**TUM-ERC approved proposal update form**

Use this form to renew the approval period of an application or to modify its contents.

It may also be used to report an Adverse Event or at close of the study.

I. **PROJECT IDENTIFICATION. (**Please provide the following):

**a. Principal Investigator**

Name: _____

Institutional Affiliation: _____

Mailing Address: _____

Phone: _____ Fax: _____

E-mail: _____

**b. TUM-ERC Approval No.**_____

**c. TUM-ERC Proposal amendment No. :** _____

**d. Project tittle:** _____

_____

**e. Dates of previous approvals/amendments (List all)**: _____

**II.** PROJECT **STATUS**. Please select the box that best defines the current status of the project for update

☐ New participant enrolment still in progress ☐ Participants taking part in study procedure

☐ Participants follow-up ongoing ☐ Approval for data analysis only

☐ Study complete ☐ Study has not begun (*Give reasons*)

☐ Study closure (*Give reasons for closure*)

**III. UPDATE REQUEST:** identify the type of action that best suits your request.

Select **all** actions that may be appropriate during the year of update

☐ Final Research Report: Please submit **one** signed copy and a soft copy of the report. Complete **all** sections of the form showing Renewal label. *Note that ERC approval will be needed during data analysis period of this activity.*

☐ Renewal only: Check this box if approval for this human participant research expires **within ten weeks** of this submission. Complete **Section IV** of this form.

☐ Renewal and Modification: Check this box if this is a request for both types of review. Complete **all** sections showing the Renewal label **only** and those sections with the applicable modification label.

☐ Modifications Only: Check this option if your request is **only** to modify the approved application content. Complete only those sections with the applicable Modification label in the section heading.

☐ Adverse Events Reports: Please provide the information required in **Section VII** of this form.

☐ Study closure: Check this option if your request is only to report the intended closure of a study. Complete **Section VIII** of this form.

**NOTES:**

1. You may not recruit new participants or continue your activity with previously enrolled participants unless you have current approval from the TUM-ERC
2. Please note that modifications may not be implemented until approved by the TUM-ERC.
3. Note also that the approval period for a modification is equal to that of the original TUM-ERC application.
4. Provide your original signature in SECTION IX: (SIGNATURE AND ANNUAL APPROVALS) of this application form.

## *IV. ANNUAL RENEWAL ONLY*

Attach a soft copy of a detailed progress report to *erc@tum.ac.ke, tum.erc.2019@gmail.com* covering activities for the past one year. Use the Also complete section V

## *V. ANNUAL RENEWAL AND MODIFICATION CATEGORIES*

**SUMMARIES**

Every request submitted in this form should be accompanied by an **abstract** summarizing the approved purpose, research procedures and participant population in this project. Also provide an up-to-date progress of this approved research project. Submit one copy of the written manuscript, if any, based on the data from this project.

**Please select from the applicable options below to modify the information in your approved application.**

### V.1 ☐ RENEWAL AND FUNDING MODIFICATIONS:

**Submit one hard copy and a soft copy**

**1.1. Please** attach **all** current and pending grant and contract information descriptors, as follows:

1.1.1 Funding Type (grant, fellowship, training, contract, other)

1.1.2 Name of the Funding Agency.

1.1.3 Principal Investigator of funded Proposal

1.1.4 Title of Proposal

1.1.5 Approval Period

**1.2. To add a new funding proposal to your application:** please attach a descriptive summary of **all** human research activity in your project that will be funded by this new proposal. Please describe any difference from what has already been approved by the TUM- ERC.

If multiple research projects aim apply to this proposal, specify what aspects of the new funding pertains to this specific research application (**Highlight the applicable section).**

**Submit two copies of the <u>new grant proposal.</u>**

**V.2** ☐ **<u>RENEWAL AND CONFLICTS OF INTEREST MODIFICATIONS:</u>**

**Submit one typed copy and a soft copy to the official email address**

If there has been a change in the financial interests of any of the members of the research team that pertains to the performance of this research, please provide a copy of the Letter of Conflict-of-Interest Resolution from your institution.

**V.3** ☐ **<u>RENEWAL AND MODIFICATIONS OF CONSENT DOCUMENTS</u>**

**1.1.1. To request the Renewal** of this application, you need to attach two copies of each **currently approved** consent/assent form and/or oral consent script.

**1.1.2. To request a Modification** to the consent/assent forms and/or oral consent script, submit one hard copy and a pdf soft copy of the new forms:

*Please highlight the modified text on one copy of the new consent form to reflect the changes being requested in either purpose, procedure, population, investigators and/or participants risks as described elsewhere in this form. (Provide a track change copy and a clean copy).*

- State the total number of approved consent forms in current use for this study.
- State whether this is a new consent form to replace a current version (and specify the approval date), or is an additional consent form.
- Indicate the language(s) of communication and provide the translation(s).

- A sample consent form and checklist are available on TUM website under the downloads

**V.4 ☐ RENEWAL AND MODIFICATIONS IN PARTICIPANT POPULATION AND/OR RECRUITMENT PROCESS:**

**Submit one hard copy and a soft copy of all revised or new recruitment materials.**

For **Renewals** of this approval, please attach a detailed account of the participant population to date according to the following information descriptors:

- What is the number of participants you are approved to enrol?
- How many participants have you enrolled since the project was initially approved?
- How many participants have you enrolled since the last renewal of your application?
- How many of your enrolled participants are currently actively participating in this project?
- How many additional participants will be needed to complete this project?

For **Modifications** of the approved participant population, provide a detailed description of the proposed changes and the reasons for these changes. Attach also a complete description of the originally approved study population (inclusion/exclusion criteria, age range, number of participants, approach and recruitment methods etc).

***V.5*** ☐ ***OTHER RENEWAL INFORMATION: For the last year of approval, please provide*** *the information below.*

- No. of on-site adverse events _____

  If you have not yet reported these Adverse Events to the TUM-SERC, please complete Category VII below.

- No. of complaints:_____ Explain how you handled each one.
- No. of participant withdrawals:_____ For each, explain why the participant withdrew from the study.
- No. of protocol violations:_____ Explain how you handled each one.

*SECTION VI: MODIFICATIONS ONLY SECTION*

**VI.1 ☐ MODIFICATION IN PROJECT PURPOSE:**

**Attach two typed copies of a memorandum and/or revised research proposal incorporating these changes.**

Describe in detail the changes/revisions to this research project, and explain the reasons for such changes.

**VI.2 ☐ MODIFICATION IN RESEARCH PROCEDURE:**

**Submit two copies of all revised forms, if applicable.**

Attach a detailed description, and explain the rationale for the proposed changes. Describe how they will affect the level of risk to research participants and what changes to the consent process may result from this modification (if you believe no changes are necessary, please state)

**VI.3 ☐ TRANSFER OF BIOLOGICAL MATERIALS:**

**Attach two copies of a detailed description of this request.**

To request approval for the transfer of biological materials, you must submit to the TUM-ERC the details of the types, destinations and purpose of the materials being transferred and amount (including the specific type of tests that will be performed). You must also specify and document the type of government clearance applicable to this transfer. A strong justification for the transfer/shipment of the biological materials is mandatory. A materials transfer form must also be filled.

**VI.4 ☐ MODIFICATION IN RESEARCH SITES**

**Submit one copy of a Letter of Support from each new site.**

The letter should acknowledge that the agency is familiar with the study purpose, procedure, and with the investigator and their affiliation with the home institutions and reason for new site. Provide a written justification for modification in research sites

**VI.5** ☐ **UPDATE LIST OF INVESTIGATORS AND COLLABORATORS**

Provide information requested below for each investigator; also indicate if an investigator is no longer associated with this research. **If the Principal Investigator is appointing a new PI, both the current PI and new PI should sign this form.**

**Name and title**_____ **Research Position**_____ **Home Institution**___

Mailing Address_____ Phone_____ Fax_____ e-mail_____

**VI.6** ☐ **PROTOCOL AMENDMENTS and INVESTIGATOR DRUG BROCHURE (for US FDA regulated studies only).**

Describe what changes are being made if no other modification options have applied above, and assess any changes in the level of risk to volunteer participants. If you believe there are no changes in risks, please state.

If submitting a protocol amendment: **submit one hard copy and a soft copy of the amendment and one copy of the revised protocol.**

If submitting an updated Investigator Drug Brochures: **submit one copy of the brochure.**

**VI.7** ☐ **REPORTING OFF-SITE ADVERSE EVENTS:**

***Submit one copy each***

Submit a memorandum stating how many new or follow ups of off-site adverse events are being reported here, list the dates of occurrence and provide a brief description of each event.

Follow-ups of previously reported events should include the date of the original report.

Assess whether or not changes are required to the consent form, and whether or not you believe changes are required.

Also state whether enrolment is still open for this study and whether or not participants are still undergoing study procedures.

**VI.8 ☐ <u>OTHER INFORMATION: (new protocol violations, letter of complication, data monitoring reports, etc).</u>**

**Please submit two copies.**

**SECTION VII: <u>ON-SITE ADVERSE EVENTS (ON-LIVE REPORT)</u>**

**For every unexpected adverse event at any of your sites, provide two copies of a written memorandum with the information outlined below.**

1. Were any of these adverse events unexpected or more serious than expected?

   ☐ Yes ☐ No

2. If yes, did you send us an Adverse Event report? ☐ Yes ☐ No
3. Was the event attributable to a study procedure? ☐ Yes ☐ No

   If No, do not complete next AE section below

4. Was the event unexpected (not described in original application or consent form)

   ☐ Yes ☐ No

5. Was the event more serious than expected? ☐ Yes ☐ No
6. How was this event graded?
   - ☐ Mild (caused no limitation of usual activities)
   - ☐ Moderate (caused some limitations of usual activities)
   - ☐ Severe (caused inability to carry out usual activities)
7. Is this kind of adverse event described in the currently approved consent form?
   - ☐ Yes
   - ☐ No

   If not, will the event require changes in the consent form in research procedure?

1. ☐ No
2. ☐ Yes if yes attach a copy of the revised consent form with the changes highlighted.

8. Have you reported this event to the study sponsor? ☐ Not applicable ☐ Yes ☐ No
   if no, explain
9. Have you reported this event to the FDA ☐ Not applicable ☐ Yes ☐ No
   If no, explain
10. Have you reported this event to the NIH? ☐ Not applicable ☐ Yes ☐ No
    If no, explain
11. Has this kind of event happened before in connection with this study? ☐ Yes ☐ No
    If yes explain
12. Who is financially responsible for treatment of this adverse event?
    - ☐ Sponsor
    - ☐ Kenyan Health Department
    - ☐ Others specify
13. What is the estimated cost of treatment?
14. Where was care provided?
15. Subject's study code number:
16. Subject's age:
17. Subject's gender:
18. Where did the event take place? (Name)
19. What time did the event start and when did it stop? date and time
20. Describe the Serious Adverse Event including a summary of all relevant clinical information.

21. Have you made any changes in study procedures to reduce the possibility that this adverse event will happen again?
    - ☐ Yes. Explain
    - ☐ No. Explain

**SECTION VIII: ☐ STUDY CLOSURE**

Attach two copies of a detailed description and justification of this request. Review the TUM SERC Study Closure Policy and complete the Study Closure Application Form

**SECTION IX: SIGNATURES AND ANNUAL APPROVALS**

**I acknowledge that this TUM SERC Approved Application Update represents an accurate and complete description of my research activities.**

Name of Principal Investigator: _____

Signature: _____ Date: _____

This box is for Committee use only

**TUM-SERC Chair Name:** _____ _____

**Signature:** _____

**Type of Update requested:** _____

**Approved/Noted/Denied:** _____

***VALID ONLY AS LONG AS APPROVED PROCEDURES ARE FOLLOWED***