**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