



## Minutes of the Tezpur University Ethical Committee Meeting

Dated: 9.12.16, Time: 3.30 PM, Venue: Office of the Dean, R&D

### Members present in the meeting:

Prof. A. Chatterjee, NEHU, Shillong: Chairman  
Prof. A. K. Mukherjee, Dean, R&D, TU: Deputy Chairman  
Dr. M. Mandal, Dept. of MBBT, TU: Member  
Prof. P. P. Sahu, Dept. of ECE, TU: Member  
Dr. Poonam Mishra, Dept. of FET, TU: Member  
Dr. Lucky Hazarika (representative of Chief Medical Officer): Member  
Dr. Raktim Pratim Tamuli, GMCH, Guwahati: Member  
Dr. Jyoti Hazarika, LGBRIMH, Tezpur: Member  
Dr. M. K. Tula, Dept. of English, Darrang College, Tezpur: Member  
Dr. S. K. Ray, Head, dept. of MBBT: Member

### Special invitees:

Prof. M. Bhyan, Dept. of ECE, TU  
Dr. R. K. Duary, Assistant Professor, Dept. of FET, TU  
Dr. T. Medhi, Assistant Professor, Dept. of MBBT, TU  
Dr. R. Doley, Dept. of MBBT, TU  
Dr. Nayan Moni Kakoty, Dept. of ECE, TU

### Agenda of the meeting:

1. Framing the general rules and guidelines for TU Ethical committee
2. Discussion on the last projects submitted to TUEC and comments received from the experts.
  - (a) Assessment of therapeutic potential of anticoagulant proteins (wild type and recombinant) from bacteria to treat cardiovascular disorders (Prof. A. K. Mukherjee, Dept. of MBBT, TU)
  - (b) Isolation, Identification and Characterization of Marker Proteins from the Venom of *Naja kaouthia* and *Bungarus fasciatus* of North East India for Development of Rapid Diagnostic Tool for Identification of Snakebite in North East India (Dr. R. Doley, Dept. of MBBT, TU)
  - (c) Comparative metagenome of human gut of North and North-eastern region of India (Dr. Raj Kumar Duary, Dept. of FET, TU)
  - (d) Lower Limb Prosthesis Gait Control (Dr. N. M. Kakoty, Dept. of ECE, TU)
  - (e) Effect of Sudarshan and Kriya and Pranayam Practices on Psychoneuroimmunological Parameters (Dr. T. Medhi, Dept. of MBBT, TU)
  - (f) Portable Peripheral Nerve Testing Instrument (Prof. M. Bhuyan, Dept. of ECE, TU)

### Minutes of the meeting:

- 1, The Dean, R&D, and Vice-Chairman, TU Ethical Committee welcome the new committee members and requested the Chairman to conduct the meeting. The Chairman requested the members to introduce themselves.
2. The Chairman briefed about the importance of this Ethical Committee and discussed about the framing of the guidelines which should be as follows:

- (a) A standard operating procedure (SoP) and a uniform participant (volunteer) consent form should be prepared by the TUEC. The same should be used by all the investigators for obtaining consent from participants/volunteers.
- (b) In the consent form, benefit of experiment (direct or indirect) and risk, if any should be well explained to the volunteers. This should be written in at least three languages English, Hindi, and/or Assamese.
- (c) All the proposals submitted for consideration of TUEC should be in a specific uniform format. A brief CV of PI and Co-PI, brief specific objectives of experiment, benefit to volunteers, and consent form should be enclosed along with the application.
- (d) Both hard and soft copy (in a single pdf format) of application along with other documents will be submitted to the Convener/member Secretary. The Convener/ member secretary will scrutinize the application and if any discrepancy is noticed the same will be returned to the PI within 3 days of receipt of application with necessary suggestion(s).
- (e) Soft copy of the proposals should be mailed to all the members by the Member Secretary/Convener of TUEC at least two weeks (14 days) prior to the date of meeting. The members will give their comment(s) at least 3 days before the meeting.
- (f) Ethical clearance number will be given against each approved project.
- (g) Dr. Tula opined that the importance of conducting the experiment and its benefit to the society should be explained to the participants (volunteers/patients or their relatives) in a very lucid language and avoiding scientific terms.
- (h) If there is any amendment (modification/addition) is required in the approved project it must has to be informed to the committee in writing. The modified procedure will be allowed to follow only after the approval of the Chairman, and Vice-chairman, TUEC.
- (i) The date of TUEC meeting need to be finalized in well advance and a common circular should be given to all the faculty members of the TU informing the date of meeting.
3. If any revision in proposal is recommended by the committee, then the PI will submit the revised proposal after incorporating the comments/observations of the committee within one month from the date of issue of letter to the member Secretary, TUEC.
4. The ethical committee meeting will be held at least twice in a year. In the next meetings, the PI will present their proposal and they need not be present in the entire meeting.
5. The TUEC may register with CENTRAL DRUGS STANDARD CONTROL ORGANIZATION, Director General of Health Services, Ministry of Health and Family Welfare, Govt. of India.
6. The proposal entitled-"Assessment of therapeutic potential of anticoagulant proteins (wild type and recombinant) from bacteria to treat cardiovascular disorders" received from Prof. A. K. Mukherjee was presented by the PI; however, decision on this project was taken in his absence. The proposal was approved in principle however, the following modifications are suggested.
- (a) A brief medical history of volunteers such as blood pressure, blood sugar level, genetic disorder (if any), food habit, medications, alcoholic, smoker/non-smoker etc. should be included in consent form. The committee members opined that these information be included in the uniform consent form to be prepared by the TU Ethical Committee.
- (b) Three (3.0) ml blood from each volunteer and twice in a week may be drawn by a trained technician/nurse/pharmacist.
- (c) Permission for collecting blood from 50 adult volunteers per year for a period of three years is recommended.
- (d) In the application, Co-PI should be changed to research student.
- (e) If the blood clotting time of volunteer is found abnormal, he/she may be adviced to consult a clinician.
7. The proposal entitled-"Lower Limb Prosthesis Gait Control" was presented by Dr. Nayan M. Kakoti, PI. The proposal was approved in principle however, the following modifications are suggested:



- (a) The volunteers should be chosen among the persons who are doing regular trade mill.
- (b) Presence of a physician at the experiment site (where the volunteers will do the trade mill) is strongly recommended.
- (c) Total number of volunteers approved for this project is 40 and recommended time for trade mill was 3 min for each volunteer. The volunteers must be free of cardiovascular disorder.
- (d) Safety measure of the test device in human subject should be judged very carefully and should be supported by documents.
- (e) If any ill effect to volunteers or accident happens during the experiment, appropriate measure should be taken and it has to be compensated.
- (f) CV of all the PI/Co-PI is required.
- (f) Ethical clearance from LGBRIMH, Tezpur is also necessary before conducting the experiment.
- (g) Last objective 4 should be deleted/excluded from the ethical proposal.
- (h) A brief medical history of volunteers such as blood pressure, medication, cardiovascular disorder etc. should be recorded.
- (i) Control subject should be non-depressant volunteers. The number of volunteers (sample size), duration of experiment, and age group of volunteers should be mentioned in the revised proposal.

8. The proposal entitled-"Isolation, Identification and Characterization of Marker Proteins from the Venom of *Naja kaouthia* and *Bungarus fasciatus* of North East India for Development of Rapid Diagnostic Tool for Identification of Snakebite in North East India" received from Dr. R. Doley, PI was presented in the meeting and discussed. The proposal was approved in principle however, the following modifications are suggested:

- (a) Two ml of blood should be drawn from each volunteer only once and the approved number of volunteers is 10. The blood will be drawn by a trained technician/nurse/pharmacist.
- (b) Patient/Participant consent form should include all the information as suggested in 6(a).
- (c) The title of the proposal is misleading. It should be amended appropriately.
- (d) If the blood clotting time of volunteer is found abnormal, he/she may be advised to consult a clinician.

9. The proposal entitled-"Portable Peripheral Nerve Testing Instrument "received from Prof. M. Bhuyan, PI was presented in the meeting and discussed. The proposal was approved in principle however, the following modifications are suggested:

- (a) The committee recommended inclusion of one physician as Co-PI in this project. The presence of physician while conducting the experiment is necessary.
- (b) Total number of volunteers approved for this project is 40
- (c) Name of the students in the proposal is not necessary and it may be withdrawn from the proposal.
- (d) Only adult will be included for experiment.
- (e) Safety measure of volunteers should be followed.

10. The proposal entitled-"Comparative metagenome of human gut of North and North-eastern region of India" received from Dr. Raj Kumar Duary, PI was presented in the meeting and discussed. The proposal was approved in principle however, the following modifications are suggested:

- (a) Because the experiment involves with microbial DNA therefore, submission of one copy of proposal to TU Biosafety committee is also suggested.
- (b) Total number of volunteers approved for this project is 40.
- (b) All the volunteers should be native of NE India.

(c) Participant consent form has to be changed.

11. The proposal entitled-"Effect of Sudarshan and Kriya and Pranayam Practices on Psychoneuroimmunological Parameters" received from Dr. T. Medhi, PI was presented in the meeting and the following modifications are suggested:

(a) The proposal is not in a proper format. Therefore, it has to be re-submitted in a proper format before being considered by the committee.

(b) No physician is involved in this project and therefore committee suggests one physician should be included as Co-PI.

(c) Involvement on one psychiatrist as Co-PI is also essential. His signature in patient consent form is suggested.

(d) Inclusion of one yoga instructor in this project is needed. All the yoga classes should be organized only in presence of a Yoga instructor.

(e) For conducting the experiments, patients should not be subjected to unnecessary radiation.

(f) Because the experiment will be done at LGBRIMH, Tezpur therefore, ethical clearance from this Institute and concurrence from the attached hospital of this Institute must be obtained before starting this project. A copy of the same has to be produced to TUEC for record.

(g) The patient consent form has to be modified specially for this project. Consent form the authorized relative/representative of the patient must be obtained, if the patient is not fit to give his own consent.

12. The meeting ended with vote of thanks from Dr. S. K. Ray, Member Secretary of the committee.

  
(Prof. A. Chatterjee)

Chairman, TUEC

Dated:

  
(Prof. A. K. Mukherjee)

Deputy Chairman, TUEC

Dated: