

**CAMPAIGN TO REDUCE TOBACCO USE AMONG AMERICAN INDIAN AND ALASKA NATIVE YOUTH  
(SAMPLE) DATA SHARING AGREEMENT  
BY AND BETWEEN  
BETTER WORLD ADVERTISING, INC. (BWA)  
AND  
(TRIBE [INSERT NAME])**

**TITLE**

This Agreement shall be known as the Campaign to Reduce Tobacco Use Among American Indian and Alaska Native Youth Data Sharing Agreement (the Campaign).

**PURPOSE**

The purpose of the Campaign is to provide in-depth information for the development of a social marketing campaign to reduce tobacco use among AI/AN youth by BWA and the U.S. Food and Drug Administration, Center for Tobacco Products (FDA). To implement an effective campaign, this project aims to understand tobacco use among AI/AN youth and apply findings to developing messages, creative tactics, and executions and test them to ensure that are appropriate to and effective for this audience. This research will be done through qualitative research methods such as focus group discussions and quantitative research methods such as surveys with participants such as youth, parents, guardians, community members and tribal leaders. This is social science research and discussions will be held with participants about youth tobacco use and initiation, related attitudes and beliefs, media channel use, and thoughts about creative once it is developed.

As the funder for the Campaign, the FDA will provide oversight and feedback to BWA on the data collection, analysis, and dissemination process. The project will be reviewed and approved by an Institutional Review Board (IRB), either FDA's IRB, or other IRB designated by FDA, and tribal IRB, to ensure that all federal and tribal requirements for ethical research and human subjects' protection are met.

This Agreement shall set forth the terms and conditions of data sharing between BWA and the Tribe to perform the Campaign's research data collection, analysis, use and protections.

This Agreement will:

- Establish that research will be limited to the Campaign;
- Establish and provide Campaign data sharing expectations and responsibilities;
- Protect the Tribe, participants, and BWA's campaign funder, FDA, from unauthorized use of data from this research project; and,
- Minimize the potential for adverse effects of the Campaign data on the Tribe and individual community research participants.

## DATA COLLECTION

BWA and the project's research team will perform the following activities on behalf of the Campaign:

- Ensure that the Campaign meets tribal, FDA, and Indian Health Service (IHS) requirements for ethical conduct with human subjects' research, including IRB review.
- Provide training on research protection and ethics of human subjects for all research project staff, including those from the Tribe, involved in conducting research as part of the Campaign.
- Ensure that all individuals have gone through the informed consent process where the study, its risks and benefits are explained, any questions are asked, participants are made aware of their rights, and adult participants have signed a consent form, youth an assent form and their parents or guardians a consent form before participants take part in the study. During the consent process, participants and their parents or caregivers will be notified that they may withdraw from the study at any time.
- Ensure that all Campaign data is collected in a manner that is both culturally congruent and relevant to the AI/AN participants.
- Protect participants and their privacy during data collection. All information provided by individuals who participate in research will be kept private to the fullest extent allowable by law.

The Tribe will perform the following activities in support of the Campaign;

- Allow BWA and the project's research team to contact tribal members to recruit participants. Promptly notify BWA of any concerns with regards to participant privacy or the AI/AN Project.
- Work with BWA and the project's research team to minimize challenges to successful recruitment, participation, data collection and protection of participant privacy.

## DATA MANAGEMENT, ANALYSIS, AND FINDING DISSEMINATION

BWA, and the project's research team, will perform the following activities on behalf of the AI/AN Youth Project:

- Any personally identifying information, including any that participants mention (e.g. names of family and community members), will be deleted from transcripts and datasets. Only de-identified transcripts and datasets will be shared with the FDA and the Tribe. Data will not be shared with any other institution, community, or entity without expressed written permission from the Tribe and BWA.
- Ensure that de-identified transcripts and datasets will be stored electronically on secure servers by BWA, the Tribe, if appropriate, and the FDA for up to 3 years after termination of the Campaign in order to allow both research teams to have access to the data to ensure completion of the project aims and to fulfill FDA-approved publication and dissemination activities. Paper consent and assent forms will be stored in locked file cabinets by BWA staff. Upon completion of the post-3-year period of the Campaign, unless BWA receives FDA and tribal approval for continued access to the data, the data related to the project housed at the BWA must be destroyed.
- Provide findings of research results to Tribe, FDA and other critical tribal community stakeholders and produce publications, conference presentations, reports, or dissemination materials in partnership with and with the approval of the FDA and Tribe.
- Ensure that no data will be attributed to a specific community without prior approval of that Tribe.
- Under no circumstances will BWA or its research partner, share data or data findings without explicit tribal and FDA approval.

The Tribe will perform the following activities in support of the Campaign:

- Work with BWA and research team to identify key contacts for this project. These key contacts will represent the Tribe and participate in the preparation and writing of publications, conference presentations, reports, or dissemination materials.
- Conduct a timely review of publications, conference presentations, reports, or dissemination materials and provide comments and/or approval within a time frame agreed upon by Tribe, FDA and BWA.

**TERMINATION**

- Any party, BWA or Tribe, may terminate this Agreement by giving thirty (30) days written notice of termination.
- No party, BWA or Tribe, may amend or alter this Agreement without prior written approval of both parties.
- By signing this agreement, BWA recognizes and accepts responsibility to ensure appropriate research conduct in relation to the data sharing and collection, as described in the Agreement.

**AGREEMENT PERIOD**

- This Agreement will be in effect from [Date] through the completion of the Campaign.
- The protections specified in this agreement regarding data sharing and data collection, use and dissemination will remain in effect as long as the Tribe and FDA have use of the data generated or the products (including dissemination materials) of this project.

This agreement made this [Date], between BWA and Tribe acknowledges the responsibilities set forth by the Campaign established herein. Both parties agree to abide by the terms of this agreement.

IN WITNESS WHEREOF, the parties have executed this agreement;

For the [Tribe [Insert Name]]:

\_\_\_\_\_ Date\_\_\_\_\_

Name  
[Title]  
[Tribe Name]

Better World Advertising, Inc.:

\_\_\_\_\_ Date\_\_\_\_\_

Les Pappas  
President  
Better World Advertising, Inc.