**Protocol Form**

**Using this document:**

* The purposed of this document is to provide you with a guide for providing the information that the KABU-ERC needs in order to review your protocol. Each question provides instructions as well as suggestions for completing the question. After every **Instruction** section, there is a **Response** area; please provide your answer in **Response** area.
* If you have questions about how to respond to a question, contact our office for additional help.

**Submitting a protocol:**

* This document has three parts: **Section A “Investigator’s Agreement**,” **Section B “Protocol Information,”** and **Section C “Description of the Research Study.”** To submit a protocol, complete this document and email it and any accompanying materials (i.e. consent forms, recruitment materials, instruments) to email
* **Please note that we can only accept forms in Microsoft Word format and in this form only. Do not submit your responses in a separate document.** We do not accept hand-written documents (with the exception of the signature on the Investigator’s Agreement). Please submit the electronic form in its entirety; do not remove the signature pages from the document even though you will submit these pages as a pdf/hard copy. Do not alter this form; simply provide your responses in the **Response** area. **Forms that are not completed correctly will be returned to you and you will be required to complete them correctly before they are accepted. No exceptions!** If you need help using our form, please contact our office.
* **Section A “Investigator’s Agreement”** must also be submitted with signatures. Signed materials can be submitted by mail, P.O Private Bag 20157 Kabarak or email (scanned document to email Signed materials can also be submitted in person to our office
* You will be contacted in 7-14 business days regarding your submission (depending on the protocol queue). **A. Investigator Agreement**

**BY SIGNING THIS DOCUMENT, THE INVESTIGATOR AGREES:**

1. That **no participants will be recruited** or data accessed under the protocol **until** the Investigator has received the **final approval or exemption letter** signed by the Chair of the Institutional Review Committee (KABU-ERC) or designee.
2. That any **modifications of the protocol or consent form** will not be implemented without prior **written approval** from the KABU-ERC Chair or designee except when necessary to eliminate immediate hazards to the participants.
3. That any **deviation from the protocol and/or consent form** that are serious, unexpected and related to the study or a **death** occurring during the study **will be reported promptly to the ERC Review Board** in writing.
4. That all protocol forms for **continuations of this protocol** will be **completed** and returned **within the time limit stated** on the renewal notification letter.
5. That **all participants will be recruited and consented as stated in the protocol approved** **or exempted** by the KABU-ERC board. If written consent is required, all participants will be consented by signing a copy of the consent form that has a non-expired IRB approval stamp.
6. That the KABU-ERC office will be notified within **30 days** of a **change in the Principal Investigator** for the study.
7. That the KABU-ERC office will be notified when **the active study is complete**.

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| **Principal Investigator (print)** | **Date** |
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| **Protocol Title** | **Protocol Number (ERC office only)** |
|  | |
| **Principal Investigator’s Signature** | |

**FOR STUDENT AND STAFF PROPOSALS ONLY**

**BY SIGNING THIS DOCUMENT, THE FACULTY SUPERVISOR HAS READ THE PROPOSAL FOR RESEARCH AND AGREES:**

1. To **assume overall responsibility** for the conduct of this research and investigator.

2. To **work with the investigator**, and with the ERC Review Board, as needed, in **maintaining compliance with this agreement**.

3. That the **Principal Investigator is qualified to perform this study**.

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| **Faculty supervisor (print)** | **Date** |
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| **Faculty supervisor’s Signature** | |

**The ERC Review Board reserves the right to terminate this study at any time if, in its opinion, (1) the risks of further experimentation are prohibitive, or (2) the above agreement is breached.**

**Protocol Form**

**B. Protocol Information**

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| **KABU-ERC Protocol Number (assigned by ERC office, leave blank):** | | |  |
| **KABU-ERC Grant Approval number:** (If you received a Grant Approval prior to submitting a protocol, please include the number issued by our office. If you did not submit a Grant Approval Form, please leave this line blank.) | | |  |
| **Submission Type** (delete all those that don’t apply): | | | **New Protocol**  **Resubmission of previously rejected protocol**  **Updated protocol form (includes all previous modifications)**  **Reopening expired protocol**  **4th Year Submission** |
| **Protocol Title:** | | |  |
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| **Principal Investigator:** | | |  |
|  | Professional Title: | |  |
|  | School | |  |
|  | Department | |  |
|  | Campus Box number: | |  |
|  | Mailing Address | |  |
|  | Telephone: | |  |
|  | KABU e mail address (no aliases, please): | |  |
|  | Preferred e-mail address for correspondence (if applicable): | |  |
|  | You are (delete all those that don’t apply): | |  |
|  | This research is for (delete all those that don’t apply): | | **Class project**  **Master’s Thesis**  **Doctoral Dissertation**  **Faculty Research**  **Other (please describe)** |
|  | Primary contact for the protocol (if other than the principal investigator): | |  |
|  |  | Contact’s Email: |  |
|  |  | Contact’s Phone: |  |
| **Faculty supervisor:** | | |  |
|  | School | |  |
|  | Department | |  |
|  | Campus Box number: | |  |
|  | Telephone: | |  |
|  | KABU e mail address (no aliases, please): | |  |
|  |  | | |
| **Other Researchers\*:** | | |  |
|  | Please list all other researchers in this study that are associated with KABU.\* Please provide the following information for each researcher: Name, KABU email address (no aliases, please.) | |  |
|  | Please list all other researchers not associated with KABU.\* Please provide the following information for each researcher: Name, Institution, Phone Number, Mailing Address, Email Address. | |  |
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| **Funding Source: If research is funded, please provide the following:** | | |  |
|  | Name of the funding source | |  |
|  | Type of funding source (delete all that **don’t** apply): | | Private grant (non-profit institution)  Private grant (for profit institution)  Government of Kenya (NRF)  KABU grant  Sub Contract |
|  | Describe the funding source (optional unless you selected “sub contract” above) | |  |
|  | funding period (month/year): | |  |
|  | grant number: | |  |
| **Anticipated start date for collecting and analyzing data:** | | |  |
| **Anticipated completion date for collecting and analyzing data:** | | |  |

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| **C. Description of the Research Study** |
| 1. **Study Overview:** Give a brief overview of your project. Consider the following when framing your response:    * + What is your purpose in conducting this research?      + Include information about the study’s logistics (where and when it will be conducted, what instruments you will use). What will you be asking participants to do, and what do you hope to learn from these activities?      + If your study has more than one phase, please clearly map out the different phases.      + If your study is a multi-site study, please describe. |
| **Response 1: (enter response below this header)** |
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| 1. **Participants: Please describe as best you can the population(s) you plan to work with.** Please describe them in the terms that are most pertinent to your project. We need to understand how working with them will further your research objectives and what steps need to be taken in order to minimize risk to them. **Please respond to questions a-e in this section.** |
| * 1. Please fill in the following blanks below. If you are working with more than one population, please provide information for each group. |
| **Response 2-a: (enter response below this header)** |
| Age:  Gender:  Race:  Estimated number of participants: |
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| * 1. Describe how participants will be identified and selected to participate in the study. Are there specific populations that you will be targeting and if so, why? Are there potential participants that you will exclude from the study and if so, why? |
| **Response 2-b: (enter response below this header)** |
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| * 1. Is the population and/or individual participant “Risk -sensitive”? (You will have an opportunity to discuss the risks in more detail in the “Risks” section.) Is the population and/or individual participant “Vulnerable”? (This issue relates to the participant’s capacity consent; you will have an opportunity to discuss your consent procedures in more detail in the “Consents” section.) |
| **Response 2-c: (enter response below this header)** |
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| * 1. Will you deceive and/or withhold information from the participants about the study? If so, please justify why deception and/or withholding information from the participants is necessary and describe the deception. Using deception requires specific consent forms and processes; please describe this process in the **Consent section** under **Response 3-a** and **3-b**. |
| **Response 2-d: (enter response below this header)** |
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| * 1. What special experience or knowledge do you have that will allow you to work productively and respectfully with your participants? What special experience or knowledge does your faculty sponsor have in relation to your research participants? |
| **Response 2-e: (enter response below this header)** |
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| 1. **Consent:** Consent is an on-going process that starts when you first inform your participant about the study through your recruitment/advertising efforts and ends when the participant’s data are no longer needed. The ERC regulations require a Formal consent process takes place where you provide participants with specific information about the study (usually provided in the consent form) and the participants are required to sign the form. Not every study will fit this mold and there are some alternative methods for conducting the formal consent procedure. **In general, the Board needs to understand how participants will be recruited and consented to participate in the study.** Please note that if your study qualifies for exemption, you will not be required to follow the regulations for consent, but the Board may require that you provide information about the study to the participant. **Please respond to questions a-d in this section.** |
| * 1. How will you approach/recruit participants to participate in your research? **Please provide all materials used to contact participants in this study. These materials could include letters, emails, flyers, advertisements, etc. If you will contact participants verbally, please provide a script that outlines what you will say to participants.** |
| **Response 3-a: (enter response below this header)** |
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| * 1. What is your consent process? Who will present the consent information and how will it be presented? How will you document consent? Are your participants able to sign a form, and if not, how will you document consent? Will you use more than one form (if you use more than one version of the consent form, each form needs to have a unique title in order for our staff to keep track of the different forms)? When and where will participants receive the consent form? Who will give them the consent form? Will you pay participants? |
| **Response 3-b: (enter response below this header)** |
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| * 1. Are any of your participants unable to consent (i.e. vulnerable population)? These populations include (but are not limited to): minors (participants under the legal age of consent), prisoners, and participants with diminished mental capacity. These participants generally need a parent (or surrogate) consent form and a participant assent form (prisoners being the likely exception unless they are minors too). |
| **Response 3-c: (enter response below this header)** |
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| * 1. What is your relationship to your participants? Do you know them personally or hold any position of authority over them? Do any of the researchers (including the Faculty supervisor) have positions of authority over the participants, such as grading authority, professional authority, etc.? Are there any relevant financial relationships? |
| **Response 3-d: (enter response below this header)** |
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| 1. **Material/data collected**: For most ERC studies, the risk to participants often lies in the information that is collected from them. Thus the manner in which the data are collected, how they are stored, and how the data are reported in your research is an important part of determining the risk to participants. When you develop your procedures, consider **minimizing or eliminating the collection of identifying information** where possible and **provide justification** as to why it needs to be collected. **Please respond to questions a-d in this section.** |
| * 1. Are any of the data already collected? (If you are only using archival data, please use the Archival Data protocol form instead of this form.) Are the data publicly available or part of a private collection? Please describe the data set(s) and provide a list of data fields you will use (when applicable). What will you do to protect the confidentiality of the pre-existing data? |
| **Response 4-a: (enter response below this header)** |
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| * 1. What will you do to protect the privacy of your participants? Describe the process of collecting data from your participants. What will you do to protect the confidentiality of your participants? Describe the kinds of information you will gather and the material forms it will take. Describe the level to which the participant’s identity will be known, if that information will be collected (and why), and how the identifying information will be linked with the participant’s data. If you don’t intend to collect identifying information, describe your process for keeping the data anonymous. |
| **Response 4-b: (enter response below this header)** |
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| * 1. Will you use audio recordings, photographs, video recordings or other similar data recording devices? Please justify why it is necessary to use these devices, how you will use them, and what you will do with the data after they are collected. |
| **Response 4-c: (enter response below this header)** |
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| * 1. How will your materials be Stored? Discuss both how you plan to store it while you are collecting and actively analyzing it, and your long term plan for maintaining it when the active research phase is finished. How will your data be reported in your study? Will you report the results in aggregate or will individual data be discussed? |
| **Response 4-d: (enter response below this header)** |
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| 1. **Risks:** Almost any intervention into other people’s lives carries with it the potential to cause them social, psychological, physical, or legal harm. However, not every interaction will put a participant at risk beyond what is considered minimal. **Please describe to the Board the potential risks and the probability of harm to the participants in your study.** In this section, consider the following when framing your response:  * Describe the risks to the participants in your study. Does your study include “risk-sensitive” participants (as identified in the Participants section)? What is the probability that harm could occur? * Describe what you will do to minimize these risks. Describe what you will do if a harmful situation occurs. * Would a loss of confidentiality of any of your materials put participants at risk? If so, how will you prevent this from happening? |
| **Response 5: (enter response below this header)** |
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| 1. **Benefits:** Benefits help to outweigh the risks to the participants, though not every study will have direct benefits to the participants. In this section, consider the following when framing your response:  * Will there be any benefits to the participants in your study? If so, what are they? * What is the general importance of the knowledge you expect to gain? |
| **Response 6: (enter response below this header)** |
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