

## Course syllabus

### TMCD503 Introduction to Clinical Research

#### Academic Year 2016-2018

1. **Institute** Mahidol University
- Faculty/Department** Faculty of Tropical Medicine, Department of Clinical Tropical Medicine
2. **Course Name:**
  - a. **Course Code:** TMCD 503
  - b. **Course Title:** Introduction to Clinical Research
3. **Number of credits:** 1 (1-0-2)
4. **Programme use:** Graduate Diploma Programme in Tropical Medicine and Hygiene  
Master of Clinical Tropical Medicine
5. **Prerequisite:** None
6. **Type of Course:** Elective subject
7. **Condition: class size:** None
8. **Session/Academics year:** The first semester of each academic year

**9. Course description:**

Basic research methodology and applications in study process including protocol writing, ethical issues and consent form, diagnostic tests, designing case-record form, sampling and allocation under good clinical practice (GCP) and epidemiological and clinical trials including etiologic study, how to conduct the study, data management, publication and presentation

**10. Course expected learning outcomes:**

The students should be able to

- 1) Explain the good clinical research
- 2) Discuss fundamental knowledge using in clinical research, writing of proposal, good clinical research management
- 3) Differentiate the research methodology in clinical research
- 4) Critique research methodology and ethic in clinical research

## 11. Course outline and constructive alignment

	Topics	Hours			Instructors	Course learning outcomes	Programme ELOs	Learning Activities	Assessment
		Lecture	Lab	Self-study					
1	Introduction to Clinical Research and Clinical Trial Design	1	0	2	Prof Arjen Dondorp/Prof Sasithon/Dr Prakaykaew	1,2,3,4	2.2	Lecture, slide presentation	Student participation, Discussion
2	Research Methodology	1	0	2	Prof Sasithon/Dr Prakaykaew/Dr Natthida	3,4	2.2	Lecture, slide presentation	Student participation, Discussion
3	Grant application	1	0	2	David Gandy/Dr Prakaykaew/Dr Borimas	2,4	2.2	Lecture, slide presentation	Student participation, Discussion
4	Protocol	1	0	2	Prof Punnee	1,2,3,4	1.1,2.2	Lecture, slide presentation	Student participation, Discussion
5	Informed Consent	1	0	2	Asst Prof Supat/Asst Prof Jittima	1,2	1.1,2.2	Lecture, slide presentation	Student participation, Discussion
6	Diagnostic tests	2	0	4	Assoc Prof Varunee/Assoc Prof Vipa	2	3.3	Lecture, slide presentation	Student participation, Discussion
7	Good Clinical Practice (GCP)	2	0	4	Prof Punnee	1,2,4	1.1,2.2	Lecture, slide presentation	Student participation, Discussion
8	Literature search	1	0	2	Ms Duangjai	2	2.2	Lecture, slide, presentation, demonstration, practice	Student participation, Discussion, Practice in class
9	Ethics in Clinical Research	2	0	4	Assoc Prof Yupaporn	1,2,4	1.1	Lecture, slide presentation	Student participation, Discussion
10	How to develop GCP compliant documents	1	0	2	Asst Prof Jittima	1,2,3,4	1.1,2.2	Lecture, slide presentation	Student participation, Discussion
11	Systemic review and Literature Review	2	0	4	Asst Prof Chusak	2,4	3.3	Lecture, slide presentation	Student participation, Discussion
	<b>Total</b>	<b>15</b>	<b>0</b>	<b>30</b>					

**12. Teaching and Learning Activities**

Lecture, scenario, Discussion

**Teaching media**

PowerPoint presentation

Discussion

**13. Course achievement and evaluation**

Attendance	50%
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Discussion and course participation	50%
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Note<sup>1</sup> Students must attend at least 80% of all activities.

**14. Course evaluation**

Discussion and comments session at the end of the course

Questionnaire for contentment and suggestion for the course

**15. References**

15.1. Spriet A, Simon P. Methodology of clinical drug trials. Translation of Methodologie des essais cliniques des medicaments by Edelstein R, Weintraub M with a preface by Lasagna L. Basel, New York: Karger, 1985.

15.2. MRC Guidelines for Good Clinical Practice in Clinical Trial

15.3. GCP/ICH Guidelines

15.4. Mandell GL, Bennett JE, Dolin R. Mandell Douglas, and Bennett's Principles and Practice of Infectious Diseases. 6<sup>th</sup> ed. Philadelphia: Churchill Livingstone; 2005

**16. Instructors:**

As in course outline

**17. Course responsibility:**

Prof Punnee Pitisutthithum

Department of Clinical Tropical Medicine, Faculty of Tropical Medicine, Mahidol University