Course Title:	**The Regulation of Biomedical Research (MMPH6218)**
Department offering the course:	Department of Law/ School of Public Health
Objective:	This course aims to: • explore the ethical, legal and social framework of biomedical research and human experimentation; • help legal practitioners understand and keep abreast of developments in the rapidly developing field of biomedical research, and to equip them with the basic language and vocabulary necessary to follow and keep abreast of legal and ethical developments in the field.
Content:	Topics include: • Legal and ethical regulation of biomedical research in all its common aspects, particularly in the context of international standards for clinical trials (pharmaceutical trials); direct human experimental and biomedical research involving human subjects; 'non-invasive' epidemiological and other studies involving only the use of data; human tissue banking; cohort studies; biobanking; genetic testing and screening, genomic research; the use of 'legacy' diagnostic tissue or data collections; the sharing of personal, medical and genomic information ('Big Data'); public 'diseases registries' and the use of medical information for public health purposes; the legal and ethical regulation of multi-centre and multi-jurisdictional collaborative biomedical research; international standards for ethical governance of biomedical research at the institutional level; electronic medical records databases; data-mining and the implications of migration to large-scale national health records systems; • Fundamental concepts such as the informed consent of subjects (at common law and under ICH rules) with particular emphasis on the consent given by or on behalf of minors, incompetent subjects and vulnerable populations, return of benefits to research subjects or research subject populations, assessment of risks, randomized controlled trial (RCT) and clinical equipoise will be considered in the context of clinical trials, as well as the impact and requirements of the Guidelines of The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH); • Ethical requirements to be met for research protocols and publication of results in first-tier medical journals according to the ICMJE Guidelines will also be considered.

Learning Outcomes:	On completion of the module, the students are expected to: • Describe and explain the differences between the relationships of physician-patient, and that of researcher-subject, with special attention to the conflict of interests which may arise where the physician also acts as researcher, and where the patient is also the subject, or the source of the subject research tissue or data; • Propose and describe measures for the management and resolution of such conflicts in specific settings, such as that of the registered physician who is at once a practicing clinician as well as a biomedical researcher in a research and teaching hospital; • Critically examine the approaches to the taking of consent from research subjects, particularly in the context of clinical trials, minors, incompetent persons, or vulnerable populations; • Describe and explain the international framework for the conduct of clinical trials under the ICH Guidelines regime; • Critically examine and analyze current international developments in the legal and ethical regime for the sharing of medical and genetic information as well as of research tissue and genetic samples; • Consider what regulatory gaps exists in Hong Kong that needs to be filled from the legal and ethical perspective, with a view to establishing Hong Kong as a leader internationally the field of biomedical research, particularly in the field of tissue banking, biobanking and genomic research.
Prerequisite:	None
Duration:	1 semester; 30-36 class hours
Continuous Assessment:	Class participation (30%)
Examination method/ duration:	Take-home final examination (70%)