The University of Washington gratefully acknowledges the wisdom and expertise of Dr. William Freeman and the Institutional Review Board of the Northwest Indian College, located on the lands of the Lummi Nation, who created the original DMBSOA template that forms the basis for these Agreements, and generously shared and authorized its adaptation and broad reuse.

Data, Material, and Biospecimen Sharing and Ownership Agreement
Between
"[Tribal Council]"
And
"The University of Washington on behalf of its Center for Disaster Resilient Communities"
And Read and Reviewed By
"Nicole Errett, Director; and Jamie Donatuto, Director of Tribal Engagement; University of Washington Center for Disaster Resilient Communities; University of Washington Office of Sponsored Programs"

This Data, Material, and Biospecimen Sharing and Ownership Agreement ("Agreement") is entered between the [Tribe] ("Tribe") and the University of Washington ("UW"), individually a Party and collectively the Parties.

I. PARTIES.

The parties above are collaborating in the development, implementation, and dissemination of various projects and priorities to support disaster resilience in the Tribe community. Dr. Nicole Errett is the Director of UW's Center for Disaster Resilient Communities (CDRC); Dr. Jamie Donatuto is CDRC's Director for Tribal Engagement. Together, they lead a team of Investigators who will conduct Projects subject to the terms of this Agreement.

In consideration of Tribe authorizing activities relating to supporting disaster resilience in the Tribe community, [TRIBE], UW agree as follows:

II. 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 Tribes did not include them, thus depriving Tribes of beneficial research.

The purpose of this Agreement is to prevent these historical practices from occurring in Projects

conducted jointly by the Parties. 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 UW. This Agreement describes the use, control, and authorization to share Tribe Data, Material, and Biospecimens related to joint Research Projects to minimize their misuse and to maximize benefits to the Tribe.

III. SPECIFIC AIMS / OBJECTIVES OF THE PROJECTS.

The Tribe shall approve proposed Specific Aims developed for any Research Project subject to the terms of this Agreement prior to formal submission of such Specific Aims or proposal to any funder or agent thereof. Further, the Tribe shall approve any proposed change to the Specific Aims / Objectives of a Project prior to implementation at Tribe. If the Tribe does not approve of such proposed change(s), the Tribe shall notify UW and PI to immediately cease performance of the relevant 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 relevant Project.

IV. DEFINITIONS.

"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 a Research Project.

"Data" means primary source information gathered in the course of a 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 a 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 45 C.F.R. Part 46, and related C.F.R.s. For Clinical Trials whose results will be submitted to regulatory authorities such as the Food and Drug Administration, ICF shall satisfy the requirements of ICH E6, 21 C.F.R. Part 50. For purposes of this Agreement, the Informed Consent Form means the ICF approved by the applicable IRB and Tribe for each Project. 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 a Research Project, such as photographs and recordings, except Biospecimens.

"Principal Investigator" or "PI" means the lead scientist or scholar responsible for the design, execution, and management of the Research Project.

"Protocol" means the formal, detailed, plan and description of a Project at [Tribe]. The Protocol describes the objectives, design, research methods, statistical considerations, and organization of a 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" means various methods of disseminating information about and results from 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 Project" or "Project" means the conduct of any Research Project, as described in the relevant IRB Application Form prepared by the Project's Principal Investigator (PI).

"Project Team" means the PI and other Investigators at [name of Tribe(s)], each site, and each center, who are engaged in and participating collaboratively on a specific Research Project conducted under and pursuant to the terms of this Agreement.

"Clinical Research Site" means the designated clinical research sites where a Clinical Trial will be conducted in strict accordance with a specific 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.

"CRO" means a Contracted Research Organization(s), if any, involved in a Clinical Trial.

"Specific Aims" means a summary of the Research Project goals.

"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 a Research Project, Clinical Trial, or other activity and who provides monetary support to one of the Partners under a Sponsored Project.

"Sponsored Project" means a transaction between a Sponsor and one of the Parties in which the Sponsor supports a specific scope of work carried out by the Party for organized research, instruction, or other sponsored activity in exchange for something of value such as data, results,

intellectual property rights, and/or technical reporting. If a Party is awarded a Sponsored Project, that Party will issue a contract or subaward to the other Party and the Parties will execute a related Scope of Work.

"Scope of Work" means a written agreement where the details and scope of the sharing for each specific Research Project are set out between the parties using the template set out in Exhibit 1. Each Scope of Work incorporates by reference the terms and conditions of this Agreement.

V. TERMS.

1) **Ownership and Control of Data, Material, and Biospecimens.** The 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 any relevant Research Project(s) shall be the property of the Tribe, and are under the control of the Tribe for such uses not needed or related to achieve Specific Aims, but shall remain in the custody of the Sponsor or its contractors or 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. Parties agree that Data, Material, and Biospecimens shall not be shared with third parties other than those defined or identified in the Protocol and approved by the Tribe, 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 the 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, the Tribe agrees that it shall not share (for use or review) any Data with any third party other than the relevant Sponsor(s), its contractors and its designees.

2) **Non-exclusive License to Data and Materials.** In accordance with Section 1 (Ownership and Control of Data, Material, and Biospecimens), the Tribe hereby grants a royalty-free, nonexclusive license to UW and other relevant research entities listed in a Project's Protocol to achieve the Specific Aims of any Research Project subject to this Agreement.

   To achieve those Specific Aims, the royalty-free, non-exclusive license permits UW to:
   a) Submit all Protocol-required Data to the Sponsor, the CRO, or their designee(s);
   b) 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 the relevant Project. Use of the Data and Material for any purpose other than to achieve the Specific Aims of a Research Project is prohibited unless the Tribe has given explicit prior written approval;

c) 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 the relevant Project. Use of the Data and Material for any purpose other than to achieve the Specific Aims of a Research Project is prohibited unless the Tribe has given explicit prior written approval;
d) Allow the Sponsor to provide any information regarding a Clinical Trial, including Data, to governmental organizations both inside and outside the U.S., for all legitimate public health, regulatory, or business purposes provided that such sharing of the Data achieves the Specific Aims of the relevant Project. Use of the Data for any purpose other than to achieve the Specific Aims of a Research Project is prohibited unless the Tribe has given explicit prior written approval;
e) 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); and
f) Subject to Section 4 (Disclosure of Tribe or AI/AN Information from the Research in Publication) of this Agreement, allow the Sponsor, Clinical Research Site, Research Investigators, and any other entities involved in a specific Clinical Trial to make results 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 a relevant Protocol or to achieve anything not listed in relevant 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 any Research Project, the royalty-free non-exclusive license to examine and use the Data and Material from the Tribe and its members also concludes or terminates. All those Data and Material will be returned to the 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 Research participants were promised confidentiality of specific items or components of Data and Materials by the Investigators, then those components of the Data and Materials must be anonymized or de-identified for all participants in the Project before being given to the Tribe.

3) **Non-exclusive License to Biospecimens.** In accordance with Section 1 (Ownership and Control of Data, Material, and Biospecimens), the Tribe hereby grants a royalty-free, nonexclusive license to UW, specifically the CDRC Research Team and any other Parties indicated in the relevant Protocol, to achieve the Specific Aims or Objectives of a Research Project executed under and subject to the terms of this Agreement for a period of three (3) years from the final shipment of Biospecimens from the Tribe / participants to the research entity charged with primary responsibility for maintaining the Biospecimens and conducting

the Biospecimen research. To achieve such Specific Aims, the royalty-free, non-exclusive license permits the CDRC Research Team and other relevant Parties as approved by the Tribe to:

a) Conduct assays and analyses using Biospecimens as described in the Protocol, provided that such conduct is consistent with achieving the Specific Aims of the relevant Research Project. Use of Biospecimens for any purpose other than to achieve the Specific Aims of a Project is prohibited unless the Tribe has given explicit prior written approval;
b) Transfer Biospecimens collected during the conduct of a Project to Project Sponsor, CRO, other Party, or their designee(s), and allow use of the Biospecimens consistent with the relevant Protocol and Informed Consent, provided, that such transfer of Biospecimens achieve the Specific Aims of a relevant Research Project. Use of the Biospecimens for any purpose other than to achieve the Specific Aims of a Research Project is prohibited unless the Tribe has given explicit prior approval; and
c) Transfer Biospecimens to a laboratory to conduct assays and analyses, provided that such transfer of Biospecimens achieve the Specific Aims of a relevant Research Project. Use of the Biospecimens for any purpose other than to achieve the Specific Aims of a Research Project is prohibited unless the Tribe has given explicit prior approval; and
d) 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 the Specific Aims of a Research Project executed under this Agreement 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 the Tribe. If needed, more time can be added by mutual agreement with the Tribe.

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.** Unless waived by Tribe, every distribution, publication, and use will contain a disclaimer that includes the following or similar language: "The views expressed do not necessarily represent the views of [Tribe] or UW."

(a) Development of Publications. Research Projects conducted under this Agreement are "multicenter research projects." The Centers are: the Tribe, UW, and others as approved by the Tribe and detailed in Project Protocols. Projects executed under this Agreement will appoint a "steering and publications committee" with representatives from each research Center. The representatives on the committee from Tribe are chosen by the Tribe. The 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 II. PURPOSE OF AGREEMENT. For those reasons and by exercise of its Inherent Tribal Sovereignty, the Tribe must review, require modification if necessary, and approve or disapprove all publications that contain the Tribe's data prior to any submission, publication, or distribution. The Tribe retains the right to approve, disapprove, or require modifications in use of the 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.

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

5.1 Research. Before any research Data and Materials are collected or human participant/subject research is undertaken with the Tribe, the IRB of the Tribe, and/or any other IRB that the Tribe wants or accepts, and the Tribe itself must review and approve the plans for the relevant Research Project.

5.2 Suspension or Termination. Upon approval by the relevant IRB and the Tribe, the IRB(s) reserve(s) the right to suspend performance of a Research Project by UW 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 Tribal 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 and with 21 C.F.R. § 56.113 if a Project is a Clinical Trial to be reported to the FDA. The Tribe reserves the right to suspend performance of any Research Project by UW or terminate their approval of a Research Project executed under this Agreement.

5.3 Protocol. The Tribe and the relevant IRB shall approve of the Protocol, Informed Consent Form (ICF), and any amendments thereto prior to such alteration, amendment, or document becoming effective. If the Tribe does not approve of such Protocol, ICF, or amendment or alteration, the Tribe shall notify UW, and UW shall immediately cease performance of the relevant 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. Informed Consent Forms 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 Sharing and Ownership Agreement (DMBSOA) with University of Washington (UW), and acknowledged by the Director and Director of Tribal Engagement for the UW Center for Disaster Resilient Communities (CDRC). 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."

5.5. Future use of Data, Materials, and Biospecimens. Even if stated or permitted in any proposed ICF, the Research Team, UW, and all others shall not be permitted to use the Data, Materials, or Biospecimens collected for any Research Project for any future use or purpose other than stated in the Research Project's 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. UW 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) Any other pertinent documents requested by the Tribe, e.g., recruitment documents.

6) **Confidentiality.** The Tribe, UW and CDRC Researchers are responsible for Data, Material, and Biospecimen collection and analysis for Research Projects conducted with the Tribe. The Tribe and UW 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 the 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 the Tribe, the Parties will protect both the personal privacy of individual participants involved in the Research Project, and also the privacy of the Tribe, subject to applicable Tribe, Federal, state, and local laws and regulations.

6.2 Certificate of Confidentiality. The Parties agree that they 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 promptly provide notice as

permissible before production, in order to permit the Tribe to intervene or respond as appropriately. Research Projects executed under this Agreement and funded by the National Institutes of Health may be issued a Certificate of Confidentiality.

6.3 Security. For the duration of the Research Project, the Tribe and UW 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. The Tribe and UW 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.

6.4 Exclusions. Confidential Information excludes any information which UW can establish by competent written proof (a) is or becomes a matter of public knowledge through no fault of UW; (b) was in UW's possession before receipt from the Tribe; (c) was independently developed by UW without use of the Confidential Information; or (d) is received by UW, without restriction as to further disclosure, from a third party having an apparent bona fide right to disclose the information to UW.

7) **Data and Materials.** CDRC Researchers will collect Data and Materials consistent with this DMBSOA as authorized by the IRB(s) for relevant Research Projects to complete any Specific Aim/Objective, reports, and dissemination activities consistent with the terms herein. UW shall analyze any Data and Materials received in connection with a Research Project consistent with the relevant Protocol and this Agreement.

8) **Access to Data and Materials.** Except as specified herein, the 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 a Research Project may 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 UW or its contractor and their employees performing tasks in furtherance of a Research Project 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 of said Research Project, its 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 from the [name of Tribal Council], after proceeding through the review and approval processes of the relevant 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 a specific Research Project for a purpose not explicitly included in the Specific Aims (Objectives) of

said 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 the Tribe, after proceeding through the review and approval processes of the relevant IRB(s) for said Research Project and the Tribe's review and approval processes.

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

A. recognize and accept responsibility to ensure appropriate conduct by their respective employees, investigators, faculty, and agents, that is consistent with the terms of this Agreement; and
B. 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
C. recognize the inherent sovereignty of the Tribe and consent to its jurisdiction as it relates to this Agreement, any Research Project executed under this Agreement, and accompanying Protocol; and
D. acknowledge that co-housing Data, Materials, and Biospecimens is predicated upon the Tribe and UW's acknowledgement that:
    a. the Tribe maintains control over the use of, and is sole owner of, Tribe-specific Data and Materials; and
    b. Tribe Biospecimens are owned by the Tribe or co-owned (if applicable) by the Tribe and UW, but will remain in the custody of the UW consistent with Section 1 (Ownership and Control of Data, Material, and Biospecimens) subject to the Tribe and UW's compliance with the obligations in this Agreement.

10) **Applicable Law and Dispute Resolution**

a. **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 Tribal law, by applicable Washington State law, and in the absence of applicable Washington State law then Federal law.

b. **Dispute Resolution.** Any dispute arising under this Agreement shall be submitted jointly to authorized representatives of this Agreement (or his/her/their designee or successor). If the authorized representatives 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.

c. **Tribe 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.

d. **UW Sovereign Immunity.** Nothing in this Agreement is intended to be or shall constitute or shall be construed as a waiver, limitation, or modification of UW's sovereign immunity from unconsented suit.

11) **Amendment.** This Agreement may not be amended except by written agreement of the Parties. Any other Party(ies) that Acknowledge(s) this Agreement shall be afforded the opportunity to comment on, question, and offer suggestions about any Amendment.

12) **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 any Research Project or under this Agreement at any time prior to the effective date of termination.

13) **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).

14) **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 by the Tribe and by the relevant IRB(s) for any Research Project executed under this Agreement in accordance with Section 5 (Approval by IRB and Tribe) of this Agreement.

15) **Liability.** N/A.

16) **Indemnification.** To the extent permitted by law, including in the case of UW, RCW 28B.20.250 et seq., UW (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 UW shall not be obligated to indemnify, defend, or hold harmless the Tribe to the extent such claims, losses, or expenses arise from the Tribe's 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 either Party'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.

17) **Applicable Laws.** The Parties shall comply with all applicable Washington State and Federal laws and regulations, including the Privacy Act, HIPAA, and other laws and regulations protecting privacy, and Tribal law.

18) **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.

19) **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.

20) **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.

21) **Points of Contact.** 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:
    a. List by name, position, & e-mail address [List Tribal contact first]
    b. Amanda Snyder; Director, Office of Sponsored Programs; osp@uw.edu

22) **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, [Tribe] and UW, 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.

Name, Tribal Chair — Date
[Tribe]

Macie Owens, Senior Contract Specialist, Office of Sponsored Programs — Date
University of Washington

Name, Tribal IRB — Date
[Tribal IRB]

Name, IRB Chair — Date
[Second authorized IRB]
….

Principal Investigator – Read and Reviewed:

Nicole Errett, Director, UW CDRC — Date
University of Washington

Jamie Donatuto, Director for Tribal Engagement, UW CDRC — Date
University of Washington

ATTACHMENT A:
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 by the Tribe, UW, 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 the Tribe, Washington 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, Washington 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.

EXHIBIT 1:
Scope of Work

Effective Date: Date of last signature

End Date:

Tribe:

UW Principal Investigator:

UW eGC1/NAA:

Project Title:

Related Funding Sponsor:

Related Grant/Contract Number:

Data Description: *(if none, enter "none")*

Material Description: *(if none, enter "none")*

Biospecimen Description: *(if none, enter "none")*

Additional Terms:

Scope of Work: