**MEMORANDUM OF UNDERSTANDING AND**

**DATA USE AGREEMENT**

**THIS MEMORANDUM OF UNDERSTANDING AND DATA USE AGREEMENT** (“**Agreement**”) is entered into as of [Date] (“**Effective Date**”), by and between the [Tribe], a federally recognized Indian Tribe located at [Address] (the “**Tribe**”), and [Cancer Center/University], a [State of formation] [Entity type] located at [Address] (“**Research Partner**”).

**RECITALS**

**WHEREAS**, the Tribe is a federally recognized Indian Tribe located on the [Territory] in [Region] (the “**Territory**”); and

**WHEREAS**, Research Partner is a [insert description]; and

**WHEREAS**, Research Partner operates multiple specialized centers of research supported by clinical resources including its [Add Center or Department]; and

**WHEREAS**, the Tribe and Research Partner believe it would be mutually beneficial to partner with one another to jointly develop certain tribal community health profiles and other health related data compilation and use projects, with the potential long term benefit of facilitating the Tribe’s ability to enhance the health, safety, and welfare of community members in health care and disease management matters; and

**WHEREAS**, in furtherance of the partnership between the parties, the Tribe and Research Partner desire to set forth the terms and conditions under which the Tribe will share, and Research Partner will use, the Tribe’s Data (hereinafter defined), which may include demographic information, socio-economic information, medical information, health care information, and other health and community related data, for the purpose of the Project (hereinafter defined) and as further agreed to and described herein; and

**WHEREAS**, the Tribe has granted the Research Partner permission to conduct [Project Description] (the “**Project**”), as further described in the Project Scope and Parameters attached hereto and incorporated herein as Exhibit A, and a copy of the Tribe’s authorization for the Project is attached hereto and incorporated herein as Exhibit B; and

**WHEREAS**, Research Partner has developed a study protocol governing the Project, a copy of which is attached hereto and incorporated herein as Exhibit C (the “**Study Protocol**”), which has been approved by an institutional review board (“**IRB**”) with jurisdiction and standing; and

**WHEREAS**, the purpose of this Agreement is to define the responsibilities and expectations of the Tribe and Research Partner with respect to Tribe’s sharing, and Research Partner’s use, of the Data for the Project.

**NOW, THEREFORE**,in consideration of the foregoing recitals and the mutual promises herein made and exchanged, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties agree as follows:

1. **Guiding Principles.** All activities under this Agreement will be performed consistent with the following overarching principles:
	1. The Tribe’s responsibilities to its community include planning, providing for, and protecting the health, safety, and welfare of its members. In connection with these sacred responsibilities, the Tribe has an obligation to ensure that access to and use of the Data is controlled in a manner that is respectful to its cultural values, community priorities, and tribal sovereignty.
	2. Research Partner recognizes and respects the paramount interests of the Tribe with respect to its Data, its members, and its community. Research Partner commits to a transparent process that ensures respect of, and the protections and security for, this vital and sensitive Data.
	3. Should a question arise about use or disclosure of the Data not specifically provided for under this Agreement, the parties recognize and agree that such use or disclosure shall not occur in the absence of a written agreement signed by both parties expressly identifying and authorizing such use or disclosure. The parties further commit to working with one another to quickly resolve such questions.
	4. Open lines of communication throughout the Term (hereinafter defined) are paramount to ensuring that the rights, interests, and expectation of the parties are being protected and met. To this end, the parties commit to periodic meetings, no less than monthly, so that Research Partner can update the Tribe on the status of the Project and the parties can timely address any issues or concerns that may have arisen.
2. **Project Purpose and Scope.**
	1. Project Purpose: The Tribe and Research Partner are collaborating to plan, develop, and implement a research study about health outcomes and future benefits for the Tribal community. This Agreement applies solely to the Project described in Exhibit A. Each of the parties agree to work jointly towards developing the scope and parameters of the Project to be incorporated into Exhibit A and are subject to the terms of this Agreement. For the avoidance of doubt, the parties agree that no data sharing or Project development will begin unless and until there a Project Scope and Parameters duly executed by both parties to be attached and incorporated into this Agreement as Exhibit A. In the event of any conflict or inconsistency between the Project Scope and Parameters and the remaining terms of this Agreement, the Project Scope and Parameters shall control; provided, however, that any ambiguity in this Agreement shall be resolved in favor of a meaning that complies and is consistent with applicable law protecting the privacy, security, and confidentiality of the Data.
	2. Project Scope: The Project shall be conducted in accordance with the terms of this Agreement (including, for avoidance of doubt, the Project Scope and Parameters and the Study Protocol) and appliable: (i) Research Partner research policies and procedures; (ii) professional standards; (iii) federal and state laws, rules, and regulations, including but not limited to those governing the privacy and security of health information; and (iv) Tribal law.
	3. Definitions.
		1. “**Data**” shall mean any and all information gathered, captured, or generated by the Tribe, Tribal members, or Tribal community sources and provided to Research Partner for the Project, including summaries, reports, and field notes. Data may include PHI (hereinafter defined) in the form of Limited Data Set(s) (hereinafter defined). Data shall not include the Tribe’s cultural traditions, customs, history, and/or stories and shall not be collected or recorded during the Term/for the Project. In the event any such information is inadvertently recorded and disclosed to or otherwise obtained in any way, Research Partner agrees to promptly deliver the information to the Tribe and permanently delete any remaining related records in its possession, whether in physical form, electronic form, or otherwise.
		2. “**HIPAA**” shall mean the United States Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, and the regulations promulgated thereunder at 45 C.F.R. Parts 160 and 164, as the same may be amended from time to time.
		3. “**Individually Identifiable Health Information**” shall have the meaning given to that term by HIPAA at 45 C.F.R. § 160.103 or any successor regulation thereto.
		4. “**Invention**” shall mean any and all inventions, improvements, developments, intellectual property, discoveries, patents, trademarks, copyrights, and innovations, whether or not patentable, that arise from the performance of the Project.
		5. “**Limited Data Set**” shall mean PHI that excludes the certain direct identifiers in accordance with HIPAA and is transferred to Research Partner by or on behalf of Tribe under this Agreement. Limited Data Set(s) used or disclosed under this Agreement shall meet the requirements described in 45 C.F.R. § 164.514(e) or any successor regulation thereto.
		6. “**Minimum Researcher Qualifications**”, regardless of the title of such person engaged by the Research Partner to work on the Project, shall mean such person: (i) has undergone a criminal background check, the results of which were satisfactory to and in the sole discretion of the Tribal Representative; (ii) has executed a confidentiality and non-disclosure agreement in a form satisfactory to and in the sole discretion of the Tribal Representative; and (iii) meets any additional minimum requirements for researchers identified in the exhibits hereto.
		7. “**Privacy Standards**” shall mean the Standards for Privacy of Individually Identifiable Health Information as set forth at 45 C.F.R. Parts 160 and 164.
		8. “**Protected Health Information**” or “**PHI**” shall have the meaning given to that term by HIPAA at 45 C.F.R. § 160.103 or any successor regulation thereto.
		9. “**Research Partner Invention**” shall mean any Invention that is conceived or reduced to practice by Research Partner Personnel (hereinafter defined).
		10. “**Research Partner Personnel**” shall mean Research Partner’s faculty, employees, fellows, students, agents, and permitted subcontractors who participate in the Project.
		11. “**Tribal Council**” shall mean the governing body of the Tribe responsible for administering Tribal laws within its jurisdiction.
		12. “**Tribal Representative**” shall mean the official designee of the Tribe with documented authority to make a given determination on the Tribe’s behalf. If other than the Tribal Council, the Tribe shall provide Research Partner with a copy of such law, resolution, designation, appointment, or other Tribal action (the “**Designation**”) granting the identified body or individual the authority to act on behalf of the Tribe upon the Effective Date, and the Tribe agrees that Research Partner may rely upon such Designation until notified by the Tribe of its expiration, amendment, or termination.
3. **Creation and Disclosure of Limited Data Set.** Prior to the commencement of the Project, the Tribe (or Tribal Representative) and the Research Partner will establish the process and protocols that will allow Research Partner to use the Data. This process will result in the creation and mutual acceptance of the Project Scope and Parameters and will detail, if applicable, the process for Research Partner to create a Limited Data Set from Tribe’s PHI for inclusion in the Data used for the Project.
4. **Obligations of Research Partner.**
	1. Project Management. The Research Partner shall be specifically responsible for the following in connection with the Project:
		1. Preparing, compiling, and delivering the Project.
		2. Ensuring that the Project is reasonably acceptable to the Tribe.
		3. Coordinating on-Territory activities with the Tribal Representative.
		4. Providing periodic updates on the Project to the Tribal Council and the Tribal Representative.
		5. Considering, in good faith, incorporating written comments from the Tribe (if any) and other sources into the Project or any publication based upon the Data.
		6. Reasonably cooperating with Tribe’s reasonable requests to facilitate maintenance of its relationship with its grantors and ensuring compliance with all applicable grant requirements applicable to the Data.
	2. Data Use Conditions. As a condition of receiving access to the Data and its use in creating a Limited Data Set for purposes of carrying out the Project, Research Partner shall comply with all applicable federal, state, and Tribal privacy and security laws, including HIPAA. Research Partner further shall:
5. Not use or disclose the Data except as necessary to fulfill the purposes of this Agreement and the Project unless otherwise required by law.
6. Not to use or further disclose the Data in a manner that would violate the Privacy Standards if done by the Tribe.
7. Use appropriate safeguards to prevent use or disclosure of the Data other than as provided for by this Agreement.
8. Report to the Tribe any use or disclosure of the Data not provided for by this Agreement of which Research Partner becomes aware.
9. Ensure that any agents, including a subcontractor, to whom it provides the Data agrees to the same restrictions and conditions that apply to the Research Partner with respect to such information prior to any use of the Data.
10. Ensure that any researcher employed or contracted to assist in the Project meets the Minimum Research Qualifications; and
11. Not identify the individuals who are the participants of the Data or contact such individuals.
12. **Obligations of the Tribe.**

5.1 Project Facilitation.The Tribe shall:

1. Provide qualified staff assistance to assist Research Partner Personnel in the analysis of collected Data and the preparation of Project materials.
2. Assist with the dissemination of the final report to the Tribal community, in accordance with Section 7.6 herein.
3. Review and agree to any and all draft reports and conference handouts that the Research Partner desires to present, to ensure accuracy of the Data, materials, and descriptions of the Tribe and its members within the Project**.**

5.2 Grant Facilitation. The Tribe agrees to work with Research Partner to provide such information and support as may be necessary to obtain or preserve any grant funding necessary to support the Project, consistent with the priorities of the Tribe.

1. **Data Management, Sharing and Ownership.** The Tribe and the Research Partner agree to the following binding guidelines for data management, sharing, and ownership:
	1. Data Ownership. The Tribe shall maintain sole ownership, and all rights of control over the Data.
	2. Data Access. Any entity other than Research Partner (or its funding source) or the Tribewho wishes to access, view, or use the Data must formally request in writing and be granted express permission by the Tribal Council or their designee.
	3. Data Protection. If agreed to in Exhibit A, Research Partner may be responsible for data collection and analysis. In such cases, Research Partner shall be responsible for keeping all Data containing Individually Identifiable Information and their sources confidential. By signing this Agreement, Research Partner recognizes and accepts responsibility for the acts and omission of the Research Partner’s Personnel in connection with use of the Data.
	4. Data Storage. For the duration of the Project, Research Partner will house all physical and electronic Data consistent with the requirements of the Study Protocol. After termination of the Project and upon completion of any additional time allotted by the Tribal Council to fulfill Project-approved publication or dissemination activities, all Data retained by Research Partner must be provided to the Tribe or destroyed at the Tribe’s express written direction in accordance with the terms of this Agreement.
	5. Data Use. The parties agree to establish a dissemination plan to utilize and disseminate the Data to Research Partner’s various departments, academic audiences, and the Tribal community. No Project results will be disseminated outside of Research Partner without approval by the Tribal Council or the authorized Tribal Representative. Any secondary research or analysis or follow-up process that could be conducted using the Data must be approved by the Tribal Council or their designee prior to the start of such secondary research or analysis.
	6. Reporting Requirements. Upon completion of the Project, Research Partner will provide the Tribe with a community-specific report and an aggregate report that includes findings from the Project.
2. **Publication and Inventions.**
	1. Research Partner is encouraged to make public the results of the Project. Research Partner is hereby granted a royalty free, nonexclusive right to use the Data to develop and publish reports or other academic publications for educational and research purposes in furtherance of the aims of the Project, provided that the confidentiality of all Individually Identifiable Information is maintained at all times and prior approval is first obtained from the Tribal Council or designee prior to publication.
	2. Research Partner’s representatives and the personnel of the participating Tribal government shall reasonably collaborate with each other with respect to publication or other dissemination of information concerning the Project. Research Partner and the Tribe shall jointly author such publications and other dissemination of information, provided that the Tribe may waive its joint authorship rights.
	3. Research Partner may permit graduate students to participate in the Project if preapproved in writing by the Tribe. Such graduate students may use the Data for use in their thesis or dissertations; provided, however, that the students, through Research Partner, shall negotiate with the participating tribal government(s) to define the scope of the research and the nature of the information that can be published in any thesis or dissertations. These negotiations shall result in a written agreement between the graduate student (through Research Partner) and the participating tribal government(s) to specify as precisely as possible the nature of the graduate student's research topic and the information that will be published in the resultant thesis and dissertation.
	4. Research Partner shall promptly notify Tribe of any Research Partner Inventions, whether deemed patentable or not. Inventorship shall be determined in accordance with United States patient law (if patentable) or by mutual agreement between the parties (if not patentable), considering the role and contributions of individuals involved in the performance of the Project.
	5. In the case of a joint Invention, Research Partner and the Tribe agree to negotiate a joint invention agreement that shall provide, *inter alia*, for the sharing of patent costs, income, and invention management responsibilities.
3. **Standards; Indemnities and Related Compensation for Possible Damages.**
	1. The Project shall be developed in accordance with an established work plan and Project schedule as described in the Study Protocol.
	2. Research Partner represents that the services performed by Research Partner Personnel will be of a high quality and performed in a professional manner in accordance with industry standards and practice, and in compliance with all relevant federal, state, and local laws and regulations, as well as applicable Tribal law.
	3. Research Partner represents that any and all work related to the Project, and all other material(s) resulting from the services performed by Research Partner Personnel, if not expressly licensed to Research Partner or reprinted with permission, shall be its original work, to be developed by the Research Partner, and shall not infringe upon or misappropriate any third party’s copyrights, patents, trade secrets or other intellectual property rights or the terms of any license or contract applicable to Research Partner.
	4. Research Partner shall, to the extent allowed by law, indemnify, defend, and hold the Tribe harmless for all losses, damages, claims, actions, and costs (including attorneys’ fees) caused by the gross negligence or the willful misconduct of Research Partner Personnel in connection with the Project.
4. **Human Subjects.** Any research involving a “human subject”, as the term is defined under 45 C.F.R. Part 46, or a community participant, shall be conducted in accordance with the requirements of the same section, commonly referred to as the revised “Common Rule”. For the avoidance of doubt, additional regulations may apply to human subject research (*e.g*. regulations of the United States Food and Drug Administration and HIPAA), and all will be followed by both Parties to the extent applicable.
5. **Confidential Information.** In addition to the Data, Research Partner and theTribe may choose, from time to time, in connection with work contemplated under this Agreement, to disclose confidential information to each other (“**Confidential Information**”), which shall be information marked as “confidential” or of the nature that a reasonable person knowledgeable in the field would recognize it to be confidential or proprietary. The parties will use reasonable efforts to prevent the disclosure to unauthorized third parties of any Confidential Information of the other Party and will use such information only for the purposes of this Agreement, and for five (5) years after the termination of this Agreement; provided that the receiving Party's obligations hereunder shall not apply to information that:
6. Is already in the receiving Party’s possession at the time of disclosure; or
7. Is or later becomes part of the public domain through no fault of the receiving Party; or
8. Is received from a third party with no duty of confidentiality to the disclosing party; or
9. Was developed independently by the receiving party prior to disclosure; or,
10. Is required to be disclosed by law or regulation.

It is understood by Tribe and Research Partner that the exceptions a., b., c., and d. above do not apply to identifiable medical and/or personal information developed or acquired during the performance of this Agreement. It is also understood by Tribe and Research Partner that the exceptions a., b., c., and d. above do not apply to cultural information identified by the Tribe as confidential cultural property and information.

Given the resources exhausted to develop this document and establish the collaborative methodologies and data sharing processes herein, and notwithstanding anything to the contrary, the parties recognize that the form and content of this Agreement is the proprietary to Roswell Park Cancer Institute Corporation d/b/a Roswell Park Comprehensive Cancer Center (“**Roswell Park**”). Tribe and Research Partner may not, and may not permit others to, duplicate, share with any third party, or commercially exploit the form or content of this Agreement without Roswell Park’s prior written consent. Roswell Park is committed to working with Native Nations and using this form agreement as an educational tool for Native Nations and research institutions, however Roswell Park must be afforded recognition for authorship at all times.

* 1. **Grant Application.** The parties acknowledge that future funding for the Tribe may be sought through grants/other organizations using reports and Data from the Project. Each party shall use its reasonable best efforts to review, comment on, and assist in the preparation of any grant application concerning the Project, secondary analyses thereto, or additional activities to the mutual benefit of Research Partner and the Tribe.

# Term; Termination.

* + 1. The term of this Agreement shall commence on the Effective Date and shall expire three (3) years after completion of the Project, unless sooner terminated as provided for in Section 11.2 (the “**Term**”).
		2. This Agreement may be terminated by either party at any time before its expiration without cause and without penalty upon ninety (90) business days’ written notice to the other party.
		3. To the extent medically feasible, upon receipt of notice of termination from Tribe, the Research Partner shall cease all research activities within the Tribe’s Territory unless further authorized by the Tribe. Additionally, Research Partner shall promptly, in Tribe’s sole discretion, either return or destroy the Data received hereunder. Notwithstanding the foregoing, to the extent that the Tribe agrees that it is not feasible for Research Partner to return or destroy the Data, Research Partner shall continue to extend the protections of this Agreement to such Data and limit further use and disclosure of such Data to those purposes that make the return or destruction of such Data infeasible.
		4. Nothing herein shall be construed as a release of either party from any obligation that matured prior to the termination or expiration of this Agreement. Any provisions that remain to be performed, or by their nature are intended to be applicable, following any expiration or termination of this Agreement, shall remain in full force and effect after such expiration/termination.
	1. **No Joint Venture.** This Agreement shall not be interpreted or construed to independently create an association, joint venture, or partnership between the parties or to impose any partnership obligation or liability upon any party. No party shall have any right, power, or authority to enter into any agreement or undertaking for, or act on behalf of, or to act as or be an agent of representative of, or to otherwise bind, any other party.
	2. **Insurance.** Throughout the Term, Research Partner shall maintain a commercial insurance policy or program of self-insurance at commercially reasonable levels for the activities in which it is engaged pursuant to this Agreement.
	3. **Dispute Resolution.**
		1. In the event a dispute arises from or relates to this Agreement and the parties are unable to reasonably settle the dispute through good faith discussions, the dispute shall be referred to a mutually agreeable mediator within thirty (30) business days of a written request for non-binding mediation submitted by either party. The parties will share the costs of mediation equally.
		2. As a sovereign and federally recognized Indian tribe, the Tribe enjoys and exercises its sovereignty in a manner consistent with its tribal priorities. As an extension of this sovereignty, as recognized by applicable law, the Tribe also enjoys sovereign immunity from unconsented lawsuits against it. The Tribe and Research Partner both agree that nothing in this Agreement shall be construed as a waiver of sovereign immunity by the Tribe, whether express or implied, in whole or in part, nor as a consent by the Tribe to the jurisdiction of any federal or state court.
	4. **Entire Agreement; Counterparts.** This Agreement, including all exhibits attached hereto and incorporated herein, constitutes the entire agreement of the parties regarding the subject matter described in this Agreement, and all other promises, representations, understandings, arrangements, and prior agreements, written or oral, are merged into and superseded by this Agreement.
	5. **Modification.** This Agreement may only be modified by a written agreement of the parties signed by an authorized representative of each party. Notwithstanding the foregoing, the parties agree that amendment of this Agreement may be required to ensure the parties are complying with changes in state and federal laws and regulations relating to the privacy, security, and confidentiality of PHI or the Data. In the event of such a change in law or regulation that requires an amendment to this Agreement to ensure the parties’ ongoing compliance with such law or regulation, neither party may unreasonably withhold its execution of the amendment when reasonably necessary for either party to abide by applicable law.
	6. **Notices.** Any notice or other communication required or permitted under this Agreement shall be in writing, specifically refer to this Agreement, and shall be deemed effective upon receipt. The notice or communication shall be sent through regular mail, return receipt requested and postage prepaid, to the parties at the following addresses:

Research Partner: [Address(es)]

Tribe: [Address(es)]

* 1. **Third Parties.** Nothing in this Agreement, express or implied, is intended to nor shall be construed to confer upon any person, firm, or corporation other than the parties to this Agreement, any remedy or claim under or by reason of this Agreement as third-party beneficiaries or otherwise. The terms and conditions of this Agreement are for the sole and exclusive benefit of the parties to this Agreement.
	2. **Assignment; Subcontract.** Neither party shall assign its interest in or delegate the performance of its obligations under this Agreement to any other person or entity without the prior written permission of the other party. Research Partner may subcontract responsibilities under this Agreement to another person or entity with the express written consent of Tribe, provided that such subcontractor(s) agree to be bound by the terms of this Agreement.
	3. **Remedies.** Except as otherwise provided for herein, no remedy conferred by any of the specific provisions of the Agreement or available to a party is intended to be exclusive of any other remedy, and each and every remedy shall be cumulative and shall be in addition to every other remedy given hereunder, now or hereafter existing at law or in equity or by statute or otherwise. The election of any one or more remedies by a party shall not constitute a waiver of the right to pursue other available remedies.
	4. **Force Majeure.** Notwithstanding any other provision of this Agreement, no party to this Agreement shall be deemed in default or breach of this Agreement or liable for any loss or damages or for any delay or failure in performance due to any cause beyond its reasonable control.
	5. **Waiver of Breach; Severability.** The waiver by any party of any breach by any other party of any provision of this Agreement shall not operate or be construed as a waiver of any subsequent breach by the nonbreaching party or parties. In the event any provision of this Agreement shall be found invalid, illegal, or unenforceable, the validity, legality, and enforceability of the remaining provisions shall not in any way be affected or impaired.
	6. **Headings.** The headings preceding the text of each section of this Agreement are for convenience only and shall not be construed to define, modify, expand, limit, or otherwise interpret the substance of this Agreement.
	7. **Publicity.** Unless otherwise required by law, neither party shall use the name, brand, logo, or trademarks of the other party in any form or adaptation thereof in any advertising, promotion, sales literature, or otherwise hold itself out as affiliated with the other party, without the prior written approval of the other party.
	8. **Execution.** This Agreement may be executed in any number of counterparts, each of which shall be deemed to be an original, and all of which together shall constitute one and the same agreement. A facsimile, PDF, or other electronic signature shall create a valid and binding obligation of the party executing (or on whose behalf such signature is executed) and shall be deemed an original signature for all purposes under this Agreement.

**IN WITNESS WHEREOF**, the parties hereto have executed this Agreement as of the Effective Date.

**[TRIBE]**

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

By: [name], [title]

**[RESEARCH PARTNER]**

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

By: [name], [title]

**EXHIBIT A**

**PROJECT SCOPE AND PARAMETERS**

[ATTACHED SEPARATELY]

*Project Scope and Parameters must:*

1. *Bear signatures of Tribe and Research Partner.*
2. *Provide sufficient information such that each party understands the information to be transferred under this Agreement (e.g. number of participants and/or experiments included, the name of the study the data was obtained under, and if there is a particular study that needs to be acknowledged/cited as the source of the data).*
3. *Provide sufficient information such that each party understand the project that Research Partner will perform using the Data (e.g. objective or purpose of the work, a general description of the actions to be performed by Research Partner using the Data and possibly the anticipated results, and whether or not Research Partner is permitted to link the Data with other data).*

**EXHIBIT B**

**TRIBAL RESOLUTION AUTHORIZING PROJECT**

[ATTACHED SEPARATELY]

**EXHIBIT C**

**STUDY PROTOCOL**

[ATTACHED SEPARATELY]