

MCTM 5331 : Ethics of Translational Medicine

Moving a compound from pre-clinical studies into humans is a necessary step in the translational process. The current system of demonstrating safety and efficacy in animals, then first-in-human phase I trials, to larger cohorts and multi-center trials has many scientific and ethical decision points and challenges that investigators, review boards, and regulatory agencies must address in readying a novel therapeutic for wide- spread use. Important consideration will be given to conflicts of interest that involve both clinical issues of ethics, existing guarantees for clinical trials participants , and how anticipated risks are weighed against predicted benefits to society. Students will evaluate case studies of actual clinical trials to see what contributed to the outcome.

Credits 3

Course ID

008022