

her failing to participate in the study. In this situation, continued parental or legal guardian consent should be sufficient to allow participation in the study.

12.6. Assurance that the research participants shall receive information that becomes available during the research relevant to their participation including their rights, safety and wellbeing is documented.

12.7. The provisions made for receiving and responding to queries and complaints from research participants or their representatives during the course of a research project.

12.8. Any payments proposed to be made to subjects/ patients have to be documented and notified to IEC and included on the ICD (Informed Consent Document)/ ICF (Informed Consent Form).

12.9. Audio Visual (AV) Recording of Informed Consent process shall follow as following:

12.9.1. According to ICMR guidelines, when a participant is willing to participate but not willing to sign or give a thumb impression or cannot do so, then verbal/oral consent may be taken on approval by the EC, in the presence of an impartial witness who should sign and date the consent document. This process can be documented through audio or video recording of the participant, the PI and the impartial witness, all of whom should be seen in the frame. However, verbal/oral consent should only be taken in exceptional circumstances and for specific, justifiable reasons with the approval of the IEC. It should not be practiced routinely.

12.9.2. In case of vulnerable subjects in clinical trials of New Chemical Entity (NCE) or New Molecular Entity (NME) including procedure of providing information to the subject and his understanding on such consent, should be maintained by investigator for record: In case of clinical trial of anti-HIV and anti-leprosy drugs, only audio recording of the informed consent process of individual subject including the procedure of providing information to the subject and his understanding on such consent should be maintained by the investigator for record.

13. PROCESS OF CONDUCTION OF IEC, AMALA MEETINGS:

13.1. The committee would meet once in every 3 months or whenever it is necessary. If needed where the situation is justified the meeting may be called more than once in 3 months.

13.2. The meetings would be called by the Member Secretary and the notice for the meetings would be sent usually 7 working days prior to the scheduled date.

13.3. The member-secretary will record the minutes of the meeting and circulate the same to the members within a month of the meeting.

13.4. The meeting may take place in physical presence of the members at designated venue or via online mode.

14. PROTOCOL REVIEW PROCEDURE:

14.1. The IEC, AMALA should review every research proposal involving human subjects (as per the checklist). It would ensure that a scientific evaluation has been completed before ethics review is taken up.



Betsy

Dr. BETSY THOMAS
MD, FRCOG, DNB, MICOG
PRINCIPAL
AMALA INSTITUTE OF MEDICAL SCIENCES
AMALA NAGAR, THRISSUR-680 555