



CERTIFICATE

OF ATTENDANCE

This is to certify that

Boonying Prathum

Attended the training course

Good Clinical Practice &
Human Subject Research in
Biomedical Science

Completion Date: 10/09/2025

Expiration Date: 09/09/2028

Organized by
Faculty of Tropical Medicine, Mahidol University



Name: Boonying Prathum

Institution Affiliation: Nakhon Si Thammarat Rajabhat University

Email: boonying_pra@nstru.ac.th

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Good Clinical Practice & Human Subject Research in Biomedical 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
- Research Involving mothers and child
- Research Involving Incapable person, Prisoners, Institutional subordinate
- Risk and benefit assessment / Risk management
- Conflicts of Interest in Human Subjects Research
- Research integrity
- Biomedical science: Records-based research
- Biomedical science: Hospital-based research
- Community-based research
- Laboratory-based research
- Human genetics
- Biobank
- 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

