

**The required information for a PI to submit research protocol on NTDs (Initial Review) are:**

1. A submission form VCDREC (Research Proposal submission form) has to be filled in by the principal investigator and signed by the supervisor if the PI.
2. The investigator submits Nine (09) hard copies of the proposal and attaches the submission form to the front of each copy of the proposal.
3. Send a soft copies of the submissions to [admin@vcdrec.org](mailto:admin@vcdrec.org), [vcdmohrec@gmail.com](mailto:vcdmohrec@gmail.com)
4. Insert a **version number** and **Version date** on the protocol, consent forms and data collection tools. This is essential for version control and monitoring document use. **Include page numbers on the proposal as well for easy review.**
5. Evidence of Payment to the REC-Vector Control Division, Centenary Bank Mapeera Brach, Account NO. 3100050317, Swift Code: CERUBUGKA an equivalence in Ugandan Shillings based on daily **US\$ rates**. Please see information below on the rates that apply.

| REC-VECTOR CONTROL DIVISION RESEARCH CLEARANCE GUIDELINES |                                |                |  |   |                                |                                       |   |
|---|--------------------------------|----------------|--|---|--------------------------------|---------------------------------------|---|
| Bank Name   | Centenary Bank, Mapeera Branch | Type of review | Industry sponsored Clinical Trial Research | Non-industry sponsored Non Clinical Research (USD \$) | International Student research | Ugandan & EAC students research (PhD) | Ugandan & EAC students research (Masters) |
| US\$ Account  | N/A                            | Initial review | 600 \$                                     | 400 \$  | 400 \$                         | 300 \$                                | 28 \$ or 100,000 UGX                      |
| UGX Account   | 3100050317                     | Amendments     | 350 \$                                     | 300 \$  | 200 \$                         | NO FEE                                | NO FEE                                    |
| Swift Code  | CERUBUGKA                      | Expedited      | N/A  | 600 \$  | 200 \$                         | NO FEE                                | NO FEE                                    |
|   |                                | Annual renewal | 300 \$                                     | 200 \$  | 200 \$                         | NO FEE                                | NO FEE                                    |
|   |                                | Fast track     | 800 \$                                     | 600 \$  | 600 \$                         | NO FEE                                | NO FEE                                    |

6. Proposal should be submitted two weeks before the date of the meeting of the month; (VCDREC holds Monthly meetings are usually held every **1<sup>st</sup> Thursday** of the month, so for one to be considered for this meeting they should submit before the beginning of every month, the mode of operation is **first come first serve basis**).
7. First track and Expedited reviews take a maximum of **2-weeks** while normal **reviews take 3-4weeks**. Please note that VCDREC will provide feedback based on the application request made and type of study.
8. All research activities should include a local Investigator (Ugandan) to be part of the study. A written approval from the home institution must be submitted with the VCDREC application.
9. **Please note that a complete proposal must meet the following requirements for Initial Review (Checklist)**
  - Cover Letter
  - VCDREC Research Summary form
  - Full research Proposal including appendices (Time frame, Budgets, Consent/Assent forms with respective local translations, Data collection tools with respective translations and CVs of all Investigators on the study)

**Requirements when responding to VCD-REC Comments**

Usually after review by the VCDREC, the research investigators and team will receive comments and/or suggestions that require them to address/respond to before final approval is granted. This is how you should go about it:

1. A cover letter addressed to the VCDREC Chair

2. A compliance Report providing itemized responses to VCDREC comments and guidance for the changes made to the protocol if any
3. Printed four **(04)** copies of the revised protocol with track changes
4. Printed four **(04)** clean copy of the revised protocol.
5. A soft copy of both **revised track changed version** and **revised clean copy** of the protocol.

### **Requirements for continuing Review**

Approvals from the VCDREC, last for a period of **calendar one year** and therefore Principal Investigators are required to request for renewal of approval 02 months before the date of expiry, if the study is ongoing. This requires the following

1. A cover letter addressed to the VCDREC Chair requesting for renewal.
2. Investigators are required to submit the an annual progress report using the attached Template (**Annual Report Template**)
3. **Copy of UNCST Approval**
4. Any Publications arising from the study during the calendar year.
5. Evidence of Payment to the REC-Vector Control Division, Centenary Bank Mapeera Brach, Account NO. 3100050317, Swift Code: CERUBUGKA an equivalence in Ugandan Shillings based on daily **US\$ rates**.

### **Requirements for Amendment of the protocol**

An amendment refers to any made to the previously approved proposal, and any change/ amendment requires VCDREC approval before implementation even the change of a question in a questionnaire or change in title would require VCDREC review, as long as the change is being made to the protocol that has already been approved.

### **Requirements for an ammendment**

1. A cover letter addressed to the VCDREC Chair requesting for an ammendment.
2. Investigators are required to submit the printed four **(09)** copies of the revised/amended protocol with track changes
3. Investigators are required to submit the printed four **(09)** copies of the clean revised/amended protocol.
4. A soft copy of both **revised track changed version** and **revised clean copy** of the amended protocol.
5. **Copy of UNCST Approval if already had**
6. Evidence of Payment to the REC-Vector Control Division, Centenary Bank Mapeera Brach, Account NO. 3100050317, Swift Code: CERUBUGKA an equivalence in Ugandan Shillings based on daily **US\$ rates**.

### **Requirements for Expedited Review of a Protocol**

An expedited review, refers to review of a proposal in the quickest way possible, there's no requirement for a meeting, the chairman can either review the submitted proposal or assign it to any other designated VCDREC reviewer (s), the P.I should expect to get IRB comments within a week which they have to respond to before approval is granted. However not all studies can fit the criteria for expedited review, the VCDREC chairman and Administrator have to review the proposal in line with the VCDREC SOPs to determine if it fits the criteria for expedited review, therefore the PI should only pay VCDREC fees before confirming that their proposal has been reviewed.

**The following List of requirements apply:**

1. A cover letter addressed to the VCDREC Chairman requesting for expedited review, explaining why you think the study qualifies for expedited review.
2. A submission form should be attached to (04) copies of the proposal to be submitted for review.
3. The Investigator should wait to hear from the Committee confirming to them if their study qualifies for expedited review, (the Investigator can be notified within two days)
4. The Investigator pays **US\$350** to the Bank Accounts of VCDREC and brings the Photocopy of the receipt to the REC Administrator.