**Archival Data 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**.

|  |  |
| --- | --- |
|  |  |
| **Principal Investigator (print)** | **Date** |
|  |  |
| **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**.

|  |  |
| --- | --- |
|  |  |
| **Faculty supervisor (print)** | **Date** |
|  | |
| **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**

|  |  |  |  |
| --- | --- | --- | --- |
| **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:** | | |  |
|  | | |  |
| **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. | |  |
|  | | |  |
| **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:** | | |  |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **C. Description of the Research Study** | | | | | | | | | | | | | | | |
| 1. **Study Overview:** Give a brief overview of your project. If your study has more than one phase, please clearly map out the different phases. Consider the following when framing your response:    * + What is your purpose in conducting this research? How does the project contribute to the advancement of knowledge and why is it worth doing?      + Provide the Board with an overview of the data you will use. What does the data consist of? Are you using data sets, video tapes, audio tapes, journal entries, transcripts, etc.?      + What is the estimated number of participants in the data? If you are using data sets, include a list of the data fields you will use either in this section or as an addendum to this form. | | | | | | | | | | | | | | | |
| **Response 1: (enter response below this header)** | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | |
| 1. **Data:** In this section, please describe the how the data will be obtained and handled confidentially. **The IRB-SBS asks that if it is possible for you to de-identify your data (i.e. strip the data of participants’ identifiable information), please construct your study in this manner. Data collection in which the subject is not identifiable (i.e. anonymous) offers more protection to participants and can be exempted in most cases.**   Answer the questions below by marking the correct box with an “x” and providing additional responses where appropriate. | | | | | | | | | | | | | | | |
| * 1. The data in this study consist of: | | | | | | | | | | | | | | | |
|  |  | **Publicly-Available data** | | | | |  | **Private data** | | | | |  | **Both private and public data** | |
| * 1. Describe below how you will gain access to data. If you will use ANY private data, also include proof of permission to access the data: | | | | | | | | | | | | | | | |
| **Response 2b: (enter response below this header)** | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | |
| * 1. Describe below how you will store data. | | | | | | | | | | | | | | | |
| **Response 2c: (enter response below this header)** | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | |
| * 1. Do any of the archival materials or data contain identifying information? | | | | | | | | | | | | | | | |
|  | | |  | **Yes** | | | | |  | **No** | | | | |  |
| **If YES, explain what identifying information will be kept and why identifying information is necessary for the study. If it is not necessary for the study, then explain when and how the data set will be de-identified.** | | | | | | | | | | | | | | | |
| **Response 2d: (enter response below this header)** | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | |
| * 1. Can the names of the participants be deduced from the de-identified data set(s)? Can the participants be re-identified (i.e. their identities could be reconnected to their data)? | | | | | | | | | | | | | | | |
|  | | |  | **Yes** |  | **No** | | | | |  | **NA/ All data are identifiable** | | | |
| **If YES, please describe how identities might be deduced and/or the participant’s might be reconnected to their data. What will you do to prevent this from happening?** | | | | | | | | | | | | | | | |
| **Response 2e (enter response below this header)** | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | |
| * 1. Will you merge multiple data sets? | | | | | | | | | | | | | | | |
|  | | |  | **Yes** |  | **No** | | | | |  | **NA/ All data are identifiable** | | | |
| **If YES**, **how will this affect the confidentiality/ anonymity of the data (if at all)?** | | | | | | | | | | | | | | | |
| **Response 2f: (enter response below this header)** | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | |
| 1. **Risks** : Accessing other people’s data carries with it the potential to cause them social, psychological, physical, or legal harm. However, accessing data (particularly de-identified data) will often not put a participant at risk beyond what is considered Minimal. **Please describe to the Board the potential risks and the probability of harm in using the proposed data.** In this section, consider the following when framing your response:  * **Describe the risk 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 3: (enter response below this header)** | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | |
| 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 the data analysis provide any benefits to the participants? If so, what are they? * What is the general importance of the knowledge you expect to gain? | | | | | | | | | | | | | | | |
| **Response 4: (enter response below this header)** | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | |