Mahidol University
Faculty of Tropical Medicine

# CERTIFICATE

## OF ATTENDANCE

This is to certify that

*Boonying Prathum*

Attended the training course

## Good Clinical Practice & Human Subject Research in Applied Science

**Completion Date:** 12/09/2025

**Expiration Date:** 11/09/2028

Organized by
Faculty of Tropical Medicine, Mahidol University

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**Completion date:** 12/09/2025
**Expiration date:** 11/09/2028

## Good Clinical Practice & Human Subject Research in Applied Science

- Research Involving Human Subjects
- History and Ethics of Human Subjects Research
- Institutional Review Board (IRB) Composition, responsibility and review process
- Types of protocol review
- Recruitment process, Informed consent process, Reconsent process, Informed opt-out
- Modifications and waivers of informed consent
- Informed Consent Process for Internet Research and Electronic Informed Consent
- Risk and benefit assessment / Risk management
- Conflicts of Interest in Human Subjects Research
- Research integrity
- Biomedical science: Records-based research
- Medical devices
- Emerging technology
- Privacy and confidentiality
- PDPA related to medical research
- Laws and regulations related to research
- Data sharing and material transfer agreement
- Safety report
- Deviation/Violation report
- Overview of International Council for Harmonisation (ICH)
- Sponsor responsibilities / Sponsor obligations in FDA-regulated research
- Audits, inspection, and monitoring of research studies
- Investigator's responsibilities
- Data governance
- Essential documents
- Managing investigational agents according to GCP requirements