



3000703 วิธีการวิจัยทางเวชศาสตร์คลินิก

Research Methodology in Clinical Sciences

Semester 1/2021

Time and venue: Thursday 14:00-16:00 hrs. via Zoom Meeting

No.	Date	Topic	Instructor
1	19 August 2021	- Development of research questions - Types of study design	Asst. Prof. Chaichana Nimnuan, M.D., Ph.D.
2	26 August 2021	- Descriptive study - Cross-sectional study	Assoc. Prof. Thira Woratanarat, M.D.
3	2 September 2021 (10.00 – 12.00 hrs.)	Case control study	Prof. Narin Hiransuthikul, M.D., Ph.D.
4	9 September 2021 (10.00 – 12.00 hrs.)	Cohort study	Prof. Narin Hiransuthikul, M.D., Ph.D.
5	16 September 2021	Diagnostic test	Asst. Prof. Chaichana Nimnuan, M.D., Ph.D.
6	23 September 2021	- Mixed Method Research - AI and Big data in Medicine and Public Health	Assoc. Prof. Krit Pongpirul, M.D., Ph.D.
7	30 September 2021	RCT (I) - CONSORT guideline - Parallel, cross-over and factorial trial design - Pragmatic trial - Superiority, equivalence and non-inferiority study	Prof. Stephen Kerr, Ph.D.
8	7 October 2021	RCT (II) - Randomization and blinding - Interlim analysis - Intention to treat vs per protocol	Lecturer Wonggarm Kittanamongkolchai, M.D.
9		Proposal development and grant application	Self-study
10	14 October 2021	Proposal discussion and feedback (1)	All staff / Advisor
11	28 October 2021	Clinical trial initiation process - Feasibility survey	Lecturer Wonggarm Kittanamongkolchai, M.D.

No.	Date	Topic	Instructor
		<ul style="list-style-type: none"> - IRB application - Clinical trial agreement - Clinical trial insurance - Clinical trial registration - Project budgeting and financing 	
12		<ul style="list-style-type: none"> - Data management and CRF design - REDCap 	Self-study (Online module)
13	4 November 2021	CRF and eCRF workshop/feedback (optional)	Lecturer Wonngarm Kittanamongkolchai, M.D. Lecturer Phanupong Phutrakool, M.D.
14	11 November 2021 (14.00 – 15.00 hrs.)	Recruitment strategy <ul style="list-style-type: none"> - Clinical workflow - Lab/biobank management - Drug and placebo management - Data quality monitoring - Conducting a multi-center study 	Assoc. Prof. Thanyawee Puthanakit, M.D.
15	18 November 2021	Manuscript writing and tips for submission	Assoc. Prof. Thanyawee Puthanakit, M.D.
16	25 November 2021	Sponsor-initiated trial <ul style="list-style-type: none"> - Overview: Global trends, Asia trends, patient/society/economic contributions - Feasibility survey - Site selection - Site initiation - Budget negotiation - Essential documentation - CV - GCP - IB - CTA - MTA - Source doc, CRF - IRB - Clinical trial insurance - Recruitment strategy - Protocol compliance and quality assurance - IP management 	clinical research associate (CRA) Lecturer Wonngarm Kittanamongkolchai, M.D. (clinical study manager, Novartis Thailand) <ul style="list-style-type: none"> - Workshop - Field study (CRC)

No.	Date	Topic	Instructor
		<ul style="list-style-type: none">- Document storage and retention- Monitoring and audit- Finance	
17	2 December 2021	Project/Draft proposal presentation and Feedback	All staff / Advisor