UNIVERSITY of the WESTERN CAPE

BIOMEDICAL RESEARCH ETHICS COMMITTEE (BMREC)

APPLICATION FORM FOR ETHICS APPROVAL

Please type directly into the blocks provided.
Do not copy & paste text from your protocol.

PURPOSE OF THE PROJECT

For degree purposes ☐ **Staff research** ☐

Section 1: Researchers' details

PRIMARY RESEARCHER / THESIS SUPEVISOR(S)	
Title: (Mr/Ms/Dr/Prof)	
First Name:	
Last Name:	
UWC Department:	
Email address:	
Relevant qualifications:	
Professional Board and registration number:	
CO-PRIMARY RESEARCHER INFORMATION	
Title: (Mr/Ms/Dr/Prof)	
First Name:	
Last Name:	
UWC Department/Place of employment:	
Contact telephone number:	
Email address:	
Relevant qualifications:	
Professional Board and registration number:	

UNIVERSITY of the WESTERN CAPE

DETAILS OF STUDENT	
Title: (Mr/Ms/Dr/Prof)	
First Name:	
Last Name:	
UWC Department	
Contact telephone number:	
UWC Email Address:	
Proposed Degree:	
Professional Board and registration number:	

Section 2: Project Description

1. What is the title of your study?

2. What kind of study design is proposed and what is your main research aim?

2. Who or what are the proposed research participants in your sample?
(Include information on the population, selection process and sample size)

3. Where will the research be carried out?
(Be specific: Town, community, suburb, school, institution, clinic, etc.)

4. Please describe the methodology (e.g. data collection process and tools)

5. Does the project involve only the use of information already collected by others (secondary data)?

YES ☐ NO ☐

(If you answered yes, to the above, there may be no need to complete the rest of the form)

5.1 Motivate here why the data to be used means that there is no need for further ethical clearance (e.g. you will make use of publicly available census data).

5.2 Indicate whether the secondary data you are using, was subject to ethical or legal clearance when it was initially collected

YES ☐ NO ☐

6. What is the proposed work plan for this study?

STEPS	**DATES**

Section 3: Ethics considerations

7. How will you address the ethical issues encountered in your study?
(Information, consent, confidentiality, de-identification, conflict of interest, permissions, right to withdraw, data security and disposal, POPIA compliance, etc.)

8. Is your research on children below the age of 18? If yes, please consult Section 71 of the National Health Act 61 of 2003 for guidance on conducting research with participants under the age of 18 years.

(Delete the non-applicable answer)

YES	NO

9 If your participants are from a vulnerable group (children, institutionalised people, mental health patients or others), please justify specifically the necessity of doing your research in this group.

10. As defined in section 26 of POPIA, special personal information is personal information relating to: health, sex life, religious or philosophical beliefs, race, ethnic origin, trade union membership, political persuasion, biometrics or criminal behaviour. Motivate for the need to access this level of personal information for your study and indicate in the table below to what extent personal information will be used in your research activity.

11. Please note that the answers to these questions will establish the level of risk of your study. Higher risk studies will be required to submit a Data Management Plan along with their applications.

	YES	NO
Is the personal information of children used in the research activity?		
Does the activity involve further processing of personal information that was collected for another purpose?		
Will the personal information be available for further processing in other research activities?		
Will the personal information be collected from a source other than the data subject?		
Will the personal information be linked with personal information collected by another institution?		

Will the personal information be transferred to another country?		

12. If the participants need any kind of health care or debriefing what will be arranged? Please add contact details for the services listed.

13. Are any adverse effects anticipated during the course of this research project? Please describe these and explain how these will be handled.

14. If your study plans to involve fieldworkers/research assistants in the data collection, how will they be prepared for the data collection and how will their safety be ensured throughout the data collection process?

15. How will the research data be secured and stored? When and how (if at all) will data be disposed of? (including, for example, survey data and interview transcripts):

    Please note that the research material should be kept for a minimum period of at least five years in a secure location by arrangement with your supervisor (*if student study*).

16. Is this research supported by funding that is likely to inform or impact in any way on the design, outcome and dissemination of the research?
    YES ☐ NO ☐

    If yes, please provide an explanation.

17. Has any organization/company participating in the research or funding the project, imposed any conditions to the research?
    YES ☐ NO ☐

18. Do you, or any individual associated with or responsible for the design of the research, have any personal, economic interests (or any other potential conflict of interests) that could reasonably be regarded as relevant to this research project?
    YES ☐ NO ☐

    If yes, please provide full details.

Section 4: Formalisation of the application

I certify that all information provided above is correct and that it will apply throughout the performance of the proposed research and that I shall be responsible for the safeguarding of the confidentiality of human subjects' information involved.

I agree to comply with the UWC Biomedical Research Ethics Committee's Standard Operating Procedures, its Terms of Reference and the SA Department of Health *Ethics in health research: Principles, Structures and processes,* and, if applicable, the SA Department of Health, *South African good clinical practice guidelines (Please provide evidence of training received if your study includes clinical trials).*

I agree to submit an Annual Progress Report to BMREC outlining progress and updates on this project.

	NAME	**SIGNATURE**	**DATE**
Primary Researcher / Thesis Supervisor			
Co-Primary Researcher			
Head of Department			
Student Researcher			

PLEASE ENSURE THAT ALL THE RELEVANT SIGNATURES HAVE BEEN OBTAINED BEFORE SUBMITTING YOUR APPLICATION TO YOUR FACULTY COMMITTEES.
INCOMPLETE APPLICATION WILL NOT BE REVIEWED BY BMREC AND WILL AUTOMATICALLY RETURNED TO THE FAULTY COMMITTEE

PLEASE NOTE ETHICS APPLICATIONS APPROVAL CAN ONLY BE SUBMITTED FOR EXPEDITED REVIEW IF:

The study is classified as a low-risk study
Access to funding is dependent on expedited ethics clearance
Urgent health crises are dependent on the results of the study

- **Hereafter, please list all the appendices referred to in your proposal in all the languages relevant to your study.**
- **This should be followed by a full research proposal and supervisor profile forms (***in the case of student researchers***).**