Post-approval Requirements

Ethics Committee, Faculty of Tropical Medicine, Mahidol University

1. The Certificate of Ethical Approval (CEA) for each research study is valid for 1 year only, from the date of approval.

   PI must extend the certificate using Progress Report Form/ Certificate of Ethical Approval Extension Request Form (FTM ECF-008-RR) 2 months prior to the expiry date.

   If extension without modifying the project details, PI are requested to send copy of the stamped approval Research Proposal Submission Form.
2. PI must submit the signed letter of permission from authorized person of the implementing institution when the PI received.
3. PI must submit progress reports after approval according to the stipulated EC requirements related to the identified risk that specified in the cover letter, using Progress Report Form/ Certificate of Ethical Approval Extension Request Form (FTM ECF-008-RR).
4. Reporting Serious Adverse Event
   4.1 For reporting Local SAE
   - Local serious adverse events which are fatal or life threatening: PI must report to EC immediately, no later than 24 hours after the PI becomes aware of the event.
   - Local serious adverse events which is non-fatal or non life threatening: PI must report to EC immediately, no later than 7 calendar days after the PI becomes aware of the event.

   4.2 For reporting any Non-Local Serious Adverse Reactions
   - Sponsor must report non-local serious adverse reaction including SUSARs to EC at least every 6 months accompanied by a brief report highlighting the main point of concern.
   - Other adverse reactions that may increase risks to subjects, the sponsor must report to EC as soon as possible but no later than 15 calendar days.
   - Other type of reports, the sponsor must report to EC at least every year or periodically or on request.

   The document format is a photocopy of completed SAE report form according to provision of the sponsor.
5. Reporting Suspected Unexpected Serious Adverse Reactions
   5.1 For reporting Local SUSARs which are fatal or life threatening:
   - Sponsor must report to EC as soon as possible using CIOMS form, no later than 7 calendar days after the sponsor becomes aware of the event.
   - If the initial report is incomplete, the sponsor must report to EC relevant follow-up information and complete report as soon as possible, within additional 8 calendar days.
   - Sponsor must report any significant new information as a follow up report within 15 calendar days

   5.2 Local SUSARs which are non-fatal or non life-threatening:
   - Sponsor must report to EC as soon as possible using CIOMS form, no later than 15 calendar days after the sponsor becomes aware of the event.
   - Further relevant follow-up information should be given as soon as possible.
6. All Adverse Events (AE) related and not related to the study are required to notify the EC in 1 year of the event notification to PI using PI form or the sponsor-required documentation.
7. For the unanticipated problems and unscheduled mandatory (medication errors, unexpected complications, protocol violations) must be reported in written to EC within 5 working days of the event notification to PI form or the sponsor-required documentation. For protocol deviation must be reported in 1 month.
8. If the PI wishes to amend any research document (e.g. Research Proposal, Participant Information Sheet, Informed Consent Form/ Informed Assent Form, Leaflet or Questionnaire), the Request for Protocol Amendment Form (FTM ECF-023-RR) should be filed, with the amended documents attached, and with the specified version and date shown in the footer of each document. The signatures of the PI (and any Co-PI) must be inscribed in the research proposal in ink.
9. If the PI wishes to notify the Ethics Committee of study closure, the Notification of Study Closure form (FTM ECF-010-RR), and final report should be filed.

Remark: 3 copies of the documentation sent to the EC. If a full board review is necessary, an EC officer will advise the PI of any additional documentation requirements.