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

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

**SCF Concept approval:** Required prior to submitting funding application when SCF customer-owners are research participants or population of interest, if SCF employees are members of the study team, or if the research conducted involves information from Alaska Native Medical Center (ANMC) administrative or medical records.

## CONCEPT PROPOSAL

Date submitted: XX/XX/XXXX

Submitted by: XXX

Title of submission: XXX

**Principal Investigator (PI):**

Name: XXX

Phone: XXX

E-mail: XXX

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

Name: XXX Email: XXX

Name: XXX Email: XXX

Name: XXX Email: XXX

**Institutions/Organizations Involved/Locations (city/state):**

XXX

XXX

**Funding source(s):** XXX

**Expected start date:** XX/XX/XXXX

**Expected end date:** XX/XX/XXXX

**Study site(s)** **(facility/department, point of contact, city, and state):**

XXX

**Are you requesting a determination of research or QA/QI?** **[ ]** Yes **[ ]** No

If yes, please also submit a completed Definition of Research Questions document.

**Will this project qualify for expedited Institution Review Board (IRB) review or be**

**exempt from IRB review**? **[ ]** Yes **[ ]** No

If yes, please describe

**Will Alaska Native/American Indian people be involved in the conduct of the research?**

**[ ]** 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).

**Will medical records or identifiable information or specimens be collected for this study?** If yes, please describe:

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

If yes, please describe:

**General goals and objectives of the study:**

1. XXX
2. XXX

**Potential benefits:**

1. XXX
2. XXX

**Risks/potential harms:**

1. XXX
2. XXX

**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.).

Will this study be collecting bio-specimens? **[ ]** Yes **[ ]** No

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

**[ ]** Yes **[ ]** No

If yes, please describe.

If temporary storage will be needed indicate where this will occur:

**Will this project be requesting use of stored bio-specimens at the Alaska Area Specimen Bank?**

**[ ]** Yes **[ ]** No

If yes, please describe.

Note that the Alaska Area Specimen Bank is only for long-term storage of specimens upon consent from participants. It is not to be used for temporary storage (e.g. specimens that may be going to outside labs).

**Are there potentially any sensitive issues?** **[ ]** Yes **[ ]** No

If yes, please describe.

**Provide plan for dissemination of findings to the tribal health organization(s) and Alaska Native people:**

XXX

**PLEASE ALSO SUBMIT:**

**[ ]  One page narrative summary in Microsoft Word format of the proposed project.**

**[ ]  Definition of Research Questions.**

**Definition of Research Questions**

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 ofthe 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 todescribe, 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** |

**OR**

|  |  |
| --- | --- |
| **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 oflabeling or advertising for a drug or biologic? | **No Yes** |

**OR**

|  |  |
| --- | --- |
| **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)?  | **No Yes** |

Please do not reformat this form or submit in a PDF format

Use Arial 11 font, Single spaced

Submit documents to scfresearchreview@scf.cc and to ResearchReviewCmtee@anthc.org