กำหนดการอบรม

1. **ประชุมวิชาการประจำปีชมรมจริยธรรมการวิจัยในคนในประเทศไทย (NRCT, MedResNet & FERCIT)**
2. **อบรม เรื่อง Human Subject Protection Course & GCP**

ฝ่ายวิจัย คณะแพทยศาสตร์ จุฬาลงกรณ์มหาวิทยาลัย

วันจันทร์ ที่ 21 – วันอังคาร ที่ 22 พฤษภาคม 2561

ห้องประชุม 229/1 ชั้น 2 อาคารแพทยพัฒน์ คณะแพทยศาสตร์ จุฬาลงกรณ์มหาวิทยาลัย

Day 1 : 21 May 2018			
Time	**Topics**		**Speakers**
08.00 - 08.50	Registration		
08.50 - 09.00	Welcome Address		Tada Sueblinvong
09.00 - 10.00	Ethics of early phase drug and vaccine trials in multicenter multinational setting	plenary	Nithya Gogtay
10.00 - 10.15	**Break**		
10.15 - 11.45	Impacts of 2016 ICH-GCP on early phase clinical trials	plenary	Punkae Mahaisawariya Nimit Morakote
11.45 - 12.30	ประชุมสามัญประจำปีของชมรม FERCIT เลือกประธานชมรมฯ	กรรมการและสมาชิกชมรม FERCIT	
12.30 - 13.30	**Lunch**		
13.30 - 14.30	Social value and impact of CIOMS 2016 on ethical review	plenary	Chaichana Nimnual
14.30 – 14.45	**Break**		
14.45 – 16.00	Do Revised CIOMS and ICH-GCP affect Informed consent Process, broad consent and informed consent opt out? (อภิปราย)	plenary	Nimit Morakote Nut Koonrungsesomboon
Day 2 : 22 May 2018			
Time	**Topics**		**Speakers**
08.00 - 09.00	ลงทะเบียน, ตรวจสอบถามถูกต้องของ ชื่อ – นามสกุล		
09.00 – 10.30	Roles and responsibility of Clinical trial Stakeholder on human subject protection (อภิปราย)	Discussion	Kwanchanok Yimtae (Instituion & CRC) Thipaporn Tharavanij (IRB) Virote Sriurangpong (Investigator) Unnop Jaisamran (Moderator)
10.30 - 10.45	**Break**		

Note: 1. Attendance should have over 80% attending time and return the evaluation form to receive Certificate of Attendance.

2. The above Certificate of Attendance can be submitted as GCP training achievement to Med Chula IRB.

10.45 – 11.45	Risk assessment on clinical trials of Traditional Medicine (Herbs & Herbal products)	plenary	Supatra Porasupatana
11.45 - 12.00	**Lunch**		
13.00 - 14.00	Confidentiality, Privacy & COI management	plenary	Sahapol Anannumchareon
14.00 - 14.15	**Break**		
14.15 - 15.15	Role of CAB on Human Subject Protection	plenary	Udom Likhitwonnawut
15.15 - 15.45	Summary Question& Answer Adjourn	Tada Sueblinvong	

Brief outlines

Speaker	Topic	Outlines
Nithya Gogtay	Ethics of early phase drug and vaccine trials in multicenter multinational setting	**-**Ethical issues -Models of review by ethics committee: single IRB, regional IRB or separate review by individual IRB
Punkae Mahaisawariya	Impacts of 2016 ICH-GCP on early phase clinical trials	Changes in 2016 ICH-GCP from previous version.
Nimit Morakote	Impacts of 2016 ICH-GCP on early phase clinical trials	Impact of changes in 2016 ICH-GCP on clinical trials
Chaichana Nimnual	Social value and impact of CIOMS 2016 on ethical review	What is the meaning of social value? How to evaluate social value of research proposal when review?
Nut Koonrungsesomboon	Do Revised CIOMS and ICH-GCP affect Informed consent Process, broad consent and informed consent opt out?	Informed consent in early phase clinical trials. Can broad consent and consent opt out be applied.
Nimit Morakote	Do Revised CIOMS and ICH-GCP affect Informed consent Process, broad consent and informed consent opt out?	What do 2016 CIOMS & ICH-GCP mention on Informed consent in early phase clinical trials?
Supatra Porasupatana	Risk assessment on clinical trials of Traditional Medicine (Herbs & Herbal products)	Can traditional medicine and clinical trials cause any harm? How to protect subjects?
Udom Likhitwonnawut	Role of CAB on Human Subject Protection	What is CAB and its role? Do we need CAB in all clinical trials?

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