

## NOTICE OF APPROVAL

REC: SBER - Reciprocal review form

30 June 2020

Project number: 15433

Project Title: Coronavirus Rapid Mobile Survey (CRAM)

Dear Prof Servaas Van Der Berg

### **Co-investigators:**

Miss Grace Bridgman, Dr. Gabrielle Wills, Prof Ronelle Burger, Prof Rulof Burger, Dr. Dieter Von Fintel, Dr. Anna Smith, Dr. Nicholas Spaul

Your REC: SBER - Reciprocal review form submitted on 25 May 2020 was reviewed and approved by the REC: Social, Behavioural and Education Research (REC: SBE).

Please note below expiration date of this approved submission:

### **Ethics approval period:**

Protocol approval date (Humanities)	Protocol expiration date (Humanities)
30 June 2020	29 June 2021

## **SUSPENSION OF PHYSICAL CONTACT RESEARCH DURING THE COVID-19 PANDEMIC**

Due to the Covid-19 pandemic and resulting lockdown measures, all research activities requiring physical contact or being in undue physical proximity to human participants has been suspended by Stellenbosch University. Please refer to a [formal statement](#) issued by the REC: SBE on 20 March for more information on this.

This suspension will remain in force until such time as the social distancing requirements are relaxed by the national authorities to such an extent that in-person data collection from participants will be allowed. This will be confirmed by a new statement from the REC: SBE on the university's dedicated [Covid-19 webpage](#).

Until such time online or virtual data collection activities, individual or group interviews conducted via online meeting or web conferencing tools, such as Skype or Microsoft Teams are strongly encouraged in all SU research environments.

If you are required to amend your research methods due to this suspension, please submit an amendment to the REC: SBE as soon as possible. The instructions on how to submit an amendment to the REC can be found on this webpage: [[instructions](#)], or you can contact the REC Helpdesk for instructions on how to submit an amendment: [applyethics@sun.ac.za](mailto:applyethics@sun.ac.za).

### **GENERAL REC COMMENTS PERTAINING TO THIS PROJECT:**

#### **INVESTIGATOR RESPONSIBILITIES**

Please take note of the General Investigator Responsibilities attached to this letter. You may commence with your research after complying fully with these guidelines.

**If the researcher deviates in any way from the proposal approved by the REC: SBE, the researcher must notify the REC of these changes.**

Please use your SU project number (15433) on any documents or correspondence with the REC concerning your project.

Please note that the REC has the prerogative and authority to ask further questions, seek additional information, require further modifications, or monitor the conduct of your research and the consent process.

#### **CONTINUATION OF PROJECTS AFTER REC APPROVAL PERIOD**

You are required to submit a progress report to the REC: SBE before the approval period has expired if a continuation of ethics approval is required. The Committee will then consider the continuation of the project for a further year (if necessary).

Once you have completed your research, you are required to submit a final report to the REC: SBE for review.

**Included Documents:**

Document Type	File Name	Date	Version
Proof of Ethics Clearance	Commerce_Ethics_Approval_Letter_Daniels_2020_04_017	17/04/2020	Final
Default	CRAM Questionnaire v1.8.3 for ethics	17/04/2020	1,8,3
Default	16003094-national-income-dynamics-study-coronavirus-rapid-mobile-survey-nids-cram	17/04/2020	final
Default	NIDS-CRAM DMP	17/04/2020	final
Default	NIDS-CRAM DMP	17/04/2020	final
Research Protocol/Proposal	v13 - CRAM Overview (27 April 2020)	27/04/2020	13

If you have any questions or need further help, please contact the REC office at [cgraham@sun.ac.za](mailto:cgraham@sun.ac.za).

Sincerely,

Clarissa Graham

REC Coordinator: Research Ethics Committee: Social, Behavioral and Education Research

*National Health Research Ethics Committee (NHREC) registration number: REC-050411-032.*

*The Research Ethics Committee: Social, Behavioural and Education Research complies with the SA National Health Act No.61 2003 as it pertains to health research. In addition, this committee abides by the ethical norms and principles for research established by the Declaration of Helsinki (2013) and the Department of Health Guidelines for Ethical Research: Principles Structures and Processes (2<sup>nd</sup> Ed.) 2015. Annually a number of projects may be selected randomly for an external audit.*

## Principal Investigator Responsibilities

### Protection of Human Research Participants

As soon as Research Ethics Committee approval is confirmed by the REC, the principal investigator (PI) is responsible for the following:

**Conducting the Research:** The PI is responsible for making sure that the research is conducted according to the REC-approved research protocol. The PI is jointly responsible for the conduct of co-investigators and any research staff involved with this research. The PI must ensure that the research is conducted according to the recognised standards of their research field/discipline and according to the principles and standards of ethical research and responsible research conduct.

**Participant Enrolment:** The PI may not recruit or enrol participants unless the protocol for recruitment is approved by the REC. Recruitment and data collection activities must cease after the expiration date of REC approval. All recruitment materials must be approved by the REC prior to their use.

**Informed Consent:** The PI is responsible for obtaining and documenting affirmative informed consent using **only** the REC-approved consent documents/process, and for ensuring that no participants are involved in research prior to obtaining their affirmative informed consent. The PI must give all participants copies of the signed informed consent documents, where required. The PI must keep the originals in a secured, REC-approved location for at least five (5) years after the research is complete.

**Continuing Review:** The REC must review and approve all REC-approved research proposals at intervals appropriate to the degree of risk but not less than once per year. There is **no grace period**. Prior to the date on which the REC approval of the research expires, **it is the PI's responsibility to submit the progress report in a timely fashion to ensure a lapse in REC approval does not occur**. Once REC approval of your research lapses, all research activities must cease, and contact must be made with the REC immediately.

**Amendments and Changes:** Any planned changes to any aspect of the research (such as research design, procedures, participant population, informed consent document, instruments, surveys or recruiting material, etc.), must be submitted to the REC for review and approval before implementation. Amendments may not be initiated without first obtaining written REC approval. The **only exception** is when it is necessary to eliminate apparent immediate hazards to participants and the REC should be immediately informed of this necessity.

**Adverse or Unanticipated Events:** Any serious adverse events, participant complaints, and all unanticipated problems that involve risks to participants or others, as well as any research-related injuries, occurring at this institution or at other performance sites must be reported to the REC within **five (5) days** of discovery of the incident. The PI must also report any instances of serious or continuing problems, or non-compliance with the RECs requirements for protecting human research participants.

**Research Record Keeping:** The PI must keep the following research-related records, at a minimum, in a secure location for a minimum of five years: the REC approved research proposal and all amendments; all informed consent documents; recruiting materials; continuing review reports; adverse or unanticipated events; and all correspondence and approvals from the REC.

**Provision of Counselling or emergency support:** When a dedicated counsellor or a psychologist provides support to a participant without prior REC review and approval, to the extent permitted by law, such activities will not be recognised as research nor the data used in support of research. Such cases should be indicated in the progress report or final report.

**Final reports:** When the research is completed (no further participant enrolment, interactions or interventions), the PI must submit a Final Report to the REC to close the study.

**On-Site Evaluations, Inspections, or Audits:** If the researcher is notified that the research will be reviewed or audited by the sponsor or any other external agency or any internal group, the PI must inform the REC immediately of the impending audit/evaluation.