert description and subheadings, include the data to be collected, tools used to collect the data, etc.>**
- 3.2 Task 2 **<Insert description and subheadings, include the data to be collected, tools used to collect the data, etc.>**

4. Data Management, Sharing, and Ownership

4.1 Data Ownership, Sharing, and Management: **<Tribal Nation>** and the **<Institution/Researcher>** agree to the following binding guidelines for data management, sharing, and ownership:

- 4.1.1 Data Ownership: **<Tribal Nation>** shall maintain sole ownership and control of the project data and materials. The **<Institution/Researcher>** and **<Funding Source, if applicable>** are hereby granted a royalty free, nonexclusive right to use the data to develop and publish reports or other academic publications for educational and research purposes in furtherance of the aims of the research project. This right is granted, provided that strict confidentiality of all personally identifiable information is maintained at all times and approval is obtained from **<Tribal Nation IRB>** prior to publication or research dissemination.
- 4.1.2 Inventions: It is understood among the **<Tribal Nation>** and the Researcher that no subject inventions, as defined in 37 CFR 401.14, shall result from the participation of the Researcher in the Research Agreement.
- 4.1.3 Return of Traditional Indigenous Intellectual Property: It is not the intent of this project to collect Traditional Indigenous Intellectual Property. To the extent that any Traditional Indigenous Intellectual Property is inadvertently recorded in any way, **<Institution/Researcher>** agrees to immediately deliver the information, including all relevant products of research, to the **<Tribal Nation>** and destroy any remaining related records, whether in physical form, electronic form, or otherwise.
- 4.1.4 Data Access: Any entity other than **<Institution/Researcher>**, **<Funding Source>**, or **<Tribal Nation>** who wishes to access, view, or use the project data must formally request in writing and be granted express permission from the **<Tribal Nation IRB>**.
- 4.1.5 Secondary Data Analysis: Secondary data analysis activities must receive **<Tribal Nation IRB>** approval or a determination of exemption before the investigator accesses the data. The **<Tribal Nation IRB>** may require that secondary use of data resulting from a previously **<Tribal Nation IRB>**-approved research study be submitted to the **<Tribal Nation IRB>** as a new research proposal for approval using all of the usual procedures.
- 4.1.6 Data Collection: Before any data is collected, the researcher must have an approved IRB application and approval by the **<Tribal Nation IRB>** and **<Tribal Nation Governing Body>**.
- 4.1.7 Data Protection: By signing this agreement, **<Researcher Name>** recognizes and accepts responsibility to ensure appropriate researcher conduct in relation to the data. The researcher is responsible for data collection and analysis, and for keeping all data containing personally identifiable information and their sources confidential. The researcher will remove all personally identifiable information from any and all data collected as a result of the project in accordance with applicable federal, state, tribal, and their employer institution's laws and regulations.
- 4.1.8 Data Storage: For the duration of the project, **<Researcher Name>** will house all physical and electronic data in secured, locked physical and electronic systems, including locked file cabinets and secure, password-protected databases on secure

servers with the **<location>** offices. The researcher will also maintain and keep the de-identified project data to the limited extent necessary to complete any study aims, reports and dissemination activities authorized by the **<Tribal Nation IRB>**. After completion of the project and upon completion of the time allotted by the IRB to fulfill project-approved publication or dissemination activities, all data retained by researcher(s) must be provided to **<Tribal Nation>** per “Data and Materials Return” in section 4.1.10, or destroyed at the Tribe’s express written direction.

4.1.9 Data Use: In connection with the project data, the parties agree to establish a “Dissemination Plan” to utilize and disseminate the data, to both academic audiences and the **<Tribal Nation>** community. No project results will be disseminated without approval by the **<Tribal Nation IRB>**

4.1.10 Data and Materials Return: The research data and materials obtained from research projects is owned by **<Tribal Nation Legal Name>** and must be returned to the Tribe within **<amount of time in months or years>** after the proposed project is completed. Researchers must return the data and materials according to the management and return process identified in the existing **<Tribal Nation IRB>** Policies & Procedures Manual. The return of the data must be documented by **<Tribal Nation>** and by the Principal Investigator. The “**<Tribal Nation>** Data Return Form” will be used to return the data to **<Tribal Nation>**. Any copies of the data in possession of the researcher must be destroyed after they have returned the primary data and materials to **<Tribal Nation>** unless there is another agreement in writing about data and materials storage made between **<Tribal Nation>** and the researcher.

4.1.11 Reporting Requirements: Upon completion of the project, the researcher(s) will provide the **<Tribal Nation IRB>** with **<insert reports to be provided>**. Once published, researchers will send **<Tribal Nation>** an electronic and/or print copy of any published manuscripts when they become available.

5.0 Publications and Research Dissemination

5.1 Approval Required. **<Tribal Nation>** reserves the right to recommend edits, negotiate changes, and if needed, to deny publication or research dissemination regarding **<Tribal Nation IRB>**-approved research that it considers to be harmful, or potentially harmful, to individuals, tribal communities, **<Tribal Nation>** resources, or the Tribe.

5.2 Use of **<Tribal Nation>** Logo and Trademark(s). The **<Tribal Nation>** logo may not be used for research activities, publication, recruiting, or research dissemination without the express written permission of the **<Tribal Nation Governing Body>**. Use of **<Tribal Nation’s>** trademark(s) such as words, phrases, symbols or designs, or a combination of words, phrases, symbols or designs, that identifies **<Tribal Nation>** as the source must be requested on case-by-case basis prior to use.

5.3 Identifying **<Tribal Nation>** by Name. For this research project, researchers **<may/may not (choose one)>** identify the Tribe by name. If desired, **<Tribal Nation>** and the researcher may decide to select an appropriate pseudonym, for example, “Northern U.S. Tribe,” to be determined by mutual agreement in writing. When **<Tribal Nation>** is allowed to be identified by name in this Agreement, the researcher shall credit **<Tribal Nation>**, when applicable, as the appropriate source of information used to develop their intellectual property.

6.0 Dispute Resolution

6.1 The **<Institution/Researcher>** agrees to use the Appeal Process as described in the existing **<Tribal Nation IRB>** Policies & Procedures Manual.

6.2 Modification. The Parties by mutual agreement may modify the terms of this Agreement. Any such modification shall be in writing signed by all Parties.

6.2 Additional language needed in this section from Tribal Nation Legal

6.3 Additional language needed in this section from Research Institution Legal

7.0 Insurance

7.1 The Researcher represents that it carries the following insurance or is self-insured to cover the following amounts: (i) general and professional liability coverage of \$1,000,000 - \$2,000,000 aggregate; (ii) property coverage in an amount necessary to cover its property used in conjunction with the research project; and (iii) auto insurance coverage.

<Tribal Nation Legal Name>

The Researcher

Print Name

Print Name

Signature

Signature

Date: _____

Date: _____