**Data, Material, and Biospecimen Sharing and Ownership Agreement**

for the [Research] [(Other)] Project [[1]](#footnote-2)

“[Title]”

Between

“[Tribal Council]”

And

“[Institution of Principal Investigator/Researcher {e.g., University}]”

And

[…]

And Read and Reviewed By [[2]](#footnote-3)

“[Principal Investigator [PI]/Director/Researcher]”

WHEREAS, [background of need for agreement] [[3]](#footnote-4) …; and

WHEREAS, …; and

WHEREAS, ….

NOW THEREFORE, This Data, Material, and Biospecimen Sharing and Ownership Agreement (“Agreement") is entered between the (Tribe), (researcher’s institution), (Tribal IRB’s institution), and (other parties as necessary) individually a Party and collectively the Parties. [[4]](#footnote-5)

1. PARTIES. [[5]](#footnote-6)

The parties above are collaborating in the development, implementation, and dissemination of Tribe’s participation in the [Research Project / Clinical Trial / (Other)] titled “[Title of clinical trial] ("Research Project"). [Name] is the Principal Investigator (“PI”) at the [PI’s Institution] and leads a team of [Investigators/(Other)] conducting this Project*.*  The [name of Federal agency funder / other funder] funds this Project as described above. [[6]](#footnote-7)

In consideration of [describe consideration], [name Parties]agree as follows:

1. PURPOSE[S] OF THIS [RESEARCH] [(OTHER)] PROJECT.

The primary purpose[s] of this Research/Other Project is/are: …. An additional purpose of the Project is to incorporate [Tribe] as a participating organization in the conduct of the [Clinical Trial/Research/(OTHER)] Project entitled “[Title of project].”

1. PURPOSE OF AGREEMENT.

The history of research of American Indian/Alaska Natives included practices that directly violated Inherent Tribal Sovereignty and harmed both Tribes and Tribal people. Those violations included: mis-analyzing research results; publishing stigmatizing, demeaning, or offensive descriptions of Tribes without Tribal review; and using the data, materials, and Biospecimens obtained for purposes that Tribes neither knew about nor had given prior permission to use. Furthermore, some research that could have included benefits to the Tribe did not include them, thus depriving Tribes of beneficial research.

The purpose of this Agreement is to prevent these historical practices from occurring in this Research Project. By so doing, this Agreement hereby promotes and enables the [Tribe] to form trusted partnerships with leading educational and private research institutions in the U.S., including the [name of institutions and companies]. This Agreement describes the use, control, and authorization to share [Tribe] Data, Material, and Biospecimens related to the Research Project to minimize their misuse and to maximize benefits to the [Tribe].

1. [SPECIFIC AIMS / OBJECTIVES] OF THIS PROJECT.

The primary [Specific Aim / Objective] [[7]](#footnote-8) of this Project is to [(e.g.,) determine the . . . of [name of clinical trial]. The Additional Aims / Objectives to be undertaken by the Protocol [Title of Protocol] in support of this primary Specific Aim / Objective are: [[8]](#footnote-9)

1)

2)

3)

4)

….

#) Any other [Specific Aim / Objective] described in the Protocol as approved by the [Tribe].

The [Tribe] shall approve any proposed change to the Specific Aims / Objectives of the Project prior to implementation at [Tribe]. If the [Tribe] does not approve of such proposed change(s), [Tribe] shall notify [research institutions] and PI to immediately cease performance of the Project. Any Data, Materials, or Biospecimens collected prior to such termination shall not be used for any purpose other than those specified in the Specific Aims / Objectives of the Project.

1. DEFINITIONS.

V.i. RELATED TO ALL DMSOAs / DMBSOAs

"Biospecimens” means a sample of material, such as urine, blood, tissue, cells, DNA, RNA, or protein, isolated from a human subject during the conduct of the Research Project.

“Data” means primary source information gathered in the course of the Project at [Tribe] that contains personally- and Tribally-identifiable and non-identifiable data or information (including all transcripts and recordings of focus groups and interviews, as well as medical record or survey data) obtained during the course of the Project at [Tribe] related to individuals and Tribes, as well as data sets and information derived from the primary source data and information. “Data” does not mean or include information publicly available or previously published.

“Informed Consent Form” (ICF) means a signable document in which each human participant in the Project voluntarily consents or confirms their willingness to participate in the Project after having been informed of all aspects of the Project that are relevant to the person’s decision. The Informed Consent Form shall satisfy the requirements of [[9]](#footnote-10) 45 C.F.R. Part 46, and related C.F.R.s. For purposes of this Agreement, the Informed Consent Form means the ICF approved by the applicable IRB and [Tribe]. The ICF and any subsequent amendment, alteration, or change is subject to the written approval by the applicable IRB and [Tribe].

“Material(s)” means all tangible articles or objects obtained, produced, or used in the Research Project, such as photographs and recordings, except Biospecimens.

“Protocol” means the formal, detailed, plan and description of the Project at [Tribe], to be performed as provided in [Title of Project]. The Protocol describes the objectives, design, research methods, statistical considerations, and organization of the project [Title of Project]. The original Protocol, documents associated with it including the Informed Consent Form (ICF), and updates to them approved by the IRB[s] and [Tribe], shall be incorporated herein by reference, and shall apply retroactively, if necessary, and be deemed to be a part of this Agreement to the same extent as though expressly set forth herein.

“Publication” or “publish” [[10]](#footnote-11) means various methods of disseminating information about and results from the research by, for example: oral presentations (without or with printed handouts, slides, etc.); media (print, articles, journals, books, e-mails, the web, other social and/or printed media); etc. “Publications” include but are not limited to abstracts, presentations, reports, articles, academic theses, Dissertations, books, etc.

“[Research/(Other)] Project” means the conduct of the [Name] [Research/Clinical Trial/(Other)] Project at [location—Tribe or Clinic], as described in the [Name] IRB’s Application Form prepared by [name of PI].

“[Name] Project Team” means the PI and other Investigators at [name of Tribe(s)], each site, and each center.

V.ii. RELATED only to CINICAL TRIALS or RESEARCH WITH A SPONSOR [[11]](#footnote-12)

“Clinical Research Site” means the clinical research sites designated as the [description of sites] where the Clinical Trial will be conducted in strict accordance with the Protocol.

“Clinical Trial” means a biomedical or behavioral research study of human subjects that is designed to answer specific questions about biomedical or behavioral interventions (treatments, drugs, or devices, or new ways of using known treatments, drugs, or devices). Clinical trials often determine whether new biomedical or behavioral interventions are safe, efficacious, and effective. In this Agreement, Clinical Trial means the clinical trial for the Protocol.

“CRO” means [name of the Contracted Research Organization{s}, if any, and its function].

“Sponsor” means, in accordance with the definition in 21 C.F.R. § 312.3, an organization or individual who assumes legal responsibility for supervising or overseeing the [research/clinical trial/(Other)]. For the purposes of this Agreement, the “Sponsor” is [name of the supervising entity of clinical trial].

1. TERMS.
2. **Ownership and Control of Data, Material, and Biospecimens.** [Tribe] maintains sole ownership and control of all [Tribe] Data and Material, including all Data and Material relating to [Tribal] individual(s), to [Tribe] institution(s), to [Tribe] culture, history, religious and other practices, and locations of Data and Material, and to the [Tribe] itself. Such Data and Material are subject to the regulations and laws of the [Tribe] as in effect on the effective date of this Agreement and/or as adopted or amended during the term of this Agreement. The Biospecimens obtained through this Research Project shall be the property of the [Tribe] and the Sponsor co-owner], and are under the control of the [Tribe] for such uses not needed or related to achieve the Specific Aims, but shall remain in the custody of the Sponsor or its contractors or the [any other research networks needing access to the Biospecimens] for a period of three years from the date of the final shipment of the [Tribe] Biospecimens to the Sponsor. Parties agree that Data, Material, and Biospecimens shall not be shared with third parties other than those defined or identified in this Agreement and shall not be sold or used, internally or externally, for any purpose other than those described in Sections 2 (Non-exclusive License to Data and Materials) and 3 (Non-exclusive License to Biospecimens) of this Agreement without the express written permission of [Tribe].  The [Tribe] reserves any and all rights and interests, whether property, proprietary, regulatory or otherwise, in such Data, Material, and Biospecimens that are not expressly granted in this Agreement. However, [Tribe] agrees that it shall not share (for use or review) any Data with any third party other than Sponsor, its contractors and its designees. [[12]](#footnote-13)

2) **Non-exclusive License to Data and Materials.** In accordance with Section 1 (Ownership and Control of Data, Material, and Biospecimens), [Tribe] hereby grants a royalty-free, nonexclusive license to the [PI, other investigators, and research entities listed in “I. PARTIES” conducting the research on data and materials] to achieve the Specific Aims or Objectives of the research listed in “IV. SPECIFIC AIMS OF RESEARCH.”

[[13]](#footnote-14) To achieve those Specific Aims, the royalty-free, non-exclusive license permits the research entity to:

1. Submit all Protocol-required Data to the Sponsor, the CRO, or their designee(s);
2. Grant the right to the Sponsor to use all Data and Materials in its possession for all legitimate business or regulatory purposes, provided, that such sharing of the Data and Material achieves the Specific Aims of this Project. Use of the Data and Material for any purpose other than to achieve the Specific Aims of the Research Project is prohibited unless [Tribe] has given explicit prior written approval;
3. Allow all Protocol-required Data and Material to be shared among the Sponsor, biostatistical, regulatory, and analytical teams needing access, which will perform the procedures of those respectives teams, provided that such sharing of the Data and Material achieves the Specific Aims of this Project. Use of the Data and Material for any purpose other than to achieve the Specific Aims of the Research Project is prohibited unless the [Tribe] has given explicit prior written approval;
4. Allow the Sponsor to provide any information regarding the Clinical Trial, including Data, to governmental organizations both inside and outside the U.S., including, but not limited to, [list any other Federal agency entities here], and [any agencies outside the U.S. here] for all legitimate public health, regulatory, or business purposes provided that such sharing of the Data achieves the Specific Aims of this Project. Use of the Data for any purpose other than to achieve the Specific Aims of the Research Project is prohibited unless the [Tribe] has given explicit prior written approval;
5. [[14]](#footnote-15) Subject to Section 4 (Disclosure of [Tribe] or AI/AN Information from the Research in Publications) of this Agreement, allow the Sponsor, the CRO, and their designees to post the Clinical Trial Protocol or results to a mandatory clinical research website (e.g., www.clinicaltrials.gov ) in the form of [format of data results]; and
6. [[15]](#footnote-16) Subject to Section 4 (Disclosure of [Tribe] or AI/AN Information from the Research in Publication) of this Agreement, allow the Sponsor, [other entities involved], Clinical Research Site, and Research investigators to make the results of the Clinical Trial publicly available through scientific publications and presentations.

Except as otherwise described in this Section 2 (Non-exclusive License to Data and Materials), any use of Data and Materials for future, unspecified research or any other purpose not described in the Protocol or to achieve anything not listed in the Specific Aims requires prior written approval by the [Tribe] prior to its use. No further right to reproduce, publish or otherwise use the Data and Material is granted, expressed or implied.

At the conclusion or termination of the Research Project, the royalty-free non-exclusive license to examine and use the Data and Material from [Tribe] and its members also concludes or terminates. All those Data and Material will be returned to [Tribe], that is, to the owner of those data and materials. If the Data and Material have not been de-identified, copies of each participants’s own data and material may be returned to the participant if requested. If any participants were promised confidentiality of specific items or components of data and materials by the Investigators, everyone’s components of the data and materials must be anonymized or de-identified before being given to [Tribe]. [[16]](#footnote-17)

3) [[17]](#footnote-18) [[18]](#footnote-19) **Non-exclusive License to Biospecimens.** In accordance with Section 1 (Ownership and Control of Data, Material, and Biospecimens), [Tribe] hereby grants a royalty-free, nonexclusive license to the [PI, [Research/(Other)] Team , and research entities listed in “I. Parties” conducting the research on the Biospecimens to achieve the Specific Aims or Objectives of the research listed in “IV. SPECIFIC AIMS OF RESEARCH” for a period of three (3) years [[19]](#footnote-20) from the final shipment of Biospecimens from the [Tribe / participants] to the [research entity] that has primary responsibility to maintain the Biospecimens and conduct the Biospecimen research. To achieve those Specific Aims, the royalty-free, non-exclusive license permits the [Research/Clinical Trial/(Other)] Team to:

1. Conduct assays and analyses using Biospecimens as described in the Protocol, provided, that such conduct is consistent with achieving the Specific Aims of this Research Project. Use of the Biospecimens for any purpose other than to achieve the Specific Aims of the Project is prohibited unless the [Tribe], has given explicit prior written approval;
2. Transfer Biospecimens collected during the conduct of the Project to the Sponsor, the CRO, other Party, or their designee(s) and allow use of the Biospecimens consistent with the Protocol and Informed Consent, provided, that such transfer of Biospecimens achieve the Specific Aims of this Research Project. Use of the Biospecimens for any purpose other than to achieve the Specific Aims of this Research Project is prohibited unless the [Tribe], has given explicit prior approval; and
3. Transfer Biospecimens to [name of laboratory conducting the analyses] to conduct assays and analyses, provided, that such transfer of Biospecimens achieve the Specific Aims of this Research Project. Use of the Biospecimens for any purpose other than to achieve the Specific Aims of this Research Project is prohibited unless the [Tribe] has given explicit prior approval; and
4. If the Sponsor or any Party stores Clinical Trial specimens or Biospecimens, at a repository, the Sponsor, Party, and repository shall be responsible for gatekeeping and ensure that such Biospecimens are used only as described in this Agreement.

Except as otherwise described in this Section 3 (Non-exclusive License to Biospecimens), any use of Biospecimens for future, unspecified research or any other purpose not listed in “IV. SPECIFIC AIMS OF RESEARCH” with procedures described in the Protocol requires prior written approval by the [Tribe] prior to its use. Upon the third year from the date of the final shipment of [Tribe] Biospecimens to the Sponsor or any Party, the Sponsor or Party shall respectfully dispose of all Biospecimens collected under this Agreement and send confirmation in writing of such to [Tribe]. [[20]](#footnote-21)

No further right to reproduce, publish or otherwise use the Biospecimens is granted, expressed or implied.

4) **Disclosure of [Tribe] or AI/AN Information from the Research in Publications.** [[21]](#footnote-22)

(a) Development of Publications. The Research Project is a “multicenter research project.” The Centers are: the [Tribe], [Institution of Principal Investigator], and [Other]. Like many multicenter research projects, this project has a “steering and publications committee” with representatives from each research center. The representatives on the committee from [Tribe] are chosen by the Tribe. That committee must unanimously approve all publications.

(b) Tribal Review and Approval of Publications. A major purpose of this DMBSOA is to prevent stigmatizing, demeaning, or highly inaccurate descriptions of the [Tribe] specifically and AI/AN Tribes, communities, and people in general, as described in III. PURPOSE OF AGREEMENT. For those reasons and by exercise of its Inherent Tribal Sovereignty, [Tribe] must review, require modification if necessary, and approve or disapprove all publications that contain [Tribe’s] data prior to any submission, publication or distribution. [Tribe] retains the right to approve, or disapprove, or require modifications in use of [Tribe’s] data contained therein. If requested by the Tribe, Publications shall contain a disclaimer that the Publication does not reflect the views of the [Tribe]. Tribal disapproval shall be documented in writing. The Tribe will endeavor to approve, comment on, require changes, or disapprove any publication proposed by the Research Team within twenty (20) business days of receipt.

***OR:***

***Alternate 4.a. and 4.b.:***

*4)* ***Disclosure of [Tribe] or AI/AN Data in******Publications.*** *[[22]](#footnote-23) [[23]](#footnote-24)*

*(a) Authorized Publications. Publications, presentations, or other materials intended for public disclosure, including public disclosures of any multi-site study results, that contain Data about [Tribe] or AI/AN (collectively, “Publication”) made by or on behalf of [research institutions and companies who will publish] is authorized without prior review and approval by the Tribe only for the disclosure of:*

1. *aggregate Data without any reference to race or ethnicity,*
2. *descriptive Data only on the proportion of American Indian/Alaska Native participating in the Research Project, and*
3. *Estimates of efficacy and safety Data stratified by “race and ethnicity.”*

*(b) Tribal Review and approval of Other Publications. In an effort to prevent demeaning, stigmatizing, offensive, or highly inaccurate descriptions of the [Tribe] specifically or ofAI/AN in general without Tribal review (as described in III. PURPOSE OF AGREEMENT), Publications, except for those described in Alternate Section 4(a) above, made by or on behalf of [research institution and company Parties], or their investigators must not refer to the [Tribe] nor mention use of any subset of data from the Research Project that identifies or may be used to identify the [Tribe] or individuals from [Tribe] or other American Indian/Alaska Native participants in the Project as contributing data to that subset, including any subset that contains [Tribe] or AI/AN Data and is identified as originating from or derived from the Research Project (“[Tribe] Related Publication”).  Notwithstanding the foregoing, [research institution or Sponsors publishing] may submit, publish, distribute and/or present any [Tribe] Related Publication, provided that [Tribe] has been given at least twenty (20) business days to review and comment on manuscripts and five (5) business days to review and comment on proposed abstracts. Within those times, [Tribe] may provide [Sponsor or research instiution] with notice to remove from the Publication references to the [Tribe] and/or information that may identify the [Tribe] or individuals from the [Tribe] as contributing to any subset of data and [research institution or company] must remove any such references that are specifically identified by [Tribe]. If requested by [Tribe], publication shall contain a disclaimer that Publication does not reflect the views of [Tribe].*

5) **Approval by IRB and [Tribe].**

5.1 Research. Before any research Data and Materials are collected or human participant/subject research is done with the [Tribe], the IRB of the [Tribe] for this Research Project ([Name of IRB]), and/or any other IRB that the [Tribe] wants or accepts, and the [Tribe] itself must review and approve the plans for the Research Project.

5.2 Suspension or Termination, Upon approval by the [name of IRB(s)] IRB and the [Tribe], the IRB(s) reserve(s) the right to suspend performance of the Research Project by [research institutions] or terminate their approval of the Research Project if the Project is not conducted pursuant to the IRB’s conditions, or if there are unexpected serious harms to [Tribe] participants. Any suspension or termination determinations shall include a statement of reasons by the IRB and notice shall be promptly provided to the Parties in accordance with 45 C.F.R. § 46.113  *[[24]](#footnote-25)* . The [Tribe] reserves the right to suspend performance of the Research Project by [research institution] or terminate their approval of the Research Project.

5.3 Protocol. The [Tribe] and the [name of IRB] IRB shall approve of the Protocol, ICF, and any amendments thereto prior to such alteration, amendment, or document becoming effective. If the [Tribe] does not approve of such Protocol, Informed Consent Form, or amendment or alteration, [Tribe] shall notify [research institution], and [research institution] shall immediately cease performance of the Research Project. Any and all Data, Material, and Biospecimens collected prior to such termination shall only be used consistent with the [Tribe] approved Protocol and Informed Consent Form.

5.4 Informed Consent Form. *[[25]](#footnote-26)*  The Informed Consent Form shall include the following statement: “The [Tribal Council] has reviewed and approved the study as detailed in this Informed Consent Form. The Council also entered into an legal agreement, called the [Data, Material, and Biospecimen / Data and Material] Sharing and Ownewrship Agreement ([DMBSOA / DMSOA]) with [research institutions and companies], and acknowledged by the [acknowledged parties as necessary]. The agreement protects your data and samples from misuse and from harming the [Tribe] and all American Indian/Alaska Native people. This Informed Consent Form incorporates the terms of the [DMBSOA / DMSOA].”

5.5. Future use of Data, Materials, and Biospecimens. Even if stated or permitted in any proposed ICF, the [Research/(Other)] Project], Project’s institution, and all others shall not be permitted to use the data, materials, or Biospecimens *[[26]](#footnote-27)* for any future use or purpose other than stated in the Specific Aims without the express written approval by the [Tribe] and IRB(s). All such references shall be removed from the ICF.

5.5 Pertinent Documents. [Party] shall provide the IRB and the [Tribe] the following pertinent documents and reports:

(a) The complete Protocol;

(b) All Informed Consent Forms as revised;

(c) list all other pertinent documents requested, e.g., recruitment documents.

6) **Confidentiality.**  *[[27]](#footnote-28)* Except the analysis described in Section 2 (Non-exclusive License to Data and Materials) of this Agreement, [Tribe], [research institution] and their researchers are responsible for Data, Material, and Biospecimen collection and analysis for the [Research / Other] Project conducted at [Tribe]. The [Parties to Agreement] shall be, and shall ensure that their respective employees, agents, contractors, or any other individuals authorized to work on behalf of the Parties shall be responsible for keeping all personally-identifiable data and material and their sources confidential unless otherwise agreed upon in writing by participants, IRB[s], and [Tribe]. Any personal use of Research Project Data, Material, and Biospecimens is strictly prohibited. Access to Data, Material, and Biospecimens is limited to personnel whose duties specifically require access to such Data, Material, and Biospecimen in the performance of their assigned duties. Any disclosure of Research Project Data, Material, Biospecimens or information contrary to the Agreement is unauthorized and subject to penalties identified in[Tribe], state, and Federal laws and regulations, *provided*, however, that nothing in this Section is or shall be construed to be a consent by the [Tribe] to the applicability or application of Federal or State laws and regulations.

6.1 Privacy. Subject to Section 6 above, unless otherwise permitted or requested by individual participants or [Tribe], the parties will protect both the personal privacy of individual participants involved in the Research Project, and also the privacy ofthe Tribe*,* subject to applicable [Tribe] Tribal, Federal, State, and, local laws and regulations.

6.2 Certificate of Confidentiality. The Research Project has a Certificate of Confidentiality issued by the National Institutes of Health. The parties agree that it will not reveal to a third party any restricted data as described herein that are received, learned or obtained under this Agreement, except that upon receiving, learning or obtaining such data the parties may communicate that same data as expressly required by applicable law or by compulsion of an order from a court of competent jurisdiction. If any Party (the “Recipient Party”) receives any order, summons, subpoena or similar process, or a request to produce data or materials, including Freedom of Information Act requests, that includes Data, Materials, or Biospecimens, they will promptly notify the [Tribe] and other signatories to this Agreement, and promptly provide notice as permissible before production, in order to permit [Tribe] to intervene or respond as appropriately. The Parties agree to support and defend the Research Project’s Certificate of Confidentiality.

6.3 Security. For the duration of the Research Project, [Parties] will house any physical and electronic Data and Materials in secured, locked, fire-proof systems, including locked file cabinets and secure, password-protected electronic databases on secure servers within the their respective offices and secure computers. [Parties] will maintain Biospecimens with standard “best practices” for biorepositories, to include protected access to the Biospecimens, maintained with reliable temperature-controlled units with immediate generator back-up in case of power outage, and infection control of the biohazards of Biospecimens.

7) **Data and Materials.** The [name of Project Team] will collect the Data and Materials consistent with this [DMSOA / DMBSOA] as authorized by the IRB(s) for this [Research Project] to complete any Specific Aim/Objective (see IV. [SPECIFIC AIMS / OBJECTIVES] OF THIS PROJECT), reports, and dissemination activities consistent with the terms herein. [Party] shall analyze any Data and Materials received in connection with the Research Project consistent with the Protocol and this Agreement.

8) **Access to Data and Materials.** Except as specified herein, [Tribe] retains ownership and full control of all[Tribe]Data and Materials except Biospecimens. As described in Section 3 (Non-exclusive License to Biospecimens), the Biospecimens collected during the conduct of the Research Project will be transferred to the Sponsor, the CRO, or their designee(s) *as custodians* but shall remain under the co-ownership and co-control of the [Tribe]. The [Parties] or its contractor and their employees performing tasks in furtherance of the Research Project at [Tribal site], shall have the right to access, view and use all [Tribe] Data, Materials, and Biospecimens from the Research Project only for the purposes explicitly included in the [Specific Aims / Objectives] of this Research Project, the Protocol and as provided in Sections 2 (Non-exclusive License to Data and Materials) and 3 (Non-exclusive License to Biospecimens) of this Agreement, subject to complying with Section 9 in this Agreement. Any researcher or person or entity other than those listed in this Section and in Sections 2 and 3 of this Agreement wanting to access, view, or use[Tribe]Data, Materials, or Biospecimens from this Research Project, must ask for and receive prior, explicit, written permission fromthe [name of Tribal Council], after proceeding through the review and approval processes of the IRB(s) for the Research Project and [Tribe’s] review and approval processes. Any researcher of the Research Project Team wanting to access, view, or use [Tribe] Data and Materials from this Research Project for a purpose not explicitly included in the Specific Aims (Objectives) of this Research Project or Protocol or as provided in Sections 2 and 3 of this Agreement, must ask for and receive prior, explicit, written permission from [Tribe], after proceeding through the review and approval processes of the IRB(s) for this Research Project and [Tribe’s] review and approval processes.

9) **Recognitions and responsibilities.** By signing this Agreement, the Parties:

1. recognize and accept responsibility to ensure appropriate conduct by their respective employees, investigators, faculty, agents, and contractors that is consistent with the terms of this Agreement; and
2. agree that all Research Project Team members shall sign the Confidentiality Agreement applicable to them (see Attachment), to be securely stored by the appropriate Parties; and
3. recognize the inherent sovereignty of the [Tribe] and consent to its jurisdiction as it relates to this Agreement, Research Project, and accompanying Protocol; and
4. acknowledge that co-housing the Data, Materials, and Biospecimens is predicated upon [parties] acknowledgement that:
   1. the [Tribe] maintains control over the use of, and is sole owner of, [Tribe]-specific Data and Materials; and
   2. [Tribe] Biospecimens are owned or co-owned by [Tribe] and [Research institution if co-owned] but will remain in the custody of the [research institution or company] consistent with Section 1 (Ownership and Control of Data, Material, and Biospecimens) subject to [Party]’s compliance with the obligations in this Agreement.
5. **Applicable Law and Dispute Resolution**
   1. **Applicable Law**. In the interpretation of this Agreement, this Agreement shall be governed by and construed in accordance with the substantive laws of the [Tribe], and in the absence of applicable [Tribe] law, by applicable Federal law, and in the absence of applicable Federal law then [state] State law.
   2. **Dispute Resolution.** Any dispute arising under this Agreement shall be submitted jointly to the signatories of this Agreement (or his/her/their designee or successor). If the signatories are unable to jointly resolve the dispute with thirty (30) days after notification thereof, the dispute will be referred to the respective senior executive officers of the Parties. Nothing in this Section shall prevent any Party from pursuing any additional administrative remedies that may be available and, after exhaustion of such administrative remedies, pursuing all available judicial remedies. Pending the resolution of any dispute or claim pursuant to this Article, the Parties agree that performance of all obligations shall be pursued diligently to the extent practicable.
   3. **Sovereign Immunity.**  Nothing in this Agreement is intended to be or shall constitute or shall be construed as a waiver, limitation, or modification of the [Tribe’s] sovereign immunity from unconsented suit.
6. **Amendment**. This Agreement may not be amended except by written agreement of the Parties*.* The other party(ies) that Acknowledge(s) this Agreement shall be afforded the opportunity to comment on, question, and offer suggestions about any Amendment.
7. **Term and** **Termination.** Each Party may terminate this Agreement by giving thirty (30) days written notice of termination to the other Parties and to other signer(s) that Acknowledge this Agreement below. After termination, all Parties shall remain bound to maintain the confidentiality of Data, Materials, and Biospecimens generated, received, learned, or obtained in the Research Project or under this Agreement at any time prior to the effective date of termination. [[28]](#footnote-29)
8. **Survivability.** The following Sections will survive the expiration or earlier termination of this Agreement under Section 12 (Terms and Termination): Section 1 (Ownership and Control of Data, Material, and Biospecimens); Section 2 (Non-exclusive License to Data and Materials); Section 3 (Non-exclusive License to Biospecimens); Section 4 (Disclosure of [Tribe] or AI/AN Information from the Research in Publications); Section 5 (Approval by IRB and [Tribe]); Section 6 (Confidentiality) in its entirety; Section 8 (Access to Data and Materials); Section 9 (Recognitions and responsibilities); Section 10 (Applicable Law and Dispute Resolution) in its entirety; Section 11 (Amendment); Section 13 (Survivability); Section 14 (Disclosures); Section 15 (Liability); Section 16 (Indemnification); and Section 17 (Applicable Law).
9. **Disclosures.** Notwithstanding the expiration or early termination of this Agreement,the [Tribe] retains ownership and control over all uses of the Data, Materials, and Biospecimens that are not exempted by the Agreement. Except as provided in this Agreement, the parties shall not disclose or release any Data, Materials, Biospecimens, or information covered under this Agreement, under any circumstance or at any time, without prior approval bythe [Tribe]and by the IRB(s) for this Research Project in accordance with Section 5 (Approval by IRB and [Tribe]) of this Agreement.
10. **Liability.** [outline legal liability for this clinical trial if any, otherwise “N/A”]
11. **Indemnification.** The [research institutions and companies] (each, an “Indemnitor”) shall indemnify, defend, and hold the [Tribe] harmless from and against all third party claims, losses, and expenses arising out of such Indemnitor’s negligence, misconduct, or failure to comply with the terms of this Agreement, except that the [research institutions and companies] shall not be obligated to indemnify, defend, or hold harmless the [Tribe] to the extent such claims, losses, or expenses arise from its own negligence or willful misconduct or the negligence or willful misconduct of the its agents, employees or assigns. Nothing whatsoever in this provision and/or in this Agreement is an express or implied waiver of the[Tribe’s] sovereign immunity, or is for the benefit of any third party. The [Tribe] shall promptly notify the Indemnitor upon becoming aware of any claim, loss, or expense that may be subject to this Section 16 and shall permit the Indemnitor to control the defense and settlement of any claim. Notwithstanding the foregoing, the Indemnitor will not settle a claim in a manner that admits fault or incurs liability on the part of the [Tribe] without its prior written consent.
12. **Applicable Laws.** The Partiesshall comply with all applicable [state] State and Federal laws and regulations, including the Privacy Act, HIPAA, and other laws and regulations protecting privacy, and [Tribe] law.
13. **Entire Agreement.** The terms and provisions of this Agreement and those documents incorporated by reference herein represent the entire understanding of the parties with respect to the subject matter of this Agreement and supersede any prior oral statements, discussions or understandings between the Parties.
14. **Severability.** If any term or condition of this Agreement or the application thereof to any person(s) or circumstances is held invalid, such invalidity shall not affect other terms, conditions, or applications which can be given effect without the invalid term, condition or application. To this end, the terms and conditions of this Agreement are declared severable.
15. **No Waiver.** Waiver of any breach or condition of this Agreement shall not be deemed a waiver of any prior or subsequent breach. No terms or conditions of this Agreement shall be held to be waived, modified or deleted except by an instrument, in writing, signed by the parties hereto.
16. **Points of Contact.** [[29]](#footnote-30) Any notices required by the terms of the Agreement shall be sent via recognized overnight courier or pre-paid certified mail, return receipt requested with a courtesy copy by email, to the appropriate Party’s contact designated below:
    1. List by name, position, & e-mail address ….
    2. List
17. **Representation.** Each Party represents that the individual signing on its behalf below is fully authorized to execute this Agreement on behalf of such Party. Each Party further represents that it is legally authorized to enter into this Agreement, perform the obligations under this Agreement, and make all representations and grants as set forth herein.

By the signatures of their duly authorized representative below,the[Tribe]and [name of all other Parties], intending to be legally bound, agree to all of the provisions of this **Data, Material[, and Biospecimen] Sharing and Ownership Agreement**. This **Agreement** will be in effect upon the latest date of execution. [[30]](#footnote-31)

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name, Tribal Chair Date

*[Tribe]*

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name, PI’s Institution Date

*[Research Institution]*

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name, Tribal IRB

*[Tribal IRB]*

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name, IRB Chair Date

*[Second authorized IRB]*

….

**Principal Investigator – Read and Reviewed:**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name, Principal Investigator Date

*[Research Institution]*

**ATTACHMENT:**

**Confidentiality Agreement:**

[Title of clinical trial/research project]

*Standard Agreement*

People with access to individual or Tribal data or material in the Research Project are responsible for understanding and complying with the rules for the use and disclosure of the information. Your signing of this agreement verifies that you agree to abide by the terms set out in the Data, Material, and Biospecimen Sharing and Ownership Agreement (“Agreement”) signed bythe [parties], and PI regarding the use and disclosure of Research Project data and material.

**1. Confidentiality of Research Project Data, Material, and Biospecimens.**

All data and material obtained by the Research Project are confidential, and are protected by[Tribe], state, and Federal laws and regulations. Research Project data, material, and Biospecimens may be used only for purposes directly described in the DMBSOA. Any personal use of Research Project data, material, and Biospecimens is strictly prohibited. Access to Data, Material, and Biospecimens is limited to personnel whose duties specifically require access to such Data, Material, and Biospecimen in the performance of their assigned duties.

**2. Disclosure of Information.**

Research Project data, material, and Biospecimens may not be disclosed to individuals, agencies, or institutions, and may not be used for any purpose, except as described and permitted in the DMBSOA. Questions related to disclosure are to be directed to the Research Project PI, [names]. Any disclosure of Research Project data, material, Biospecimens or information contrary to the DMBSOA is unauthorized and subject to penalties identified in[Tribe], state, and Federal laws, regulations, and policies. All elements remain in effect even after termination of your involvement or employment related to the Research Project.

*To be signed by all who have access to Research Project data, material, and Biospecimens.*

I have read the DMBSOA and this Confidentiality Agreement, and have a copy of them. I understand my personal obligations under the DMBSOA and this Confidentiality Agreement. I agree and will comply with the DMBSOA and this Confidentiality Agreement.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name (please print & sign) Date:

*Each Project Team member signs+dates a Confidentiality Agreement; the PI maintains all Agreements.*

1. *The original DMBSOA was for a research project, but this sample can also be used for non-research projects, e.g., education, environment, program improvement, public health, quality improvement, etc.* [↑](#footnote-ref-2)
2. *The DMBSOA is a legal agreement between the Tribe and Institution with legal authority over the PI. The PI signs “READ and REVIEWED” to indicate Acknowlegement and Agreement with the DMBSOA.* [↑](#footnote-ref-3)
3. *The “WHEREAS” and “NOW THEREFORE” clauses are written by the Tribe’s Office of Tribal Attorney (OTA) or equivalent. The PI may suggest project-specific content for the clauses.* [↑](#footnote-ref-4)
4. *This NOW THEREFORE clause should give the legal name of each Institutional Party.* [↑](#footnote-ref-5)
5. *This section defines the signatory Parties. The Tribal Nation is named and defined first, followed by the PI’s Institution that has legal authority over the PI (e.g., University), followed by other relevant parties.* [↑](#footnote-ref-6)
6. *This sentence can be omitted if the funder is not involved* as Investigators *in the Project.* [↑](#footnote-ref-7)
7. *Use the terms of the project, often called “Aims” or “Specific Aims” or “Objectives.”* [↑](#footnote-ref-8)
8. *Note: the Specific Aims/Objectives are* ***quoted verbatim****. The verbatim quotations thus accurately and unambiguously define, for both Tribe and researcher, what the project may and must do, and also what it must* ***not*** *do. The Tribal Nation does not authorize or permit any activity beyond those designed to accomplish the Specific Aims/Objectives* ***listed verbatim here****, per the next paragraph.* [↑](#footnote-ref-9)
9. *For ICFs of Clinical Trials whose results will be submitted to regulatory authorities such as the Food and Drug Admistration (FDA), insert here “ICH E6, 21 C.F.R. Part 50.”*  [↑](#footnote-ref-10)
10. *“Publication” was not in the original DMBSOA.* [↑](#footnote-ref-11)
11. *Do not include “Clinical Research Site,” “Clinical Trial,” “CRO, ” and “Sponsor” in most DMBSOAs/DMSOAs.* [↑](#footnote-ref-12)
12. *Include this sentence only if the research is a Clinical Trial and has a Sponsor.* [↑](#footnote-ref-13)
13. *Include this paragraph and six sub-paragraphs) only if project is a Clinical Trial and has a sponsor.* [↑](#footnote-ref-14)
14. *Subparagraph “e)” is both mandatory and a “best practice” in Clinical Trials.* [↑](#footnote-ref-15)
15. *Subparagraph “f)” is both mandatory and a “best practice” in Clinical Trials.* [↑](#footnote-ref-16)
16. *This paragraphs was not in the original DMBSOA for the double-blind vaccine trial. Because most Tribes own and control the data and material obtained from the Tribe, most Tribes have the investigators return the original data and material to the owners (i.e., the Tribe) after the data and material have been anonymized or de-identified. Many projects with Indigenous peoples also offer to return exact copies of an individual’s data and material to the person.*

    *For Projects with Biospecimens, many Tribes authorize the custodian of the Tribe’s Biospecimens (i.e., the laboratory analyzing them) to dispose the biohazardous Biospecimens in a respectful manner. Other Tribes ask the custodian to sterilize the Biospecimens to eliminate the biohazardous danger and then return them to the Tribe for proper Tribal disposition that follow safety precautions.* [↑](#footnote-ref-17)
17. *For projects without Biospecimens, keep as Section “3” so all subsequent Sections have identical numbering in DMBSOAs and DMSOAs. Insert after Section 3’s title “Not applicable to this DMSOA.”*  [↑](#footnote-ref-18)
18. *No entity, colleague, or institution that is not listed here in Section 3 is permitted to have, control, or be involved in research with, the Biospecimens. In the original DMBSOA, the Bospeciment researchers listed here were the Sponsor, UW, and Fred Hutchinson.* [↑](#footnote-ref-19)
19. *The duration should be no lomger than is needed to achieve the Specific Aims/Objectives plus a small time cushion. It should not be a routine period (e.g., “25 years”) for three reasons: (a) seldom does achieving the Specific Aims require longer than three years; (b) if needed, more time can be added by mutual agreement with the Tribe; and (c) the institutional memory about this DMBSOA is likely short.* [↑](#footnote-ref-20)
20. *Some projects offer to return an individual’s sterilized Biospecimens to that individual at conclusion of the research. Due to the biohazardous risks of Biospecimens, however, most projects either ask the holder of the Biospecimens to respectfully dispose of them, or ship all Biospecimens together to the Tribe and received by a Tribal expert in handling Biospecins for respectful disposal by the Tribe.* [↑](#footnote-ref-21)
21. *This version of Section 4 was not in the original DMBSOA, but is the version that most Tribal DMSOA have and Tribes have insisted on for years. This version is most acceptable and appropriate for almost all research. For a detailed explanation, see next Footnote to the alternate version of Section 4.* [↑](#footnote-ref-22)
22. *This version of Section 4, in the original DMBSOA, is not appropriate for almost all research. It purposefully did* ***not*** *contain the usual requirement in DMSOAs that the Tribe must review all draft publications, and either must approve or may require changes in, or may disapprove and thus prohibit publication. The Tribal attorney accepted this non-standard Section 4* ***only for the vaccine trial*** *because the trial collected no data or information that could be demeaning or offensuive or used to stigmatize Tribe[s] or AI/AN people, and also that this section specified and limited the topics of publications acceptable to the Tribe and this DMBSOA. (The Sponsor, NIH, etc. all agreed to that limitation, because the purpose of the research was similarly narrow.) But most research has broader Specific Aims and analyses, and thus potential to be used to demean or stigmatize. This Alternative approach is therefore neither appropriate nor acceptable for most research.* [↑](#footnote-ref-23)
23. *Some question whether the Tribe can speak for all AI/AN. Statements about AI/AN are, by definition, statements about [Tribe]; the Tribe thus can delete incorrect or stigmatizing statements about AI/AN. The PI, moreover, has not been authorized to speak for AI/AN. This Section is thus appropriate.*  [↑](#footnote-ref-24)
24. *Insert “and 21 C.F.R. § 56.113” if this project is a Clinical Trial to be reported to the FDA.* [↑](#footnote-ref-25)
25. ***This Subsection is crtically important,*** *because it complies with the decision by the 8th Circuit Court of Appeals in the case of Washington University vs. William Catalona (Washington University v William J. Catalona, MD, 490 F.3rd 667 [8th Circ. 2007]). That decision held that the terms of the signed ICF, that gives or donates the individual’s data, material, or biospecimens, determine the recipient and terms of the gift or donation. The Informed Consent Form thus should explicitly incorporate the terms of the DMBSOA / DMSOA.* [↑](#footnote-ref-26)
26. *Omit “or Biospecimens” if the Project does not included any Biospecimens.* [↑](#footnote-ref-27)
27. *Omit “Biospecimens” if the Project does not included any Biospecimens.* [↑](#footnote-ref-28)
28. *The original DMBSOA added, “This agreement will expire upon disposal of the Biospecimens collected under this Agreement inaccordance with Section 3.” That is deleted because it is inconsistent with Section 13.* [↑](#footnote-ref-29)
29. *”Points of Contact” are key people with the most responsibilities for making this Project and its DMSOA work. They need to know almost all e-mails themselves for thier own work, and can distribute communications to the appropriate people at the institujtional signatories. Thei screening means that high level signatories are not inundated with multiple e-mails of no relevances to them..* [↑](#footnote-ref-30)
30. *Usually the Tribal Chair is listed first, followed by the authorized signing individuals of the: Principal Investigator’s (PI’s) Insitution. then other Parties. Usually the order of who signs the DMBSOA is in reverse order, starting with the last as first signer and moving up the list.* [↑](#footnote-ref-31)