**irb reviewer checklist - Initial Review**

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| **Project Title** |
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| **Principal Investigator** | **Institution** |
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**Reviewer Conflict of interest and Tribal IRB Jurisdiction**

**1) Do you have any conflict of interest (personal, financial, academic, or other interest) that could influence your review of this protocol?**

* Are you in any way involved in the design or conduct of the study?
* Is 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.

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**Review of Research Plan**

**1)** **Are there any drugs being used in this study?**  Yes No

If yes, the device must be approved by the FDA, for use in research.

**2)** **Are there any investigational devices being used in this study?** Yes No

If yes, the device must be approved by the FDA, for use in research.

**3)** **Does the research design appear to be adequate for the question?** Yes No

**4)** **Have all relevant letters of support been obtained?** Yes No

**5)** **Do the study personnel have the appropriate qualifications**  Yes No

**6) Do all key personnel have human subjects training?**  Yes No

**7)**  **Are the facilities to be used for this study adequate?**  Yes No

**8)** **Are any medical or psychological resources that participants may need as a result** **of their participation in the research available and adequate?** Yes No

**9)** **Is the research on a topic, or involve methods or results that could potentially cause community harm?** Yes No

For example cause collective physical or social harm, affect sovereignty, or conflict with Tribal values/ beliefs.

If ‘Yes’, make a note of your concerns to bring up for discussion in the board meeting.

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**Involvement of Individuals from the Tribe**

**1)** **Does the research involve a vulnerable population/s? :**

Children

Pregnant women

Fetuses and/or neonates

Prisoners

Cognitive or mental impairment

Physical impairment or disability

Economically or Socially Disadvantaged

Other vulnerable populations?

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| --- |
| Please describe |

**2) Does the research involve use of genetic material?**  Yes No

**3) Subject Selection and Recruitment Methods:**

1. Clear and justified inclusion/exclusion criteria:

* Is it clear who will be eligible to participate in the study? Yes No
* Are all tribal members getting an equal opportunity to participate in the research?

Yes No

1. Is the targeted population appropriate, given the topic and purpose of the research?

Yes No

1. Are the methods of recruitment clearly described and acceptable?

Yes No

1. Do the methods of recruitment avoid coercion or undue influence?

Yes No

(For more detailed description of ‘coercion’ and ‘undue influence’, see the [CRCAIH Glossary of Human Subjects Protections Terms](http://crcaih.org/assets/Human_Subjects_Protections_Glossary.pdf).)

**Risks and Benefits**

1) Is research more than minimal risk? Yes No

(For definition of ‘minimal risk’, see the [CRCAIH Glossary of Human Subjects Protections Terms](http://crcaih.org/assets/Human_Subjects_Protections_Glossary.pdf))

* For more than minimal risk research, is the risk justifiable for the targeted individuals and/or for the Tribe? Yes No

2) Are the risks/potential harms clearly described? Yes No

(E.g. physical, psychological, social, legal, economic harm)

3) Is a plan for addressing participant injury/illness described? Yes No

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

\*[Land, water; plant life; wildlife; historical records or artifacts; cultural records, artifacts, practices]

1) Does it correlate with the research plan and/or lay summary? Yes No

2) Have appropriate permission/s for access and use obtained Yes No

3) Will the use/collection of the data/resources harm the source in any way? Yes No