# RESEARCH CONTINUATION/RENEWAL

**Protocol Title:**

**Principal Investigator:**

**Institution:**

**Do you have any conflict of interest (personal, financial, academic, or other interest) that could influence your fair and objective review of this protocol for re-approval?**

* Are you, your spouse, or immediate family member involved in the conduct of this research study?
* Is your advisor, mentee, or student involved in the conduct of this research study?
* Do you receive income from the institution supporting this study, or do you stand to receive a financial benefit from the conduct of the research?
* Do you receive income or stand to receive a financial benefit from a company whose business is substantially related to the subject matter of the research?

Yes No

If yes, or you think you might have another type of conflict of interest please bring it to the IRB Chair and/or board’s attention ***before*** continuing to review this research submission.

Comments/Additional Information:

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**Review of Research Plan**

1. **Indicate the type of continuation:**

Extension of study without study changes/modifications

Extension of study with study changes/modifications: If changes present, please review ‘amendment’ application submitted by investigator

1. **Is the current study protocol (including any proposed changes) more than minimal risk to the individual, community, and/or Tribe?**

Yes No Not Applicable

*If yes, have adequate protections and safeguards been put into place?*

Yes No

1. **Was a protocol deviation or adverse event report filed in the past year?**

Yes No

*If yes, was the event addressed adequately?*

Yes No

1. **Have there been any complaints about this research?**

Yes No

*If yes, were these complaints investigated and/or addressed adequately?*

Yes No

Comments/Items for Board Discussion:

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**Involvement of Human Subjects**

1. **Are the risks to the individuals involved reasonable in relation to the anticipated benefits?**

Yes No Not Applicable

1. **Were there any complaints or concerns raised about the research by the participants and/or community in the last year?**

Yes No

1. **Does the number of individuals enrolled correspond to the number approved for enrollment?**

Yes No Not Applicable

1. **Is the number of participants who discontinued participation in the last year a reason for concern?**

Yes No Not Applicable

1. **Is the consent process originally approved by the IRB still appropriate?**

Yes No Not Applicable

1. **Have there been any significant new findings or changes to the research that might reasonably affect participant’s willingness to continue in the research?**

Yes No Not Applicable

*If yes, has participant re-education and possible re-consent been addressed?*

Yes No

Comments/Items for Board Discussion:

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**Review of Products and Publications Resulting from Research**

1. **Have any products resulting from this research (e.g., abstracts, posters, presentations, publications, media releases) proved to present more than minimal risk to the individuals involved, community involved, and /or the Tribe?**

Yes No N/A

Comments/Items for Board Discussion:

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**Use/Collection of Data or other Resources from the Tribe**

(Land, water, plant life, wildlife, historical records or artifacts, cultural records, artifacts, practices)

1. **Have there been any reports of misuse or harm to tribal land, resources, and/or property in the last year, resulting from research study activities?**

Yes No N/A

***If yes, is there adequate explanation to indicate that the study is safe to proceed as planned?***

Yes No

1. **Will relevant use/access permissions (from individuals or departments) be valid for another year?**

Yes No N/A

1. **Will the continued use/collection of data/resources (including any proposed changes) harm the source in any way?**

Yes No N/A

Comments/Items for Board Discussion:

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**Resource to Guide Review:** [OHRP Guidance on IRB Continuing Review of Research](http://www.hhs.gov/ohrp/policy/continuingreview2010.html)