**NEIGRIHMS**

NORTH EASTERN INDIRA GANDHI REGIONAL INSTITUTE OF HEALTH & MEDICAL SCIENCE,

 Mawdiangdiang, Shillong- 793018, Meghalaya

(An Autonomous Institute, Ministry of Health and Family Welfare, Government of India)

**INSTITUTION ETHICS COMMITTEE**

**Instructions for Submission of Proposals to IEC, NEIGRIHMS**

Submission of proposals for IEC review may be done throughout the year. While multicentric studies approved by an Ethics Committee from another site may be submitted directly to the IEC, other studies may be submitted following approval from the relevant Scientific Committees (NSAC/PG Committee). Depending on the number of submissions, meetings will be scheduled at regular intervals.

IEC, NEIGRIHMS has adopted an IEC Manager Software (<https://iecmanager.org/institution/335>) which incorporates the ICMR common forms. This would replace section 2(IEC) of the previous format. The forms need to be filled up online and the declaration form generated needs to be signed and uploaded. All researchers are requested to register on this link and get their account activated. While you will receive the passwords on your email once the IEC admin staff approve your request, in case you don’t receive the password (and it is not in your spam), please send an email to the IEC(iec.neigrihms@gmail.com).

Please submit your proposals as ‘Investigator initiated project-Project Initial Submission-Full Board Review’. Students submitting the thesis may replace ‘Investigator initiated project’ with ‘thesis/dissertation’.

The protocol, which should contain the version number and short title of the study (as a footer in all the pages) should contain all the information pertaining to the conduct of the study. In studies approved by the NSAC, the “NSAC submission format-section 1” will be considered the protocol and should be submitted with a version number (eg. 1.0) in the footer. If any changes are advised by the NSAC or IEC, the version number in the corrected document should be changed to (1.1 or 1.2 accordingly). For multicentric studies, the protocol prepared by the lead centre would suffice (if there is no NEIGRIHMS-specific modification). The NSAC approval letter needs to be uploaded too.

            Similarly, the informed consent form/document (ICD) should have the short title of the study, the language and version number in the footer, which needs to be changed if any modifications are suggested by the IEC. The ICD should have a detailed Participant Information Sheet (PIS) as the first part. **Please ensure that this PIS is in very simple language without medical jargon, addressed to the participant.**

All the documents required are to be submitted online(**in pdf format only**). One printout of the IEC form(Project Initial Submission) which is generated on the portal, needs to be printed out and submitted, along with the signed declaration, the protocol and ICD to the office of the IEC, NEIGRIHMS.  The CVs need to be uploaded in the portal only. Please do not upload these documents(protocol, ICD, CRF,etc) as a single file. If the print out is not submitted, the proposal will not be processed. Also, if there are any deficiencies on the documents submitted online, the same will be returned to the investigator to rectify and upload the necessary documents.

Once submitted, the proposals will be reviewed by the members of the IEC and queries, if any, will be communicated to the researchers through the portal only. The queries need to be responded to and necessary changes made on the portal. **The researchers will have to appear before the IEC to clarify the details pertaining to the proposals(from the protocol and ICD they have submitted). A schedule will be circulated prior to the meeting.**

Please understand that since the software will save several details, subsequent submissions will be easier. We request your cooperation in enabling this change. While the 'Help' section on the software may be helpful, if necessary, you may contact the IEC Admin (Ms. Evangelyne Khongiong), Sub-Dean Ethics (Dr. Iada Rilang Tiewsoh) or the Member Secretary(Dr. Caleb Harris) for clarifications via email(iec.neigrihms@gmail.com).

Regards,

Member Secretary, IEC