**Modifying a Protocol**

It is important that your protocol reflects your current procedures for collecting data and interacting with participants. If you need to change what you originally submitted, it is important that you report this change. If your modification is a minor change to Section B: Protocol Information, you can submit the change to our office via our email. If you are making a significant change to Section B that would impact the level of risk to the study, or if you are making a change to Section C, please submit the Modification Submission Form, a modified copy of your protocol, and any other documents that are affected by the change.

**Submitting a Modification Request:**

To submit a modification, please do the following:

* Submit **one electronic copy** of the **Modification Form** as a cover sheet to the proposed changes.
* Submit **one signed copy** of the **Modification Form**. (Signed materials can be submitted by mail, P.O Private Bag-20157 Kabarak or email (scanned document to **email** ).
* Submit **electronic copies** **of any materials affected by the modification**, such as the **Protocol Form, Consent Form(s), instrument(s), advertisement(s)**, etc. Modify the documents so that they reflect the changed procedures. To highlight the changes in the document(s), use the **“Track Changes”** feature in Microsoft Word (please use where possible).
  + To enable the **Track Changes** feature, go to **Tools: Track Changes**
  + Please note that to show the changes made in the document, enable the **Track Changes** feature first before you make any changes to the document.
  + **If your protocol was created between 10/01/05- 09/01/07**, you will need to unprotect the document before you can use the Track Changes feature. To unprotect the document, go to **Tools: Unprotect Document.** If you are unable to navigate to the text in the gray boxes, try using the cursor instead of clicking on the box with the mouse

**Modification Submission Form: Approved/ Exempt Protocols Section C**

**Current Protocol Information:**

|  |  |
| --- | --- |
| KABU-ERC Protocol Number |  |
| Protocol Title |  |
| Principal Investigator |  |
| Primary Contact (If other than PI; include name, email address, and phone) |  |

**Types of Modifications (check all that apply):**

|  |  |  |
| --- | --- | --- |
|  | Change in study population (ages, selection criteria, inclusion of vulnerable subjects, increased numbers) | |
|  | Change in recruitment methods or advertising | |
|  | Modification of methodology and/or procedures | |
|  | Modification to consent form(s) and/or the process by which consent is obtained | |
|  | Modification in instruments/measures and/or type of data collected | |
|  | Other modification (define): |  |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Are the risks to subjects affected (increased or decreased) by the modification(s)?** | | **YES** |  | **NO** |  |
|  | **If yes,** please explain below: | | | | |
|  | | | | | |

**Provide a detailed description of and rationale for the requested modification(s). Number each separate modification.**

|  |
| --- |
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| --- | --- | --- |
|  |  |  |
|  |  |  |
| **Signature of Principal Investigator** |  | **Date** |
|  |  |  |
|  |  |  |
| **Signature of Faculty Supervisor (if applicable)** |  | **Date** |