




	<p align="center"> R.S. Jantung dan Pembuluh Darah Harapan Kita – Mochtar Riady Institute for Nanotechnology Universitas Pelita Harapan organized A SOP DEVELOPMENT & ADVANCED ETHICAL REVIEW TRAINING (Improving Review of Protocols) </p>	 
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**RUNDOWN PROGRAM SOP DEVELOPMENT
30-31st January, 2017**

DAY 1: 30 January 2017		
08.00 – 08.30	Registration / Coffee Break	Committee
Moderator : Prof. Dr.dr. Suryani As'ad M.Sc. Sp.GK		
08.30 – 08.40	Welcome Remarks, Chair of MRIN EC	Prof. dr. Irawan Yusuf, Ph.D
08.40 – 08.50	Speech, President of MRIN	Prof. George Mathew, MBBS, Master of Surgery, Doctor of Medicine
08.50 – 09.00	Speech, Founder of MRIN	Dr. Mochtar Riady
09.00 – 09.30	The Ethics Committee of the National Health Research and Development (KEPPKN) Today and The Future	dr.Triyono S., Ph.D
Moderator : Dr. Debbie S. Retnoningrum		
09.30 – 10.00	Preparing SOPs and Guidelines for IEC / IRB	FERCAP
10.00 – 10.30	Constituting an IEC / IRB	FERCAP
10.30 – 11.00	Workshop 1 – Analyzing Current IEC / IRB SOP	FERCAP
11.00 – 12.00	Group Reports	FERCAP
12:00 – 13:00	Lunch Break	
Moderator : Dr. Liliana Kurniawan, M.Sc. DMTH		
13:00 – 14.00	Procedure and required documentation for Ethical Review submission	FERCAP
14:00 – 15.00	Protocol Amendments, Continuing Review And End of Study Requirements	FERCAP
15.00 – 15.30	Coffee Break	
15:30 – 16.30	Workshop 2 – SOP for Review Protocol in Clinical Trial	FERCAP
16.30 – 17.30	Group Reports	FERCAP
19.00 – 20.30	Dinner	

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DAY 2: 31 January 2017		
Moderator : Dr. dr. Sintak Gunawan, M.A		
08.30 – 09.00	Role of Chair in the Full Board meeting.	FERCAP
09.30 – 10.00	Role of Primary Reviewers in the Full Board Meeting	FERCAP
10.00 – 10.30	Coffee Break	
10.30 – 11.45	Workshop 3 : Conducted Full Board Meeting	FERCAP
Moderator : drh. Lia Siti Halimah, MSc.		
11.45 – 12.15	Monitoring Adverse Events and SAEs	FERCAP
12.15 – 13.15	Lunch Break	
13.15 – 13.45	Site Visits	FERCAP
13.45 – 15.15	Workshop 4 – Monitoring Research Protocol by IEC / IRBs	FERCAP
15.15 – 15.45	Afternoon Break	
15.45 – 16.15	Group Report	FERCAP
Moderator : Dr. Ivet Suriapranata		
16.15 – 16.45	Audit and Inspection of IEC / IRB	FERCAP
16.45 – 17.15	Workshop 6 – Managing an IRB	FERCAP
17.15 – 18:00	Group Reports	FERCAP



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**RUNDOWN PROGRAM
ADVANCED ETHICAL REVIEW TRAINING (Improving Review of Protocols)
1 – 2 February 2017**

DAY 1: 1 February 2017		
08.00 – 08.30	Registration	Committee
08.30 - 08.40	Speech	1. Pres Dir RSJPDHK 2. Chairman of REC
08.40 - 09.15	Indonesian National Guideline and Regulations on Ethics of Health Research	KEPPKN/ drTriyono S PhD
09.15 - 09.45	IEC/IRB Review Requirement & Procedures	FERCAP
09.45 - 10.00	Coffee Break	
Moderator : Prof.Dr.dr. Bambang BS.,SpJP(K)		
10.00 -11.00	Indonesian Regulations for investigational New Drug (IND) Development	BPPOM
11.00 -12.00	Reviewing sponsored / Multicenter vs Investigator Initiated Research Protocol	FERCAP
12.00 - 13.00	Lunch Break	
Moderator : dr. Bagus Herlambang, BTKV.PhD		
13.00 - 14.00	Ethical Issues in Intervention vs Observational Research	FERCAP
14.00 - 15.00	Reviewing Clinical trial on New Medicinal product (including Stem cells)	FERCAP
15.00 - 15.15	Afternoon Break	
15.15 -17.00	Case Study and Discussion	IRB/KEP RSJPDHK

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DAY 2 : 2 February 2017		
Moderator : Dr.dr. Anwar Santoso,SpJP(K)		
09.00 - 09.50	Reviewing Public Health Research	FERCAP
09.50 - 10.40	Reviewing Cardiovascular Research	DR dr Anwar Santoso SPJP(K)
10.40 - 11.00	Coffee Break	
Moderator : Dr.dr, Cyndi L Boom, SP.An.		
11.00 - 12.00	Reviewing Traditional Medicine Research with human subject	BPPOM
12.00 - 13.00	Lunch Break	
Moderator : dr. SukoAdiarto, PhD. SpJP.		
13.00 - 14.00	Improving Informed consent	Dr.drg.MagdarinaD.Agtini,MSc
14.00 - 15.00	Vulnerable Population in Research	FERCAP
15.00 - 15.15	Afternoon Break	
Moderator : dr. Amin Tjubandi, Sp.BTKV		
15.15 - 17.00	Case study and Discussion/ Multicenter Study	KEPPKN/ Rizky Harnawan
17.00 - 18.00	Certificate Delivery and Closing	