This course is designed to introduce graduate students to ethical, policy and social issues related to regenerative medicine, specifically stem cell research. It is designed primarily for the needs of students in medicine, law, public policy and science & engineering fields who work in stem cell or related areas of research. Primary scientific and policy documents will be used as resources as well as analyses of current social and political environments. Other students and faculty are welcome but should first consult the instructor. Topics include:

- Legal, political and ethics background of contemporary dilemmas in regenerative medicine research (incl discussion of pending legislative actions, potential effects of mid-term elections, status of ethical debates)
- Understanding the relations of governments, various public groups and the media in the face of controversial research.
- Guidelines and oversight rules for research ethics
- Regulatory concerns (FDA and other)
- Clinical trial issues (adult and embryonic cells, ethics of first-in-human research, trial design considerations)
- Translational issues: commercialization, IP, delivery

**NOTE:** THIS COURSE IS TAUGHT AS A CONCENTRATED, SHORT COURSE (7 sessions). At the organizational meeting, we will choose a time and day to best accommodate everyone’s schedule. If you prefer a more in-depth course, please refer to MHB 559 Issues in Innovative Medicine: Regenerative Medicine & Nanotechnology (3 credits; graduate credit available)