INITIAL SUBMISSION APPLICATION

**Submission Date:****Project Start Date:****Project End Date:**

**Research Protocol Title:****Principal Investigator:**

**Research Study Contact:****Institution:**

**Email:** **Phone:**

* **SENIOR/KEY PERSONNEL:** Attach Curriculum Vitae for Principal Investigator. If applicable, attach certifications of Human Subjects Protections Trainings.

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| Principal Investigator:      Email:      Phone:  Institutional Address:  Student Faculty Sponsor N/A  Human Subjects Protection Training (CITI or NIH) Completion Date:  Other Relevant Qualification/ Certification:  Project Related Tasks/Duties: |
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| Investigator:      Email:      Phone:  Student Faculty Sponsor N/A  Human Subjects Protection Training (CITI or NIH) Completion Date:  Other Relevant Qualification/Certification:  Project Related Tasks/Duties: |

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| Investigator:      Email:      Phone:  Student Faculty Sponsor N/A  Human Subjects Protection Training (CITI or NIH) Completion Date:  Other Relevant Qualification/Certification:  Project Related Tasks/Duties: |

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| Investigator:      Email:      Phone:  Student Faculty Sponsor N/A  Human Subjects Protection Training (CITI or NIH) Completion Date:  Project Related Tasks/Duties: |

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| Other:      Email:      Phone:  Student Faculty Sponsor N/A  Human Subjects Protection Training (CITI or NIH) Completion Date:  Project Related Tasks/Duties: |

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| Other:       Email:      Phone:  Student Faculty Sponsor N/A  Human Subjects Protection Training (CITI or NIH) Completion Date:  Project Related Tasks/Duties: |

* **FUNDING INFORMATION :** Attach a copy of the budget documentation for the project

No Funding

Private Funding Source:

U.S. Department of Health and Human Services (HHS)

HHS Center or Institute:

Subcontract or Program Project Grant. Describe:

* **RESEARCHER FINANCIAL CONFLICT OF INTEREST**
* Have you reported a financial conflict of interest to your institution? ☐No ☐Yes

If yes, attach a copy of the ‘management plan’ or the institution’s conflict of interest determination for this research project.

* Do you, your spouse, or dependent children stand to receive financial interest from this research project in excess of $5,000 in the form of salary or any other payment, not otherwise defined as salary?

No Yes – Please Describe:

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* **OTHER IRB and TRIBAL NATION APPROVALS**
* Will study procedures and/or data collection take place at other sites?

No Yes – List each site:

List any other Institutional Review Boards that have/will review this project. Also list any Approvals or Letters of Support from other Tribal Nations. Attach copies of all approval documentation already obtained. N/A

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* **RESEARCH PROTOCOL/PROJECT DESCRIPTION:** The protocol should include the following, as applicable to the project (please attach a separate document). In this section, please provide a summary in layman’s language of the study design, research question and procedures.
* **Study Design**

Include ‘Research Question’, ‘Scientific Rationale or Background’, Project Description.

* **Research Procedures**

Include description of all research procedures, including data/specimen collection, processing, and storage procedures. Include description of data collection source, including for e.g. tribal records or environmental resources.

* **Anticipated Start Date and Completion Date/s for project**

If project has several components, write anticipated start and completion dates for each part; e.g. recruitment, enrollment, intervention, analysis, phases. Include description of duration of intervention and/or interaction with human subjects.

* **Confidentiality**

Include description of the steps that will be taken to secure data collected and/or protect the participants involved. Describe if ‘identifiers’ will be obtained with the data and remain with the data. Describe who will have access to the data collected. If there will be any transport of data, describe how that will occur and include name and address of all sites where data will be stored.

* **Informed Consent procedures**

Describe procedures and enclose a copy of each consent form to be used.

* **Compensation procedures**

Include a description of how participants will be compensated and when in the research process.

* **Recruitment methods**

Include description of how participants will be recruited. Enclose a copy of recruitment materials to be used; for e.g., flyer, web posting, email, postal letter, scripts for verbal communication. If vulnerable populations are involved, include a description of safeguards for their protection.

* **Privacy**

Describe how participant’s privacy will be protected. For e.g., interviews will be conducted in a private room.

* **Risks and Benefits to Individual Participants**

Describe risks to participants. Also describe potential risks to others who are not participants. Is your project greater than minimal risk? If yes, include your data and safety monitoring plan. Describe benefits to the participants (immediate, long term, direct, indirect); and potential benefit to others who are not involved in the research project. Provide detailed response.

* **Risks and Benefits to Tribal Nation**

Please address any risks to Tribal communities involved? Could you project present risk to the resources (e.g. environmental, plant life, wildlife) within the reservation? Describe plan to minimize risks to the Tribe and/or Tribal communities. Has appropriate (reservation) department or organizational permissions been granted? Describe benefit to the Tribe and/or Tribal communities (immediate, long term, direct, indirect). Include description of any benefit to society or others.

* **Results Dissemination**

Describe plan. Include plan for sharing of results with Tribal community.

* **Data sharing**

Please include a plan for long term storage and sharing of data for future use.

* **PARTICIPANT INFORMATION**

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| Vulnerable Populations: No Yes N/A | |
| Describe Participants. Check all that apply: | |
| Children  Adolescents  Adults  Pregnant Women  Fetuses and/or neonates  Prisoners | Cognitive or Mental impairment  Physical impairment or disability  Economically or socially disadvantaged  Other: |

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| Male Female: |
| Age Range: |
| Planned Enrollment Number: |
| Explain choice of participant population: |
| Description of Inclusion and Exclusion Criteria: |
| Planned Participation Duration: |

* **ASSURANCES**

By signing below, I attest to the following:

The information provided in this form and attached documentation is true. I will not begin my research until I have received written approval from the IRB. I will abide by \_\_\_\_\_\_\_\_\_\_\_ Tribe policy for research conducted within the exterior boundaries of the reservation.

Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed Name:

Principal Investigator

Signature\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed Name:

Faculty Supervisor (if student researcher)