Developing an Ethical Culture in Research through an Institutional Regulatory Compliance Office
Research Institute for Health Sciences (RIHES)
Chiang Mai University
Major funding agencies

- National Institute of Allergy and Infectious Diseases, NIH
- National Institute on Drug Abuse, NIH
- National Institute of Mental Health, NIH
- Fogarty International Center, NIH
- Office of AIDS Research, NIH
National Institute of Allergy and Infectious Diseases, NIH

- Adult AIDS Clinical Trial Group (AACTG)
- Pediatric AIDS Clinical Trial Group (PACTG)
- HIV Prevention Trial Network (HPTN)
- HIV Vaccine Trial Network (HVTN)
- Comprehensive International Program on Research on AIDS (CIPRA)
Requirements for U.S National Institutes of Health (NIH) funded research with human subjects

All Clinical research activities performed under NIH grant must be in compliance with

All US. Federal regulations, guidance and NIH policies applying to the conduct of research in involving human subjects and regulatory application for new drug or biological licenses when applicable
Requirements for US NIH funded Research

GCPs

US FDA
- Regulates all aspects of the pharmaceutical industry
- Title 21 of the CFR (Code of Federal Regulations)

OHRP
- Responsible for all people who participate in DHHS-sponsored research
  - 45 CFR part 46

ICH-GCP
- Glossary
- Principles
- IRBs
- Investigator
- Sponsor
- Essential Docs
CFR Title 21

Parts applicable to clinical research:

- Part 11 - Electronic Records and Signatures
- Part 50 - Protection of Human Subjects
- Part 54 - Financial Disclosure by Clinical Investigators
- Part 56 - Institutional Review Boards
- Part 312 - Investigational New Drug Application
Other Regulations & Policies.

- National regulations.
- Sponsor policies (DAIDS)
Roles and Responsibility of Regulatory Compliance Unit (RCU)

The role of the RIHES Regulatory compliance Unit (RCU) is to manage, oversee and ensure that all clinical research is conducted in ethically and in compliance with applicable government regulations, institutional policies and clinical sponsor requirements.
RCU Responsibilities (1)

1. Regulatory compliance:

- ensure investigator compliance to OHRP 45 CRF 46 and 21 CRF 50 Protection of Human Subjects, Thai regulations with submissions to IRB/EC and IBC


- Assist PIs and study coordinators with protocol, Progress report, Informed Consent, recruitment materials, AE and study drug safety information submission to IRBs/EC

- Maintain personal files with required training certification and financial disclosure (21CFR54, 312)
RCU Responsibilities (2)

2. Quality Management

- Develop and implements Quality Management Plan (QMP), based on continuous quality improvement principle.

- QMP and QA activities are audited quarterly by RCU QA specialist, sponsor monitors, who also conduct source and essential documentation audits.

- Coordinate all audits and responds to the sponsor with any necessary improvement plans.

- Track annual training for about 350 RIHES Standard Operating Procedure (SOPs)
RCU Responsibilities (3)

3. Training

- Maintain training logs for CTU required training according to sponsor policy and SOP, including regulatory review translation electronic tracking and facilitating annual review of site-and study-specific SOPs.

- Facilitate annual GCP training in Thai language and ensure all study staff are certified at least tri-annually, as required by sponsor policy.

- Organize Thai language training for NIH required training.

- Translate to Thai Human Subject Protection Training Modules and other regulatory documents.
RIHES FWA

Federal wide Assurance (FWA) for the protection of Human Subjects for International Institute

- Approved by US Department of Health and Human Services (DHHS)
- DHHS IRB/IEC Registration Number IRB 00003605
- Assurance Number FWA 00005355
Committee Review at RIHES

THAI
Ministry of Public Health

CMU
Faculty of Medicine

RIHES
Human Experimentation Committee

RIHES
Institutional Bio safety Committee

Johns Hopkins University
IRB

RIHES
Data Safety Management Board
Monitoring

At CMU RIHES
Monitoring (ICH-GCP section 5.18)

Purpose: to verify

+ The rights and well-being of human subjects are protected

+ The reported trial data are accurate, complete and verifiable from source documents

+ The conduct of the trial is in compliance with the currently approved protocol/amendment (s), with GCP and with the applicable regulatory requirements [including in country – Thai – requirements and regulations]
DAIDS studies at RIHES are subject to 4 levels of monitoring

- QC/QA site monitoring as required by DAIDS SOP
- PPD monitoring as required by DAIDS
- CRM (clinical research managers) annual monitoring as required by sponsor
- FDA audits for IND studies
What the monitor will verify

- GCP and Federal Requirements (ICH, OHRP (IRB), FDA, CFR)
- Sponsor Requirements (Protocol, DAIDS SOP)
- Protocol Adherence (SSP, Site SOP, etc.)
Verify Source Documents

- Ensure Data is Complete and Logical
- Ensure that Source Data Supports CRF
Thank you