

118 Determination Request

NOTE: A 118 determination is not an IRB approval. No work with human subjects, including recruitment, may be conducted under a 118 determination. A complete application will need to be submitted and approved by the IRB prior to involving any human subjects in this study.

Principal Investigator Name: _____

Protocol Title: _____

SECTION 1: FUNDING INFORMATION

- 1.1** Is your study funded (either directly or through a sub-award) by a Federal Agency (e.g., NIH, NSF, DOD, DOE, DOJ, etc.)? Yes No
- 1.2** Is SIU the primary awardee of this grant? Yes No
- 1.3** Is this a collaborative project that involves multiple institutions? Yes No

If yes, identify all institutions involved in this project:

- 1.4** Will IRB approval be sought outside of SIU for this project? Yes No

If yes, identify which institution will provide IRB oversight for this project:

SECTION 2: INFORMATION REQUEST

46.118 Determinations can be granted to satisfy federal sponsor requirements (e.g., Just-In-Time) to allow investigators to have access to funding to begin aspects of the project that do not involve human subjects. Under the federal regulations (§46.118) certain types of applications for grants are submitted with the knowledge that subjects may be involved, but definite plans would not normally be set forth in the application or proposal. These can fall under three categories:

- institutional type grants when selection of specific projects is the institution's responsibility;
- research training grants in which the activities involving subjects remain to be selected; and,
- projects in which human subjects' involvement will depend upon completion of instruments, prior animal studies, or purification of compounds.

2.1 Explain why human subjects study information is not available at the time of this request:

2.2 Identify the phase/specific aim of the project in which human subjects research is expected to be initiated:

2.3 Provide the expected date that a full IRB application will be submitted to the IRB:

2.4 Is there any additional information about this project that you would like to share with the ORC/IRB? Yes No

If yes, please describe:

SECTION 3: ACKNOWLEDGEMENT

3.1 I acknowledge that no work with human subjects, including recruitment, may be conducted under this 118 determination. Yes

As the Principal Investigator named above, by signing and submitting this application, I attest that I have reviewed this request prior to submission. I certify that I have read and understand the University's policies and procedures governing research activities involving human subjects. I agree to comply with the letter and spirit of those policies and ensure that all key project personnel will act accordingly. I accept my responsibilities as PI as outlined above. I acknowledge that I am responsible for the research described herein, including work done by others under my direction. I will obtain written approval from the IRB prior to initiation of any research activities, including modifications or deviations from previously approved protocols.

Printed Name of Researcher (PI)

Signature of Researcher (PI)