## CONCEPT PROPOSAL

## Southcentral Foundation (SCF) Research: (907) 729-8623

## ANTHC Research Review: (907) 729-2901

**Concept approval:** Required prior to submitting funding application.

1. Are you requesting a determination of Research?  Yes  No
   1. If yes, are you an SCF Employee?  Yes  No
      1. If Yes, please proceed with completing this form including the Definition of Research Questions document.
      2. If No, please submit an application of research determination to the AAIRB and include determination letter when submitting this form.
2. Date submitted:
3. Submitted by: [Name, and email address]
4. Title of submission:
5. **Principal Investigator (PI):**

Name:

Phone:

E-mail:

1. **Co-Investigators (provide email for Co-Is to be included in correspondence):**

Name: Email:

Name: Email:

Name: Email:

1. **Institutions/Organizations Involved/Locations (city/state):**
2. **Funding source(s):**
3. **Expected start date:**
4. **Expected end date:**
5. **Study site(s)** **(facility/department, point of contact, city, and state):**
6. **Will this project qualify for expedited Institution Review Board (IRB) review or be**

**exempt from IRB review**? Yes No

If yes, please describe

1. **Will Alaska Native/American Indian peoples be involved with the investigative team for this project?**

Yes No

If yes, in what capacity? Please describe (e.g., investigators or otherwise involved in conducting the research, member of research team, advisory committee, consultant).

1. **Will medical records or identifiable information or specimens be collected for this study?**

Yes No

If yes, please describe:

1. **Will minor children be involved in the study?**

Yes No

If yes, please describe:

1. **General goals and objectives of the study:**
2. **Potential benefits:**
3. **Risks/potential harms:**
4. **SCF/Alaska Native Tribal Health Consortium (ANTHC) resources needed for the study:**

Please describe (e.g., data analyst, recruitment space, other department, or staff time, etc.).

1. **Will this study involve bio-specimens?** Yes No

If no, skip to question 21.

* 1. **Will this project be requesting long-term bio-specimen storage at the Alaska Area Specimen Bank?**

Yes No If yes, please describe.

* 1. **Will temporary storage be needed for this project?**

Yes NoIf yes, please describe.

* 1. **Will this project be requesting use of biorepository samples?**

Yes No

If yes, check all that apply:

Alaska Area Specimen Bank

ANTHC Pathology Specimen Archive

Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. **Are there potentially any sensitive issues?** Yes No

If yes, please describe.

1. **Provide plan for dissemination of findings to the tribal health organization(s) and Alaska Native peoples:**
2. **PLEASE ALSO SUBMIT:**

**One page narrative summary of the proposed project in Microsoft Word with line numbers. In the narrative include: identified need for the proposed project, proposed methods, and how the project will benefit the Alaska Native community.**

**Definition of Research Questions – For SCF Employees only (If requesting determination of research).**

**Determination of Research letter from AAIRB (If QA/QI determination was requested from AAIRB).**

**Definition of Research Questions**

Note: Definition of Research Questions only needs to be completed and included in submission if investigator is requesting a determination of research.

Questions assist in the evaluation of whether an activity meets the definition of research according to the Department of Health and Human Services (DHHS) or Food and Drug Administration (FDA) definition.

“A systematic investigation, including research development, testing, and evaluation designed to develop or contribute to generalizable knowledge.” DHHS, 45CFR

“Any experiment that involves a test article and one or more human subjects.” FDA

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| **1. Is the activity systematic?** |  | |
| Does the proposed study involve the prospective assignment of patients to different procedures or therapies based on a predetermined plan such as randomization? | No | Yes |
| Does the proposed study involve a “control group” in whom the therapeutic or study intervention is intentionally withheld or an alternate intervention such as standard care, education only, or an intervention targeted at a different endpoint to allow an assessment of  the efficacy of the target intervention? | No | Yes |
| Will the project be conducted using a research design that will lead to scientifically valid findings? Elements of a research design include a fixed protocol, goal, methodology, population, and time period as well as statistical tests. | No | Yes |
| **2. Is the activity intended to develop or contribute to**  **generalizable knowledge?** |  | |
| Is the intent that the information learned from the project be generalizable beyond ANMC processes and practices? | No | Yes |
| Is the information or data collected about a given population used to  describe, explain, interpret, or make predictions about other members of that population? | No | Yes |
| Does the project involve an untested clinical intervention and collecting information about patient outcomes for the purpose of establishing scientific evidence? | No | Yes |

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| --- | --- |
| **3. Does the activity involve an experiment with a test article?** |  |
| Does the project involve testing the safety and efficacy of a drug or device in human subjects? | No Yes |
| Is the intent to report the results to the FDA as a well-controlled study in support of a new indication for use or in support of a change of  labeling or advertising for a drug or biologic? | No Yes |

|  |  |
| --- | --- |
| **4. Are activities public health activities?** |  |
| Are activities limited to those needed by a public health authority to identify, monitor, assess; or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in disease, or increases in injuries from using consumer products)? | NoYes |