INFORMATION FOR PRINCIPAL INVESTIGATORS

APPLICATION PROCEDURE

Note: All PIs should register on *www.nrims.uncst.go.ug* to get a researcher account and use the account to submit the relevant documents. If the person completing the application is not the PI of the project, they should use the account of the PI strictly.

1. **NEW APPLICATION TO CONDUCT RESEARCH (REQUIREMENTS FOR FULL BOARD REVIEW) Please pick what is applicable to your study**
   - ✓ Complete and signed REC application form (REC 101- 2 copies)
   - ✓ CVs for all investigators (1 copy each)
   - ✓ 2 copies of Departmental minutes (Masters students and PhD students)
   - ✓ 2 copies of the Research summary
   - ✓ 2 copies of the Full Proposal (signed)
   - ✓ 2 copies of the Consent form(s) English & Translated version (if applicable)
   - ✓ 2 copies of the Assent form(s) English &Translated version (if applicable)
   - ✓ 2 copies of the Consent/assent for future storage of specimens, English & Translated version (if applicable)
   - ✓ 2 copies of the parental approval letter and Parental consent form, English & Translated version (s) (if applicable)
   - ✓ 2 copies of the Screening tool (if applicable)
   - ✓ 2 copies of the Recruitment materials (if applicable)
   - ✓ 2 copies of the Surveys/questionnaires/instruments English & Translated version (if applicable)
   - ✓ 2 copies of the Letter(s) of support/collaboration (if applicable)
   - ✓ 2 copies of the International/collaborating IRB approval(s) (if applicable)
   - ✓ 2 copies of the Drug/Investigators' brochure (if applicable)
   - ✓ 2 copies of any other Data collection tools
   - ✓ 1 copy Evidence of payment of research review fees (if applicable) please refer to the charge structure.
   - ✓ Send a soft copy of the WHOLE package to biomedicalresearch62@gmail.com (MUST).
   - ✓ Submit the 2 hard copies to the REC Office

Researchers submitting Studies for full board review should always submit their applications 3-4 weeks to the next meeting. Please note that the School of Biomedical Sciences Research Ethics Committee (SBSREC) **ONLY** meets twice in a month in the second and fourth weeks.

Incomplete applications will **NOT** be received by the REC office.

Applicants who **DO NOT** submit soft copies before handing in the hard copies **WILL NOT** be scheduled on the agenda for the next meeting.

For researchers who are required to pay review fees and fail to do so, no action will be taken on their submissions till payment is effected.

Researchers who present their proposals to SBSREC are expected to receive feedback from the REC **WITHIN OR AFTER 2 WEEKS**. Therefore the management strongly requests that previous presenters **SHOULD** wait for formal communication via **EMAIL** from the REC Office on updates regarding the comments from the REC meeting.
You should respond to REC comments in a period of 3 months after which they will be null and void and you will be required to resubmit for fresh review and pay again.

2. REQUEST FOR AMENDMENT

- ✓ Complete and signed Amendment form REC 103 (1 copy)
- ✓ A cover letter summarizing the amendment request
- ✓ Copy of approved proposal on file
- ✓ Copy of revised proposal with track changes
- ✓ Copy of approved consent/assent forms on file (if applicable)
- ✓ Copy of revised consent/assent forms with track changes both English & Translated version (if applicable)
- ✓ Copy of approved questionnaire on file
- ✓ Copy of revised questionnaire (if applicable)
- ✓ Copy of approved data collection/ screening forms (if applicable
- ✓ Copy of international IRB approval letter (if applicable)
- ✓ New/revised Drug/investigator Brochure (if applicable)
- ✓ Copy of previous approval letters
- ✓ Evidence of payment of research review fees (if applicable)
- ✓ Send a soft copy of the WHOLE package to biomedicalresearch62@gmail.com (MUST)
- ✓ Submit the hard copies to the IRB Office

3. REQUEST FOR RENEWAL (TO BE SUBMITTED 2 MONTHS BEFORE EXPIRY OF APPROVAL)

- ✓ Complete and signed Renewal form REC 102
- ✓ A Progress Report
- ✓ Copy of approved proposal on file
- ✓ Copy of approved consent form both English & Translated version (if applicable)
- ✓ Copy of approved assent form both English & Translated version (if applicable)
- ✓ Copy of approved parental consent form both English & Translated version (if applicable)
- ✓ Copy of approved recruitment materials
- ✓ Copy of approved study questionnaire both English & Translated version (if applicable)
- ✓ Summary of SAEs reported within the expiry period (if applicable)
- ✓ DSMB report (if applicable)

- ✓ Previous approval letter
- ✓ Copy of other study documents (if necessary)
- ✓ Evidence of payment of research review fees
- ✓ Send a soft copy of the WHOLE package to biomedicalresearch62@gmail.com (MUST)
- ✓ Submit the hard copies to the REC Office

4. SUBMISSION OF SERIOUS ADVERSE EVENT REPORTS

- ✓ Complete and signed Adverse Event Reporting form REC 104
- ✓ Send a soft copy of the filled form to biomedicalresearch62@gmail.com **(MUST)**
- ✓ Submit the hard copies to the REC Office

5. SUBMISSION OF PROTOCOL VIOLATIONS & PROTOCOL DEVIATIONS

- ✓ Complete and signed Protocol Violation/Deviation form REC 107
- ✓ Send a soft copy of the filled form to biomedicalresearch62@gmail.com **(MUST)**
- ✓ Submit the hard copies to the REC Office

6. SUBIMISSION OF A STUDY CLOSE OUT/END REPORT

- ✓ Complete and signed Study Termination report form REC 105
- ✓ Send a soft copy of the filled form to biomedicalresearch62@gmail.com (MUST)
- ✓ Submit the hard copies to the REC Office

EXPEDITED REVIEW (NEW APPLICATION TO CONDUCT RESEARCH)

- ✓ A letter addressed to the chair requesting for expedited review giving justification
- ✓ Complete and signed REC application form (REC 101- 2 copies)
- ✓ CVs for all investigators (1 copy each)
- ✓ 02copies of the Research summary
- ✓ 02 copies of the Full Proposal
- ✓ 02 copies of the Consent form(s) English & Translated version (if applicable)
- ✓ 02 copies of the Screening tool (if applicable)
- ✓ 02 copies of the Assent form(s) English & Translated version (if applicable)
- ✓ 02 copies of the Consent/assent for future storage of specimens, English & Translated version (if applicable)
- ✓ 02 copies of the Parental consent form, English & Translated version (s) (if applicable)
- ✓ 02 copies of the Recruitment materials (if applicable)
- ✓ 02 copies of the Surveys/questionnaires/instruments, English & Translated version (if applicable)
- ✓ 2 copies of the Letter(s) of support/collaboration (if applicable)

- ✓ 2 copies of the International/collaborating REC approval(s) (if applicable)
- ✓ 02 copies of the Drug/Investigators' brochure (if applicable)
- ✓ 02 copies of any other Data collection tools
- ✓ 1 copy Evidence of payment of research review fees (if applicable) Contact the REC office for payment details
- ✓ Send a soft copy of the WHOLE package to biomedicalresearch62@gmail.com (MUST)

If a researcher applies for expedited review, it's advisable to wait for feedback from the REC Office on the submitted study whether it qualifies for this type of review or full board review. In case it qualifies for expedited review, the researcher is expected to receive communication from the REC Office regarding the status of their submission WITHIN 2 WEEKS.

Masters and PhD proposals DO NOT qualify for expedited review. However undergraduate students and staff are free to apply for it depending on the nature of possible risks to study participants in the study.

PhD students registered in other local/international universities and out of the country wishing to conduct research in Uganda should go through the application process like any other ordinary researcher but should ensure to have a local supervisor on the team.

MONITORING AND EVALUATION CHECKLIST FOR SCHOOL OF BIOMEDICAL SCIENCES RESEARCH ETHICS COMMITTEE [REGULATORY BINDER]

- ✓ Standard Operating Procedures of the approved study
- ✓ Approved Study Protocol
- ✓ Approved informed consent and assent forms
- ✓ Acknowledged adverse events/Serious Adverse Events reports and Unanticipated Problems
- ✓ Acknowledged Protocol deviations
- ✓ Approved Data Safety Monitoring Board Minutes
- ✓ Minutes of the research team meetings
- ✓ Approved Recruitment Materials of the Study
- ✓ Approved Case Report Forms
- ✓ Informed consent documents signed by research participants
- ✓ Study staff Logs and CVs
- ✓ All IRB related documentations
- ✓ FDA Form 1572 and 1571/IDE/NDA (for clinical trials)
- ✓ Sponsor details
- ✓ Regulatory documentation: Investigator
- ✓ Record of participant reimbursements/payments

- ✓ Drug/ Device accountability Log (where applicable)
- ✓ Laboratory documentation e.g. lab notebooks
- ✓ Product Information (where applicable)