Ethics Review Board

Fix passport photo of Principle Investigator or Lead Researcher

APPLICATION FORM

Prospective Research

This form should be completed using the *Guidance for Submitting an Application for Research Ethics Review* available on the Daystar University Website (application instructions). ***All proposals submitted to DU-ERB should be in English or Kiswahili.***

SECTION 1. ADMINISTRATIVE INFORMATION [File No: office only]

Project Title:				
State if this is first submission or resubmission. ( ) First Submission ( ) Resubmission				
If resubmission state areas revised:				
1.1 Research team information				
Principle Investigator (PI) name				
Staff/Student Number		Department		
Email		Phone		
Study start date		Study end date		
Co-investigator names and affiliations				
Contact person for this submission (if not PI)	Name			
	Email		Phone	

1.2 For student submissions:			
Degree program			
Supervisor name and department			
Supervisor Email		Phone	
Proposal Defence Date:			

Department/School clearance	
Authorizing signature(HOD/Dean): Date:	Official Stamp

1.3 Has this proposal been reviewed elsewhere? ( ) Yes ( ) No.		
If yes, please provide details	Where (with contacts)	Status (Verdict)

1.4 Research Funding	
Agency	
Award Number	

1.5 The following box *must* be checked for the submission to be accepted by the DU-ERB)
[ ] I am the **lead researcher** and agree to conduct this research following the principles of Daystar University Ethics Review Board

SECTION 2. PROJECT DESCRIPTION

2.1 Summary
2.1.1 In lay language, describe the rationale, purpose, study population and methods. Include the background information or literature to contextualize the study. Mention what new knowledge is anticipated, and whether this is a pilot project or fully developed study. [350 - 500 words]
2.1.2 If a phased review is being requested, describe why this is appropriate for this study, and which phase(s) are included for approval in this application. [ ] Not applicable

2.2 Research question
State the hypotheses, the research questions or research objectives.

2.3 Recruitment
2.3.1 Identify the study population. Describe how many participants are needed and how this was determined (Sample and sampling procedure).
2.3.2 Describe recruitment plans and append recruitment instruments. Describe who will be doing the recruitment and what actions they will take, including any screening procedures. Describe and justify any inclusion / exclusion criteria.
2.3.3 Describe any community or organizational permissions needed to recruit your participants (attach support letters). Describe any other community consent or support needed to conduct this research. (If the research involves children or people not able to give informed consent, please complete section 2.10). [ ] Not applicable

2.4 Informed consent process
2.4.1 Describe the informed consent process, including any plans for ongoing consent (how and when the research will be described to prospective participants, by whom, how the researcher will ensure prospective participants are fully informed). If non-written consent is proposed, describe the process. Address how any third party consent (with or without assent) will be managed. Append copies of all consent/assent documents, including oral consent scripts.
2.4.2 Discuss how participants will be given the opportunity to withdraw (their participation and/or their data) and any limitations on this. [ ] Not applicable
2.4.3 If an exception to the requirement to seek prior informed consent is sought, explain why. [ ] Not applicable

2.5 Methods and analysis
2.5.1 Describe the study design, where the research will be conducted, what participants will be asked to do and the time commitment, what data will be recorded using what research instruments (append copies). [ ] This is a clinical trial (physical or mental health intervention) – ensure section 2.11 is completed
2.5.2 Describe plans for data analyses.
2.5.3 Describe any compensation that will be given to participants and how this will be handled for participants who do not complete the study. Discuss any expenses participants are likely to incur and whether/how these will be reimbursed.
2.5.4 Describe and justify any use of deception or nondisclosure and explain how participants will be debriefed. [ ] Not applicable

2.5.5 Describe the role and duties of local researchers (including students and supervisors) in relation to the overall study. Identify any special qualifications represented on the team relevant to the proposed study (e.g. professional or clinical expertise, research methods, experience with the study population, statistics expertise, etc.).

2.6 Privacy & confidentiality

2.6.1 Describe any provisions for ensuring privacy and confidentiality (or anonymity). Describe who will have access to data and why, how data will be stored and handled in a secure manner, how long data will be retained and where. Discuss any plans for data destruction and/or de-identification.

[ ] This research involves personal health records (ensure section 2.12 is completed)

2.6.2 Describe how participant confidentiality will be protected when research results are shared. Discuss whether participants will be identified (by name or indirectly). If participants will be quoted address consent for this, including whether quotes will be identifiable or attributed.

2.6.3 Address any limits on confidentiality, such as a duty to disclose abuse or neglect of a child or adult in need of protection, and how these will be handled. Detail any such limits in consent documents.

[ ] Not applicable

2.6.4 Will any information that may reasonably be expected to identify an individual (alone or in combination with other available information) be accessible to other research participants/non-participants? This includes sharing information with team members, use of survey companies, use of software.

[ ] No

[ ] Yes. If yes, describe how you comply with the DU-ERB privacy protection policy.

2.7 Provision of results to participants

2.7.1 The DU-ERB encourages researchers to share study results with participants in appropriate formats. If you plan to share study results with participants, discuss the process and format.

[ ] Not applicable

2.7.2 If applicable, describe how participants will be informed of any incidental findings – unanticipated results (of screening or data collection) that have implications for participant welfare (health, psychological or social).

[ ] Not applicable

2.8 Risk & benefit analysis

2.8.1 Discuss what risks or discomforts are anticipated for participants, how likely risks are and how risks will be mitigated. Address any particular ethical vulnerability of your study population. If applicable, address third party or community risk. Risks to privacy from use of identifying information should be addressed.

2.8.2 Identify any direct benefits of participation to participants (other than compensation), and any indirect benefits of the study (e.g. contribution to new knowledge)

2.9 Conflict of interest

Describe whether any dual role or conflict of interest exists for any member of the research team in relation to potential study participants (e.g. TA, fellow student, teaching or clinical relationship, employer/employee, and/or study sponsors, and how this will be handled.

[ ] Not applicable

2.10 Research with children or people not able to give informed consent

[ ] Not applicable – go to 2.11

2.10.1 If the proposed research involves children or people not able to give informed consent, describe the plan for stakeholder's (parents, guardians, heads of institutions, etc) engagement. Attach supporting letters, research agreements and other relevant documents, if available. If stakeholder's engagement is not sought, explain why the research does not require it.

2.10.2 Describe any plans for returning results to the stakeholders and any intellectual property rights agreements negotiated with them, with regard to data ownership. If there are specific risks to the stakeholders involved, ensure these have been addressed in section 2.8.1.

2.11 Clinical trials

[ ] Not applicable – go to 2.12

2.11.1 Does the proposed research require clinical trial registration, in keeping with national and international regulations?

[ ] No. Please explain why not.

[ ] Yes. Please indicate where it was registered and provide the registration number.

2.11.2 If a novel intervention or treatment is being examined, describe standard treatment or intervention, to indicate a situation of clinical equipoise exists. If placebo is used with a control group rather than standard treatment, please justify.

[ ] Not applicable

2.11.3 Clearly identify the known effects of any product or device under investigation, approved uses, safety information and possible contraindications. Indicate how the proposed study use differs from approved uses.

[ ] Not applicable

2.11.4 Discuss any plans for blinding/randomization.

2.11.5 What plans are in place for safety monitoring and reporting of new information to participants, the ERB, other team members, sponsors, and the clinical trial registry? These should address plans for removing participants for safety reasons, and early stopping/unblinding/amendment of the trial. What risks may arise for participants through early trial closure, and how will these be addressed? Are there any options for continued access to interventions shown to be beneficial?

2.12 Use of personal health information [ ] Not applicable
2.12.1 Describe the personal health information required and the information sources, and explain why the research cannot reasonably be accomplished without the use of that information. Describe how the personal health information will be used, and in the most de-identified form possible.
2.12.2 Will personal health information be combined with information from other sources to form a composite record (data linkage)? Will the research create individually identifying health information by combining information from two or more databases without the consent of the individuals who are the subjects of the information (data matching)? [ ] No. [ ] Yes. Describe the other information and how linkage will be conducted, and/or why data matching is required.
2.12.3 Describe reasonably foreseeable risks to privacy and how these will be mitigated.

Declaration:

I _____ (Name in full) of ID No/Passport No _____ being the principle investigator of this study do hereby declare that the information provided here is true to the best of my knowledge and that I may be held liable for any false or misleading information.

Signature: _____

Date: _____

SECTION 3. APPENDICES

3.1 Appendices Checklist. Append all relevant material to this application. This may include BUT not limited to:

[ ] 2 copies of the research proposal

[ ] Payment receipt (see application guidelines)

[ ] Copy of National ID/Passport

[ ] Recruitment documents (posters, oral scripts, online postings, invitations to participate, etc.)

[ ] Screening documents

[ ] Consent/assent documents or scripts

[ ] Research instruments (questionnaires, interview or focus group questions, etc.)

[ ] Debriefing forms

[ ] Permission letters (Children and persons not able to give informed consent)

[ ] Support letters

[ ] Informed consent forms