

**Minutes of the full board meeting of 'Tezpur University Ethical Committee'**

**Date and time: 08 September, 2021 at 3.30 PM**

**[Through online Google Meet platform via link: <https://meet.google.com/qjf-zwi-y-qkq>]**

**Members present:**

1. Dr. Kangkan Pathak	- Chairperson	Present
2. Dr. Usha Sarma	- Vice-Chairperson	Present
3. Dr. Pronobesh Chattopadhyay	-Member	Absent
4. Prof. Debarshi Prasad Nath	-Member	Present
5. Prof. Manabendra Mandal	-Member	Present
6. Prof. Robin Doley	-Member	Present
7. Dr. Jonali Sarmah	-Member	Absent
8. Dr. D. K. Sarmah	-Member	Present
9. Dr. Nayanmoni Gogoi	-Member	Present
10. Mr. Nayan Gogoi	-Member	Absent
11. Dr. R. Mukhopadhyay	-Member Secretary	Present

**Agenda of the meeting:**

1. Minutes of the last meeting for confirmation
2. Registration of TU Ethical Committee
3. Discussion on the new and revised proposals
4. AoB

**Minutes of the meeting**

**Agenda 1: Minutes of the last meeting for confirmation**

1. The minutes of last meeting were referred and the matter of registration of the TUEC was discussed. The Member Secretary informed the committee that the initiative for registration with Department of Health Research (DHR) was taken up and approval from the University authority has been sought for.
2. At the outset, the members declared that there is no conflict of interest.

**Agenda 2: Registration of TU Ethical Committee**

3. The committee also recommends registration of TUEC with Central Drugs Standard Control Organization (CDSCO) also.
4. The Chairperson also informed that for any clinical trial, registration with Clinical Trial Registry-India (CTRI) is necessary. CDSCO has mandated that anyone conducting clinical trial in India must register before enrolling any research participant.

**Agenda 3: Discussion on the new and revised proposals**

5. The following revised and new proposals were discussed in details by the reviewers and committee members. The comments from the committee are tabulated proposal-wise as below:

IEC Ref. No.	Name of the Investigator/ Co investigator	Title of the proposal	Name of the Reviewers	IEC comment
DoRD/TUE C/PROP/20 20/03-R1	Prof. B. Deka	Development of an artificial intelligence-based model for early detection and prediction of breast cancer using digital mammography images	Dr. K. Pathak, Dr. U. Sarma	The committee recommended the revised proposal in principle subject to submission of corrections as mentioned below: a) In the Section C (Benefit and Risk) of Application for Initial Review, the risk should be mentioned as "Minor increase over minimal risk or low risk" b) PIS should be revised as per ICMR guideline and submitted in English as well as Assamese.
DoRD/TUE C/PROP/20 21/01	Dr. Sarat Doley	A stimulus appraisal-based study on motivation affect in L2 learning at the tertiary level with reference to Engineering students learning English as an L2 in Assam	Prof. D. P. Nath, Dr. D. K. Sarmah	The committee approved the proposal in principle subject to submission of modified Informed Consent form (ICF) and Patient information sheet (PIS) as per ICMR guideline. PIS should be in simple, nontechnical language.
DoRD/TUE C/PROP/20 21/02	Ms. Sujata Kakoti	Comparing the effectiveness of interleaving and blocked practice in teaching English speaking skills to tertiary level ESL learners: As experimental study	Dr. D. K. Sarmah, Prof. M. Mandal	The committee approved the proposal in principle subject to submission of modified Informed Consent form (ICF) and Patient information sheet (PIS) as per ICMR guideline. PIS should be in simple, nontechnical language.
DoRD/TUE C/PROP/20 21/03A And DoRD/TUE C/PROP/20 21/03B	Dr. Suman Dasgupta	Understanding the role of adipose tissue remodelling in exercise induced insulin sensitivity	Dr. P. Chattopadhyay, Prof. D. P. Nath, Prof. R. Doley, Dr. N. Gogoi	The committee recommends integrating these two proposals into one as a multicentric proposal since objectives and outcome of the two proposals are identical. The committee recommends the PI to resubmit the proposal with following suggestions: a) Clearly mention if samples will be used for future use that should

				<p>also be reflected in the PIS.</p> <p>b) In Section C (Benefit and Risk) of Application for Initial Review, the risk should be mentioned as “Minor increase over minimal risk or low risk” rather than “No risk”.</p> <p>c) The type of surgery and tissue to be collected should be clearly mentioned.</p> <p>d) A memorandum of understanding (MoU) may be signed with the collaborating hospital and TU.</p>
DoRD/TUEC/PROP/2021/04	Dr. Nayan M Kakoty	Clinical Trials of TU Bionic Hand with Transradial Amputees	Dr. K. Pathak, Dr. P. Chattopadhyay	<p>The committee opined that proposal involves vulnerable population and thus cannot be ‘exempted from review’ as suggested by the PI. The committee recommends the following:</p> <ol style="list-style-type: none"> <li>The proposal can be taken up after TUEC is registered with the regulatory authority.</li> <li>As the process of registration may take some time, the committee opted to refer the proposal to Ethics Committee of other organization which is already registered in accordance with the guidelines of ICMR.</li> </ol>
DoRD/TUEC/PROP/2021/05	Dr. Nayan M Kakoty	Music and the Brain: A Study on Neuro-Science of Assamese Music using Artificial Intelligence	Dr. U. Sarma, Prof. M. Mandal	<p>The committee opined that proposal cannot be ‘exempted from review’ as suggested by the PI. The committee suggested resubmission of the proposal with following modifications:</p> <ol style="list-style-type: none"> <li>Objective is not clear and can be modified.</li> </ol>



				b. The sample size can be increased c. The committee suggested the proposal may be resubmitted as a case/control study with Assamese and Non-Assamese speaking population d. Only one or two genres of Assamese music can be chosen. e. The title may be modified as "Music and the Brain: A Study on EEG of Assamese Music using Artificial Intelligence"
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#### Agenda 4: AoB

- The committee also opined that "Tezpur University Ethical Committee" should be rechristened as "Tezpur University Ethics Committee".
- The Chairperson suggested that Member Secretary, TUEC should follow up the already recommended proposals and request PIs to submit annual report/completion report.