Operating Guideline for the Approved Project

Office of Institutional Review Board Faculty of Dentistry and Faculty of Pharmacy, Mahidol University.

For the approved project, the IRB will emphasize on the operating guideline that the principal investigator must follow.

1. To provide an information and request for consent of the participant, the investigator must use only the participant information sheet (PIS) and informed consent form (ICF) which stamped and approved by IRB. Each participant needs to sign 2 set of ICFs, 1 set for the investigator and another set for the participant. In case of a research project that conducts with foreign countries, if there are Thai participants, the PIS and ICF must be in Thai version. If there is a foreign language version, the information in the document must be the same meaning as the Thai version.
2. The subject recruitment must be processed with voluntary participation and the subjects do not feel coerced.
3. All Documents or other tools to be used in the research project including publicity poster must be stamped and approved by IRB.
4. If it is necessary to amend the protocol, the investigator must inform the IRB and give reasons, using Form 15-16. The IRB approval must be obtained before starting the project, except solving the urgent problem to prevent harm to the participant. In this regard, the principal investigator must inform such event to the IRB within 5 working days from the date of processing.
5. The research procedure must be conducted as indicated to the IRB. If there is any deviation from the indication, the investigator must report to the IRB within 2 weeks with the given reason(s) and the regulations to prevent the repetition, using Form 18. If the investigator intends to repeat the deviation, the IRB may terminate the approval of the project.
6. The principal investigator must inform every serious and non-serious adverse events, including unexpected events affecting the safety and well-being of the participants that occurred during carrying out the research to the IRB promptly, using Form 17.
7. If there are new information involving the research project which will affect to the safety and well-being of the participants, the principal investigator must inform the IRB.
8. The certificate of approval is valid for one year, starting from the date of approval by specifying the starting and expiry date, which signed by IRB chairman and faculty dean. The principal investigator must contact the IRB office to extend the certificate of approval within 2 months before the expiry date, and provide the annual progress report, using Form 14.
9. The principal investigator must provide the close-out report form after the research is complete, using Form 14.

Additional suggestions Clinical trials should be registered for Clinical Trial Registration before starting the research at www.ClinicalTrial.gov. If there is any problem, please contact Office of Institutional Review Board Faculty of Dentistry and Faculty of Pharmacy, Mahidol University. Telephone number. +66-2-2007622.