กำหนดการฝึกอบรม

เรื่อง "การปฏิบัติการวิจัยทางคลินิกที่ดี รุ่นที่ 2"

วันที่ 13-14 เดือน สิงหาคม 2562 เวลา 08:30 – 16:30 น.

ห้อง 910C ชั้น 9 อาคารเรียนและปฏิบัติการรวมด้านการแพทย์และโรงเรียนพยาบาลรามาธิบดี

วันที่ 13 เดือน สิงหาคม 2562

Time	Topic	Speaker
08:30 – 09:00	Register & Opening	
09:00 – 10:30	Overview of Ethical Principles in Human Research and Introduction to GCP • Development of Ethical Principles for Human Research and Good Clinical Practice (GCP) • The International Conference on Harmonization Guidelines for Good Clinical Practice of (ICH GCP) • Overview of ICH-GCP • Clinical Trial Related Laws & Regulations Disclosure of Clinical Trial	Pravich Tanyasittisuntorn, M.D.
10:30 – 10:45	Coffee break	
10:45 – 12:00	Introduction to the principles of ethics in human research and GCP (continued)	Pravich Tanyasittisuntorn, M.D.
12:00 – 13:00	Lunch break	
13:00 – 14:45	Training on GCP : Role & Responsibilities • Role & Responsibilities • Investigator Responsibilities Communication with IRB/IEC Compliance with Protocol • Sponsor Responsibilities Responsibilities of the Sponsor	Pravich Tanyasittisuntorn, M.D.
14:45 – 15:00	Coffee break	
15:00 – 15:30	Institutional review board (IRB)/independent ethics committee (IEC)	Nitaya Jeanpan

	• Composition and responsibilities of IRB/IEC • Application for IRB/IEC review and approval • Review process: exemption, expedited and full review	

15:30 – 16:30	Lecture: Informed consent
	• Definition and objectives of informed consent
	• Informed consent form/patient information sheet: essential elements of information and subjects' comprehension
	• Conduct of informed consent
	  o Investigator's responsibilities
	  o Documentation
	  o Definition of impartial witness and legally acceptable representative
	• Consent renewal
	• Informed consent in vulnerable subjects
	
	Workshop: Informed consent
		Nitaya Jeanpan

16:30 –16:40	Q & A	

วันที่ 14 เดือน สิงหาคม 2562

Time	Topic	Speaker
08:45 – 09:00	Register	
09:00 – 10:15	Lecture: Safety reporting • Purposes of safety reporting • Safety report terms: adverse event (AE), adverse drug reaction (ADR), severity & seriousness, expectedness & unexpectedness • Reporting process, timelines, and documentation o Expedited report o Non-expedited report • Responsibilities of investigator/site staff, sponsor, subjects and IRB/IEC in safety reporting • Data safety monitoring board	Nitaya Jeanpan
10:15 – 10:30	Coffee break	
10:30 – 11:15	Investigational drug handling • Drug label • Drug transportation • Drug storage: storage condition and access control • Drug accountability and documentation • Drug destruction and documentation	Nitaya Jeanpan
11:15 – 12:00	ICH GCP: Essential Documents • Protocol • Case Report Form (CRF) • Source data & Source document • Investigator's Brochure **(คู่มือผู้วิจัย)** • Informed consent form • Other Essential Documents • Filing And Maintaining Eseential Documents	Pravich Tanyasittisuntorn, M.D.
12:00 – 13:00	Lunch break	
13:00 – 13:30	• Data collection and data management • Informed Consent Process การให้ความยินยอม (หลังได้รับทราบข้อมูล)	Pravich Tanyasittisuntorn, M.D.
13.30 – 14.00	Subject recruitment, subject retention, and subject compliance • Subject recruitment process and investigator's responsibilities • How to develop and implement recruitment plan • Randomization and blinding process • Subject compliance and impacts of the non-compliance	Pravich Tanyasittisuntorn, M.D.

Time	Topic	Speaker
	• Impacts of subject loss to follow-up and how to retain subjects	
14:00 – 14:15	Coffee break	
14:15 – 15:45	Quality control and quality assurance in clinical trial • Definition and purposes of QC & QA • What difference between audit & inspections is • Overview of monitor's responsibilities and monitoring activities • Audit/inspection process and how to respond to /inspection findings/observations • Common audit findings/observations	Pravich Tanyasittisuntorn, M.D.
15:45 –16:30	Test	Pravich Tanyasittisuntorn, M.D.
16:30 –16:40	Q & A	