RESEARCH INVESTIGATOR AGREEMENT

This Agreement, made and entered into this ____ day of _____, 20____, by and between the Chickasaw Nation Department of Health , a division of the Chickasaw Nation, a federally recognized sovereign Indian nation, hereinafter referred to as the "Nation," of P.O. Box 1548 , Ada, OK 74821, and [Insert name of Institutional Investigator] of [Insert Address of Institutional Investigator], herein referred to as the "Institutional Investigator", on behalf of [Insert name of Principal Investigator], hereinafter referred to as the "Principal Investigator" , [Insert where affiliated and address], the Institutional Investigator and Primary Investigator, herein referred to collectively as the "Investigators". .

WHEREAS, THE NATION wishes to enter into an Agreement with the Investigator to conduct research that will be beneficial to the health and welfare of the Nation and its citizens.

WHEREAS, the performance of such research is of mutual interest to the Nation and Investigator and is consistent with the organizational purpose and research objectives of the Investigator.

NOW, THEREFORE and in consideration of the mutual covenants, promises, agreements, understandings and conditions herein contained, the parties hereto mutually promise, to the other, agree and understand as follows, to-wit:

1. TERM OF AGREEMENT: This Agreement shall commence on [insert beginning date] and shall terminate on [insert ending date], subject to the annual review of the Agreement by the Nation's Institutional Review Board (CNDH IRB). Either party may terminate this Agreement with thirty (30) days written notice to the other party. The commencement date shall occur after approval of the Research by the CNDH IRB.

2. DESIGNATED ADMINISTRATOR: The Chair of the Nation's Institutional Review Board (or delegate), is the "Designated Administrator" of this Agreement, and shall oversee the Agreement throughout its term. All requests, issues, and/or concerns including, but not limited to, dispute resolution shall be directed to the Designated Administrator for action.

3. AUTHORIZATION FOR RESEARCH: The Agreement is further subject to any necessary authorization and/or approval by the Institutional Investigator's Institutional Review Board (IRB).

4. SCOPE OF WORK: [Name of PI] , shall be the Principal Investigator through the Institutional Investigator and shall perform and conduct the research protocol. The Principal Investigator shall be responsible for the performance of the research as outlined in the research protocol submitted

by the Principal Investigator (hereinafter referred to as "Research"), which is attached as Appendix 1 and incorporated herein by reference.

Notwithstanding the above, the Principal Investigator further agrees to comply with the following:

a) conduct the study in accordance with the Nation's policies as set forth in the Nation's Policy and Procedure Manual which includes, but is not limited to, ADM 1400 entitled "CNDH Participation in Research", ADM 1401 entitled "Patient Rights Pertaining to Research", ADM 1410 entitled CNDH Institutional Review Board" and ADM 1411 entitled "Release and Dissemination of Research Results and Findings," copies of which are attached and incorporated by reference into this Agreement;

b) conduct Research in accordance with the research protocol and will only make changes in the Research after notifying the CNDH IRB.

c) personally conduct or supervise the described Research;

d) if applicable, inform patients, or any persons used in control groups, of any drugs that are being used for investigational purposes and comply with the requirements relating to obtaining informed consent of such patients or persons;

e) if applicable, assess the ability to read and understand the information in the Investigator's protocol, which is attached as Appendix 1 and incorporated herein by reference, including the potential risks and side effects of the drugs, if any, used in the Research;

f) report to the CNDH IRB within 48 hours (or as described in the Investigator's protocol) any adverse experiences that occur in the course of the Research;

g) maintain adequate and accurate records and make such records available for inspection upon reasonable request;

h) require that the CNDH and Investigator's IRB will be responsible for the initial and continuing review and approval of the Research;

i) promptly report to the CNDH IRB all changes in the Research activities and problems involving risks to human subjects or others;

j) not make any changes in the Research without Investigator's IRB and CNDH IRB approval, except where necessary to eliminate apparent immediate hazards to human subjects;

k) comply with all other requirements regarding the obligations of investigators for human subjects research and all other pertinent requirements as determined and provided in writing to Investigator by the Nation; and

l) immediately notify all associates, colleagues, and employees assisting in the conduct of the Research of their obligations in meeting the above commitments, and that such individuals are informed of any changes.

m) The above-named Individual Investigator has reviewed: 1) The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research (or other internationally recognized equivalent; see section B.1. of the Terms of the Federalwide Assurance (FWA) for International (Non-U.S.) Institutions); 2) the U.S. Department of Health and Human Services (HHS) regulations for the protection of human subjects at 45 CFR part 46 (or other procedural standards; see section B.3. of the Terms of the FWA for International (Non-U.S.) Institutions); 3) the FWA and applicable Terms of the FWA for the institution referenced above (CNDH?); and 4) the relevant institutional policies and procedures for the protection of human subjects.

n) The Investigator understands and hereby accepts the responsibility to comply with the standards and requirements stipulated in the above documents and to protect the rights and welfare of human subjects involved in research conducted under this Agreement.

o) The Investigator will comply with all other applicable federal, international, state, and local laws, regulations, and policies that may provide additional protection for human subjects participating in research conducted under this agreement.

p) The Investigator will abide by all determinations of the Institutional Review Board (IRB) designated under the above FWA and will accept the final authority and decisions of the CNDH IRB, including but not limited to directives to terminate participation in designated research activities.

q) The Investigator will complete any educational training required by the Institution and/or the CNDH IRB prior to initiating research covered under this Agreement.

r) The Investigator will report immediately to the IRBs of both institutions any unanticipated problems involving risks to subjects or others in research covered under this Agreement.

s) The Investigator, when responsible for enrolling subjects, will obtain, document, and maintain records of informed consent for

each such subject or each subject's legally authorized representative as required under HHS regulations at 45 CFR part 46 (or any other international or national procedural standards selected on the FWA for the institution referenced above) and stipulated by the IRB.

t) The Investigator acknowledges and agrees to cooperate in the CNDH IRB's responsibility for initial and continuing review, record keeping, reporting, and certification for the research referenced above. The Investigator will provide all information requested by the CNDH IRB in a timely fashion.

u) The Investigator will not enroll subjects in research under this Agreement prior to its review and approval by the CNDH IRB.

v) Emergency medical care may be delivered without IRB review and approval to the extent permitted under applicable federal regulations and applicable tribal/state law.

w) This Agreement does not preclude the Investigator from taking part in research not covered by this Agreement.

x) The Investigator acknowledges that he/she is primarily responsible for safeguarding the rights and welfare of each research subject, and that the subject's rights and welfare must take precedence over the goals and requirements of the research.

5. ASSIGNMENT: The Investigator shall not assign or transfer any interest in this Agreement or assign any claims due or to become due under this Agreement.

6. CONFLICT OF INTEREST: The Institutional Investigator represents that neither it nor the Principal Investigator [Name of PI] presently has any interest and shall not acquire any interest, direct, or indirect, which would conflict in any manner with the performance of services required under this Agreement. Institutional Investigator and Principal Investigator hereby agree upon execution of this Agreement that each shall disclose to the Nation any and all third party or other contractual relationships that each may individually or jointly be engaged in that may in any way whatsoever have any impact or affect with or upon the subject matter of this Research Investigator Agreement with the Nation.

7. REPRESENTATIONS AND WARRANTIES: The Investigators shall make no representations, warranties or commitments binding the Nation without the Nation's written consent.

8. INDEMNIFICATION: The Investigators shall each be responsible for their own negligent and intentional acts and omissions with their liability governed by the terms of the Oklahoma Governmental Tort Claims Act, 51 Okl. St. §§ 151 et seq. Investigators are self-insured in accordance with the Oklahoma Governmental Tort Claims Act. The Nation shall be

responsible for its own negligent and intentional acts and omissions with the Nation's liability covered under terms of the United States Federal Tort Claims Act.

9. CONFIDENTIALITY: In the course of performing activities under this Agreement, the parties recognize that the Investigators may come into contact with or become familiar with protected health information, which the Nation or a reasonable person may consider confidential. This information may include, but is not limited to, information pertaining to physical health, mental health, economic, social, or cultural status. The Investigators agree to keep all such information confidential and not to discuss or divulge it to anyone other than the appropriate personnel or their designees within the Nation, or Investigator's associates, colleagues or employees assisting in the conduct of the Research and regulatory or oversight authorities who have a need to know. If such information is subject to the Health Insurance Portability and Accountability Act (HIPAA), then the Investigators agree to comply with the applicable provisions of HIPAA and shall execute and comply with the terms of a separate business associate agreement, if such an agreement is required. Nation agrees to keep Investigators information, including Research plan, data and results, confidential and not disclose such information without the prior written permission of Investigators, except as allowed pursuant to paragraph 15. infra. Either party may use the Research plan, data and results for their internal teaching and research purposes and in accordance with paragraph 15. infra.

10. ENTIRETIES: This Agreement constitutes the entire Agreement between the parties and supersedes all prior and contemporaneous written or oral agreements between them.

11. AMENDMENTS: No amendment, extension or change of the Agreement or research protocol shall be binding without all parties' prior written consent and agreement.

12. SEVERABILITY: If any provision contained in this Agreement is held for any reason to be invalid, illegal, or unenforceable, the enforceability of the remaining provisions shall not be impaired thereby.

13. WAIVERS AND GOVERNING LAW: The failure of any party to require strict compliance with any term of this Agreement shall not be deemed a waiver of that or any other term of this Agreement. Nothing contained in this Agreement shall be construed to waive the sovereign rights of the Nation, its officers, employees or agents. Notwithstanding anything to the contrary herein, Investigator does not waive any rights or remedies to which it is entitled by law.

14. EQUAL OPPORTUNITY: As applicable to Investigators, the provisions of Executive Order 11246, as amended by EO 11375 and EO 11141 and as supplemented in Department of Labor regulations (41 CFR Part 60 et. seq.) are incorporated into this Agreement and must be included in any subcontracts awarded involving this Agreement. The Investigators represent that all services are provided without discrimination on the basis of race, color, religion, national origin, disability, political beliefs, sex, or veteran's status; it does not maintain nor provide for their employees any segregated facilities, nor will the Investigators permit its employees to perform their services at any location where segregated facilities are maintained. In addition, the Investigator agrees to comply with the applicable provisions of Section 504 of the Rehabilitation Act and the Vietnam Era Veteran's Assistance Act of 1974, 38 U.S.C. §4212.

15. PUBLICATION: It is specifically acknowledged and agreed by the parties that any and all research data and findings as generated and derived by virtue of this Agreement and Research project shall be and sole ownership of same shall be retained and vested with the Nation. The parties recognize and agree that publication and/or dissemination of the Agreement's outcomes and/or results are a mutually beneficial goal and each party will be permitted to present or publish at: (i) symposia, national, or regional professional meetings and/or (ii) theses/dissertations under the supervision of the Principal Investigator. Both parties agree to abide by the terms of CNDH policy 09 ADM 1411"Release and Dissemination of Research and Results and Findings".

16. NON-DISPARAGEMENT: Each Investigator Institutional and Principal Investigator hereby individually, along with the Nation, stipulates and agrees that they may discuss non-confidential aspects of their experience with the Research project, however none of the parties shall in any shape, form or fashion whatsoever, make any disparaging remarks of any sort or otherwise communicate any disparaging information about the other or the other party's employees or officers in their professional capacities herein to any third party, including but not limited to statements on social or any other media. Further, each Investigator Institutional Investigator and Principal Investigator, along with the Nation, agree to take no action of any nature which is intended, or would reasonably be expected, to harm the other party or its reputation or which would reflect or reasonably lead to unfavorable publicity of that party.

17. LOCATION OF EXECUTION: This Agreement is deemed executed in Indian Country,

IN WITNESS of the foregoing, the persons signing below, who represent and warrant that they have the requisite authority to enter into this Agreement, accept and agree to the terms of the Agreement.

Institutional Investigator:

_____ Date:_____

[Appropriate signature block for the Institutional Investigator, signature party and title]

Principal Investigator:

_____ Date: _____

[Principal Investigator signature line, and title]

_____ Date:_____

Judy Goforth Parker, PhD, APRN-CPN
Secretary
Chickasaw Nation Department of Health

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