BMEN 6334 Ethical and Legal Clinical Trial Considerations

BMEN 6334 Ethical and Legal Clinical Trial Considerations (3 semester credit hours) This course will examine the historical events that influenced the existing federal regulations that guide clinical research as well as the current ethical codes and guidelines pertaining to the use of animals and humans as research subjects. Students will explore the framework and principles of Good Clinical Practice (GCP) as it relates to the roles and responsibilities of various stakeholders like the FDA, Investigator, Sponsor, IRB and the study subject. They will learn the main principles guiding the conduct of ethical research, the importance of transparency, balancing incentives for engineering innovation, adverse events management and determining and enforcing appropriate safety levels. This course will also cover the current reimbursement environment for clinical trials and its impact on clinical use of devices. Department consent required. Prerequisite: BMEN 6331. (3-0) Y