

ETHICS IN BIOMEDICAL RESEARCH (SECTION I - 2017)

Instructor: Jun Panee, PhD, Associate Researcher

Course Reference Number (CRN): 74863

Course Title: Ethics in Biomedical Research

Course Number: CMB 626

Course Credit: 2 credit hours

Prerequisite: graduate students, postdocs, or permission of instructor

Time: Thursdays, 10:00 am- 12:00 pm

Location: BSB 222N

Course Description

Through lectures and case discussions, students learn to identify and resolve ethical issues that arise in biomedical research, comply with local and federal regulations related to research involving human and animal subjects, and avoid research misconduct. This course meets the NIH requirements for training in responsible conduct of research (<http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-10-019.html>), and covers the NIH suggested subject matter as listed below:

- Conflict of interest – personal, professional, and financial
- Policies regarding human subjects, live vertebrate animal subjects in research, and safe laboratory practices
- Mentor/mentee responsibilities and relationships
- Collaborative research including collaborations with industry
- Peer review
- Data acquisition and laboratory tools; management, sharing and ownership
- Research misconduct and policies for handling misconduct
- Responsible authorship and publication
- The scientist as a responsible member of society, contemporary ethical issues in biomedical research, and the environmental and societal impacts of scientific research

Student Learning Outcomes

Upon completion of this course, students will be able to perform the following:

- Apply ethical principles to the design and conduct of biomedical research;

- Avoid pitfalls in the research process, including scientific misconduct;
- Conduct ethical biomedical research using animals, and develop animal protocols for the review of Institutional Animal Care and Use Committee (IACUC);
- Meet ethical, legal and regulatory requirements in recruiting participants and using human specimens and protected health information in biomedical research, develop protocols for the review of Institutional Review Board (IRB);
- Address intellectual property and conflict of interest issues in the context of biomedical research;
- Disseminate scientific findings in an ethical and responsible manner;
- Maintain scientific integrity and professionalism in accordance with relevant ethical principles, policies and laws.

Learning Experiences: Lecture, case analysis, group discussion.

Evaluation:

- Attendance: 20%
- Active participation in group discussion: 20%
- Presentation (case analysis): 30%
- Written examination: 30%

Instructor contact information

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Fall 2017 Schedule:

| Date | Topic |
|------|---|
| 8/24 | Lecture 1: Part A: <ul style="list-style-type: none">• Course overview• Attendee presentation assignment Part B: <ul style="list-style-type: none">• Influential moral theories• Moral reasoning |
| 8/31 | Lecture 2: Scientific misconduct: <ul style="list-style-type: none">• Fabrication• Falsification• Plagiarism• Policies for handling misconduct Attendee presentation: case analysis and group discussion (40 min) |
| 9/7 | Lecture 3: Research Data: <ul style="list-style-type: none">• Acquisition, management, sharing and ownership• Reproducibility Attendee presentation: case analysis and group discussion (40 min) |
| 9/14 | Lecture 4: Human Subject Research (I) <ul style="list-style-type: none">• Historical background• Ethical principles<ul style="list-style-type: none">○ Nuremberg code○ Declaration of Helsinki○ Belmont Report○ Common rule Attendee presentation: case analysis and group discussion (40 min) |
| 9/21 | Lecture 5: Human Subject Research (II) <ul style="list-style-type: none">• Informed consent• Data and safety monitoring• Confidentiality• Community engagement |

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| | Attendee presentation: case analysis and group discussion (40 min) |
| 9/28 | <p>Lecture 6: Human Specimens and Protected Health Information</p> <ul style="list-style-type: none"> • Common rule and NPRM (2015) • HIPPA • GINA • Cultural competence <p>Attendee presentation: case analysis and group discussion (40 min)</p> |
| 10/5 | <p>Lecture 7: Animals Research</p> <ul style="list-style-type: none"> • Moral theories and ethical arguments on animal experimentation • Animal welfare regulation • IACUC <p>Attendee presentation: case analysis and group discussion (40 min)</p> |
| 10/12 | <p>Lecture 8: Beginning and end of life</p> <ul style="list-style-type: none"> • Human embryonic stem cells • Use fetal tissues in research • Designer baby • End of life decision <p>Attendee presentation: case analysis and group discussion (40 min)</p> |
| 10/19 | <p>Lecture 9: Neuroethics</p> <ul style="list-style-type: none"> • Functional neuroimaging • Psychopharmacology • Brain-machine interfaces • Brainotyping • Consciousness <p>Attendee presentation: case analysis and group discussion (40 min)</p> |
| 10/26 | <p>Lecture 10:</p> <p>Part A: Intellectual property</p> <ul style="list-style-type: none"> • Copyright • Patent <p>Part B: Conflict of interest in research</p> <ul style="list-style-type: none"> • Financial conflict of interest |

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| | <ul style="list-style-type: none"> • Conflict of commitment • Conflict of conscience • Academic bias <p>Attendee presentation: case analysis and group discussion (40 min)</p> |
| 11/2 | <p>Lecture 11: Responsible authorship and publication</p> <ul style="list-style-type: none"> • Authorship criteria • Academic authorship abuse • Select journal for publication • Research impact metrics • Misbehaviors in academic publications <p>Attendee presentation: case analysis and group discussion (40 min)</p> |
| 11/9 | <p>Lecture 12: Peer review in scientific publication</p> <ul style="list-style-type: none"> • Traditional model of peer review • Flaws in the peer review system • Novel models of peer review • How to be an ethical, objective, constructive, and collegial peer reviewer <p>Attendee presentation: case analysis and group discussion (40 min)</p> |
| 11/16 | <p>Guest lectures: Genetics and forensics (Dr. David Haymer) Digital image use 101 (Ms. Kanako Iwase) Or IT security (Mr. Vance Mizuba)</p> |
| 11/23 | <p>Thanksgiving</p> |
| 11/30 | <p>Lecture 13: Academic professionalism, relationship, and environment:</p> <ul style="list-style-type: none"> • Professionalism • Environmental and societal impacts of scientific research • Mentor/mentee responsibilities and relationships • Collaboration • Laboratory resource management, sharing, and ownership • Safe laboratory practices <p>Attendee presentation: case analysis and group discussion (40 min)</p> |
| 12/7 | <p>TBD</p> |

12/14

Written exam and general discussion