**Instructions to applicants: All applicants must complete this form electronically. The final signatory page should be printed, signatures appended and dated, scanned and submitted together with this application form, along with all supporting documents (consent, assent, surveys, questionnaires, required ethics certification and any other relevant forms) in one email to the IRB Administrator at** **kcoomans@sgu.edu****. Once your application has been fully reviewed, a decision will be sent to you officially by the Chair of the IRB.**

SGU IRB Application

Reference:

**Application for Review**

 **New Revision**

**Submission date: 8 October 2018** (this date will automatically update to the last date saved)

**Principal Investigator** (Name and role, *Faculty, student, other):*

Type here:

**Co-Investigator (s), if any** *(Name and role)*:

Type here:

**Title of Project**:

Type here:

**Does the research involve human participants?: Yes No**

Type here:

**How many?**

**Anticipated Risk to Participants:**  **No risk Minimal risk Greater than minimal risk**

Type here:

**Anticipated dates of data collection (indicate if historical data)**:

Type here:

**Anticipated dates of data analysis:**

Type here:

**Study completion date**:

**Is this part of requirements for completing a course? Yes No**

Type here:

**If yes which course and school?**

**Is this research for degree purposes? Yes No**

**Are you enrolled in a degree program at SGU: Yes No**

If yes, specify the degree program

Degree(s):

If **not** at SGU, which institution are you affiliated with?

Type here:

**Faculty Advisor/supervisor name (if applicable\*)**:

Type here:

**INVESTIGATOR INFORMATION PAGE**

*Duplicate this page for however many investigators there are (if the PI is a graduate student, only the chair of their advisory committee needs to provide full details)*

**Principal Investigator:**

Title: Name:

Institution: Department:

Daytime telephone:

Email address (SGU students and faculty must provide SGU email):

**Faculty Advisor/supervisor (if PI is student):** (If applicable\*)

Title: Name:

Institution: Department:

Daytime telephone:

Email address (SGU students and faculty must provide SGU email):

**Co-investigator:** (If applicable\*)

(SGU students must specify ‘student’ and what program they are enrolled in)

Title: Name:

Institution: Department:

Daytime telephone:

Email address (SGU students and faculty must provide SGU email):

Type here:

1. **Short Title of Project:**
2. **Special considerations or requests, if any:**

*When requesting modification or extension of research already in progress, describe the unique circumstances for your request and respond only to items below directly relevant to proposed changes.*

Type here:

Type here:

1. **Purpose of the study:** *State the research question***.**
2. **Social value of the study:** *In layperson language, explain how you expect the research to benefit the community, country, or other entity*

Type here:

1. **Background and rationale:** *Provide a brief literature review stating what is known about the topic, and what is not known or documented in peer-reviewed literature; use this to explain the motivation for conducting the study; and provide full citations for references (e.g. Author. Title. Journal or book: page numbers. Year published)*

Type here:

1. **Aim of project**: *State the hypothesis, the aim/s, and specific objectives in layperson terms.*

Type here:

1. **Participant details:** *Define the inclusion/exclusion criteria, number of participants, age range, gender/s, and possible vulnerabilities of the subject population.* *Also briefly describe your knowledge, if any, of the particular social, economic and cultural background of the participants’ community and how this impacts if at all, the design of your study.*

Type here:

1. **Will any vulnerable populations be recruited?** *Prisoners, low education/income, ill, hospitalized, elderly, pregnant women, children, others.* Yes No

**If yes please provide a justification below*:***

Type here:

1. **Participants roles:** *How much time will participants have to spend; what will they have to do; where will it be done; will there be physical discomfort or psychological stress?*

Type here:

1. **Recruitment process**: *Describe how, where, and when recruitment will take place. If written materials are used, attach a copy; if verbally recruited, attach a copy of the script of what will be said to recruited persons, and by whom.*

Type here:

1. **Informed consent:** *Explain how informed consent will be sought. What proportion of the process will be verbal or written (50%, 90%)? Attach written consent forms and verbal consent scripts as separate documents.*

Type here:

1. **Study methods:** *Briefly, and in layperson terms, describe what information/data is being sought; specify types of samples, specimens or information collected, medical tests, interviews, questionnaires, or use of past medical records. Describe procedures, devices, drugs or medications, placebos, radiation exposure, and other elements involved in the investigation. Distinguish between and specify when different methods are being used to meet differing research objectives listed in the section ‘Aim of project’. Include information on why the sample size is appropriate to meet the requirements of the study.*

Type here:

1. **Sample collection (physical):**  Yes No *If yes, please answer the questions below; if no, move to item 14:*

**What type of samples (body fluids/biopsied tissues, or others) will be collected?**

Type here:

**How and where will the samples be stored during the study?**

Type here:

**Will the samples be stored for future use?**  Yes No

If yes, *for how long, where, and who will the samples be shared with. Any planned future use of collected samples must be clearly stated in the consent form/s and process.*

Type here:

**Where and how will samples be analyzed** *(for the present study)***?**

Type here:

**Describe when, how, and by whom all samples will be discarded:**

Type here:

1. **What demographic and other types of data (e.g. medical records) will be collected?** *Briefly, and in layperson terms, provide an explanation or justification for collecting private or identifying information.*

Type here:

1. **Possible risks of participating:** *Describe possible physical or emotional discomforts, incapacities, harms, or wrongs to participants or to their community that might possibly occur through their participation.*

Type here:

1. **Probable benefits of participating:**  *Specify what benefits participants will personally receive for participating, and how the community might benefit. Who will ensure that benefits promised (such as certain medical treatments) are provided, and how will these be funded?* *Describe what efforts you have made to involve appropriate local expertise and explore local collaborations wherever possible, in order to maximize the potential benefits and outcomes of your study.*

Type here:

1. **Compensation:** *State what compensation, if any, the participants will receive for participating. If none, state ‘none’. If medical care is provided as a form of compensation, specify what type/s of care and how this will be implemented.*

Type here:

1. **Data management**: *Provide information on how research materials will be stored, including but not limited to surveys, informed consent documents and collected data etc. State how long these, or the data obtained through these, will be retained and by whom. Who will have access to the information, and to whom will the data be reported and will it be reported by categories, groups, or individuals? Will participant identifying information be submitted to peer-reviewed journals, local health officials, and/or others?*

Type here:

**How long will data be stored and by whom?** W*ill the data be stored to use in future research and will this be explained during the informed consent process? Who will have access to this data?*

Type here:

1. **Confidentiality measures:** *Describe what measures will be taken to protect participant’s confidentiality.*

Type here:

1. **Funding:** *If funding is provided, specify whether it is from a commercial, charitable, or governmental sponsor; describe briefly what the funding provides, how this contributes toward providing potential benefits to participants or their communities during the research, and whether these benefits will continue to be provided after the research is completed (if so, specify for how long or an end point). Describe the role and responsibility, other than provision of funds, that the funding body has in the research.*

Type here:

1. **Conflict of interest:** *Does the principal investigator or any member of the research team have a real or perceived financial interest or possible secondary gain from this investigation?*

Type here:

1. **Compensation for injury or harm:** *What compensation will be provided for any injury or harm incurred by participants through their participation? Specify the source/s of funding, healthcare, or other compensation; state who will facilitate and ensure its provision; and how and when this information is provided to potential and/or recruited participants.*

Type here:

Signatory Page (please print this page, sign, date, scan and attach to the application form for submission to the IRB Administrator at kcoomans@sgu.edu)

By signing on the page below we affirm that this application represents an accurate and complete description of the proposed research; that the research will comply with recommendations of the SGU IRB; and that the principal investigator (PI) will report to the IRB in a timely fashion any adverse events or concerns raised by participants or others. It should be noted that, if this is a student application, the Faculty Advisor’s signature has to be appended and by doing so the Faculty Advisor has read and approved the application. The PI will await final IRB approval prior to initiating the study or implementing modifications in the study design or consent process. The PI will submit an interim report each year the research continues (or as requested by the IRB). The PI will submit a final end-of-study report as required for IRB approval.

**Date: 8 October 2018**

**Title of Project**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Principle Investigator** (*sign and date*): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Co-Investigator (s), if any** (*sign and date*):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Chair Supervisor/Advisory Committee, if any** (*sign and date*)**:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_