

Introduction to Translational Medicine,
 Course Coordinator: Guey Chuen (Oscar) Perng
 Place: 11th floor Lecture Room;
 Time: Every Thursday from 1:00pm to 3:00pm; Credits: 2

週次 Week	Class Date	Lecture	進度 Progress Description
1	9/18	1	Course introduction
2	9/25	2 Sunny Wu	Drug discovery-Proteomic explored by Microscopy
3	10/2	3 I-Hsiu Huang	Investigational product development, and The Food and Drug administration
4	10/9	4 Grace Lo	Structural Based Drug Design
5	10/16	5 Grace Lo	The principal investigator, site selection and budget negotiations
6	10/23	6	Global Good Clinical Practice/The clinical research team
7	10/30	7	Clinical study protocol elements and statistical considerations
8	11/6	8 Grace Lo	Institutional Review Boards
9	11/13	9 Sunny Wu	Informed consent and Privacy of subjects
10	11/20	10	Oral presentation on class assignment
11	11/27	11	Early clinical trials design
12	12/4	12	Study monitoring & the study site initiation
13	12/11	13 I-Hsiu Huang	Safety reporting: definitions and reporting requirements
14	12/18	14	Investigational product accountability and study site closure
15	12/25	15 I-Hsiu Huang	Compliance and quality assurance: audits and inspections
16	1/1		National Holiday
17	1/8	16	Research Ethics
18	1/15	17	Oral presentation on class assignment

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Class Assignments:

Do short presentation on writing an IRB protocol and writing a proposal for the FDA approval.

1. Identify a name of concept drug/biomarker
2. How to test the mode of action of the target drug
3. How to apply for IND/drug
4. How to apply for clinical trials/ performance
5. How to file for approval of FDA of your concept drug.