



AGENDA

GCP Training (one day course)

Ramathibodi Hospital, Faculty of Medicine, Mahidol University

22 August 2017

Time	Topics	Speakers
08.00-08.20	Registration	
08.20-08.30	Opening	Prof. Boonsong Ongphiphadhanakul
08.30-08.40	Direction of Clinical Research Participation	Clinical Research Center
08.40-09.30	Principle of ICH GCP	Pichet Kamolrungsantisuk
09.30-10.00	Role & Responsibility of Sponsor	Pichet Kamolrungsantisuk
10.00-10.15	Break	
10.15-10.45	Role & Responsibility of Investigator & site coordinator	Pichet Kamolrungsantisuk
10.45-11.15	Role & Responsibility of Ethics Committee	Pichet Kamolrungsantisuk
11.15-11.45	Quality Control & Quality assurance	Pichet Kamolrungsantisuk
11.45-12.00	Q&A	
12.00-13.00	Lunch	
13.00-14.00	Informed Consent	Nitaya Jeanpan
14.00-15.00	Data management, CRF completion and Source documentation	Nitaya Jeanpan
15.00-15.15	Break	
15.15-16.00	Safety reporting	Nitaya Jeanpan
16.00-16.45	Study medication handling	Nitaya Jeanpan
16.45-17.00	Q&A	