# 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)