

BIOMED 555: RESPONSIBLE CONDUCT OF RESEARCH (RCR) (Spring 2015)

(Listed official UNM course title: Problem Based Research Bioethics)

Class Meetings: Beginning Wed, 25 February 2015, and meeting each Wed. through 22 April 2015 from 4:00 – 5:50 PM in BMSB 309 - Harvey Library (see schedule below on page 4).

Lead Instructors: Elaine Bearer, MD, PhD (elaine.bearer@gmail.com; 272-2404 lab) and Diane Lidke, PhD (dlidke@salud.unm.edu; 272-8375 office).

Guest instructors: Angela Wandinger-Ness, PhD (ANess@unm.edu)
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Natalie Adolphi, PhD (NAdolphi@salud.unm.edu)
Kevin O'Hair, DVM (kohair@salud.unm.edu)
Mark Parshall, RN, PhD (mparshall@salud.unm.edu)
Mark Holdsworth, PharmD (mholdsworth@salud.unm.edu)
Michelle Huff (MHuff@salud.unm.edu)

Intended Students: Graduate students, postdoctoral fellows, junior faculty members who are training for a career that involves basic, translational or clinical research in the biomedical or behavioral sciences.

In this course, we will talk about these and many more ethically related questions!

What is responsible conduct of research?

How do you determine who is an author on a research paper? What should the order of authors be?

What are the responsibilities researchers and authors in disseminating data and study results?

What are the responsibilities of a peer reviewer of a manuscript? How should a manuscript be reviewed?

What kinds of behaviors and situations constitute potential conflicts of interest or commitment in research?

If you get a job at another institution, what data, records, and equipment can you take with you?

What special ethical issues occur with genetic research or other newer technologies?

Who owns the papers that you publish? Who owns the data from a research project?

What are the "three R's" in animal research? What principles must guide human subjects research?

If you engage in research with humans, how can you assure that patient privacy and safety is assured?

What are the steps to obtaining a patent or a trademark? What are the rules about copyright?

Do you ever question yourself or your judgment when conducting a data analysis and interpreting results?

Are you and your mentor a good fit? How do you appropriately collaborate with other researchers?

How is research misconduct defined and detected?

The overall subject matter covered in this course goes by several terms:

research ethics, scientific integrity, responsible conduct of research (RCR), and some others.

RCR courses such as this one for graduate and postdoctoral trainees are now required at U.S. research institutions. The content of such courses varies some but generally covers the following broad topics:

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| (1) human subjects in research; | (6) scientific misconduct; |
| (2) animal subjects in research; | (7) data management and scientific record keeping; |
| (3) responsible authorship and publication; | (8) data ownership and intellectual property; |
| (4) effective mentoring; | (9) effective collaboration in research; and |
| (5) conflicts of interest and commitment; | (10) ethical issues in technical areas such as genetics. |

This course meets the requirements set under the *America COMPETES Act of 2007* and is now mandated by both NSF and NIH for all individuals receiving any type of training funded by NSF or NIH grants.

In this course, you will learn about RCR mainly using the **case study approach**, a form of **problem-based learning** (PBL), which ethics experts believe is the best method for RCR and ethics training. After reading and hearing about considerable background material on each topic, this approach then involves careful analysis and discussion of cases involving situations that have various competing but defensible "solutions."

Required Textbook:

Francis L. Macrina. (2014). *Scientific Integrity*, 4th edition, Washington: ASM Press.

Instructors may also assign articles from the literature or from websites sent via email or as class handouts.

Students should complete all assigned readings prior to class for the date listed on page 4 below to inform their understanding of class didactics, discussions, and case analyses. Faculty will assume students have completed the assigned reading for the topic presented.

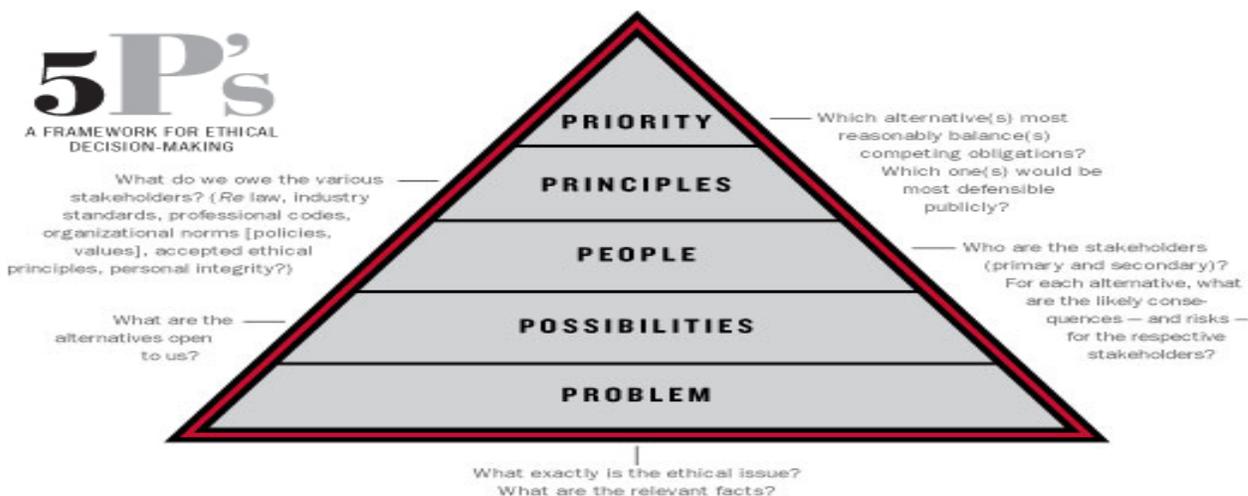
Course goals: We seek to provide a learning experience for students that will enable them to:

1. Develop and refine skills needed to solve ethical problems that might arise in the many research issues that may be encountered by most researchers during their careers.
2. Be able to identify and clearly articulate – both verbally and in writing – ethically and legally acceptable solutions to problems that arise in designing, conducting, and reporting research.
3. Develop a positive attitude towards life-long learning in matters of scientific integrity and the responsible conduct of research that can, in turn, be shared with collaborators and mentees.

Course Objectives:

Students successfully completing this course will:

1. Be familiar with relevant written guidelines and standards for the ethical conduct of scientific research, including those dealing with scientific publication and assigning authorship, use of humans and animals in research, conflicts of interest, collaborative research, and general standards for the responsible conduct of research.
2. Be able to describe conventions and normative behavior related to responsibilities for scientific mentoring, for scientific record keeping and for data ownership and dissemination.
3. Be familiar with regulations and statutes that govern the ownership, protection, and use of intellectual property in scientific research.
4. Be able to describe the relevant ethical issues and dilemmas related to the impact of various technologies such as genetics on human subject research and on society.



Course Activities: Graduate students, post-doctoral fellows, and faculty members are expected to be active participants in this **case-based** research ethics course. This course is designed to stimulate deep thinking and discussion among participants about important topics in research ethics. Students will be expected to read the chapter before the presentations, attend the presentation, and lead and/or engage in case discussion on that topic immediately following the presentation in the same class period. Each topic will be presented by a UNM expert in that area with a didactic overview of the issues. Then, class members will lead case discussions (20-30 minutes per case), facilitated by the instructors. At the end of each session, groups for the following week will be assigned and cases selected.

Student Responsibilities:

1. Prepare the assigned reading before class and prepare cases for discussion, including using web and/or other resources, such as those on page 4.
2. Attend all 8 classes. Give careful thought to what is read in preparation for class and to what is presented by each topic expert.
3. Be prepared to clearly articulate the key elements of the case, its **dilemma**, and a defensible ethical solution in oral discussion. Written notes on these issues should be brought to class to expedite discussion. Notes should include supporting examples, references and/or websites, and ethical tenets that extend the case study beyond personal opinion.
4. Students are expected to work together on the cases during week prior to the next class.

In your discussions of the cases and issues aim for an informed, thoughtful manner that does *not just* express an opinion of what is ethically “right” or “wrong” but also deals with the complex underlying issues and tradeoffs existing in each case. Almost all ethical dilemmas have 2 or more defensible solutions.

Faculty Responsibilities:

1. Faculty will use lecture, discussion or other strategies to help students understand the major issues surrounding the assigned topic and readings.
2. Faculty will facilitate discussion that flows from the expert’s presentation and related issues.
3. Students will lead the case discussions among all class members or their subgroup and help keep each other on topic. Faculty will help keep students focused.

Grading:

Students are expected to consistently make informed contributions to discussions in each class. Such discussions can only be truly informed if students have carefully completed all assigned readings. Students may miss class only for illness or important professional conflicts (e.g., a conference) – students should inform Dr. Bearer and Dr. Lidke with Cc to Kevin Reagan via email as soon as they know they will miss a class.

Lecturers will maintain a sign-in sheet of attendance and documentation of participation. Some valuable verbal contribution to every session is expected. A perfect performance will be a score of 16, with attendance (8 points) and contribution (8 points) at every session for a total of 16 points.

A is for a score of 15-16; and B, for score 12-14. Lower than 12 will not receive credit.

Spring 2015 Class Schedule:

BIOMED 555 – Responsible Conduct of Research (RCR)

Location: BMSB 309 (Harvey Library) Time: W 4-5:50

We will not have class during Spring Break week.

The class lasts 1 hour and 50 minutes each week for 8 weeks. We break most classes into two parts:

Part 1 – Instructors give didactic overview of a new topic [~45 minutes for presentation]

Part 2 – Case discussions lead by students and facilitated by faculty;

DATE	NAME	TOPIC	ASSIGNED READING**
Feb 25	Angela Wandinger-Ness	Introduction: Responsible Conduct of Research	Macrina, Chpt 1 & 2 Cases: 2.1 (mandatory) 2.2 & 2.8 (choose one)
March 4	Akshay Sood	Mentorship & Collaborative Research	Macrina, Chpt 3 & 8 Cases: 3.1, 3.2 & 3.10
March 11	Spring Break	No Class	
March 18	Natalie Adolphi	Authorship (Collaboration) and Peer Review	Macrina, Chpt 4 and ICMJE website Cases: 4.5, 4.9, 4.10
March 25	Kevin O’Hair	Animals in Biomedical Experimentation	Macrina, Chpt 6 Cases: 6.4, 6.7, 6.10
April 1	Mark Parshall	Conflicting Interests & Commitments	Macrina, Chpt 7 Cases: provided by lecturer **
April 8	Mark Holdsworth	Human Subjects in Research	Macrina, Chpt 5, H.O., and Harry Beecher article Cases: student choice*
April 11	Michelle Huff	Data Ownership / Intellectual Property	Macrina, Chpt 9 Cases: 9.1, 9.6, 9.10
April 22	Elaine Bearer	Data Management & Scientific Record Keeping, Science & Society Wrap-up Session	Macrina, Chpt 10 & 11 Cases 10.1, 10.2

*For student choice, each group should decide collectively which case they are interesting in preparing. The groups should let each other know so that every group still has a different case.

**Additional reading material and case assignments will be posted on the course website at <https://learn.unm.edu/> at least one week before the lecture.

Some Research Ethics Related Resources Worth Exploring

1. The **National Academy Press** has a number of publications online related to scientific conduct, including the monograph "On Being a Scientist," a brief introduction to RCR issues, at: <http://www.nap.edu/>

2. The US Public Health Service **Office of Research Integrity** (ORI) home page provides links to number of reports and documents related to scientific conduct: <http://ori.dhhs.gov/>

3. The **Ethics Center for Engineering and Science** has a webpage that provides access to codes of conduct, cases, and a variety of other topics related to scientific integrity: <http://onlineethics.org/>

4. **UNM Policies on research** and related issues may be found at: <http://www.unm.edu/research.html> and <http://research.unm.edu/>

5. **UNM Regents policy** on faculty can be found at: <http://policy.unm.edu/regents-policies/index.html>

6. **Advisor, Teacher, Role Model, Friend: On Being a Mentor to Students in Science and Engineering.** (1997). A monograph prepared by the *National Academy of Sciences* is a guide for faculty members, teachers, administrators, and others who advise or mentor students in the sciences and engineering. It has examples, tips, and useful summaries, is easy to read, and heightens mentoring duties and responsibilities. It is available free online at: <http://www.nap.edu/readingroom/books/mentor/>.

7. An informative website on the **Freedom of Information** (FOI) may be found at: <http://www.nfoic.org/foi-center>

8. **Biohazard Compliance for Research**, also called UNM's research bio-safety program, helps protect from exposure to infectious disease or other biological materials: <http://hsc.unm.edu/som/biohazard/>
Contact: Judy Pointer and Tim Mueller at 272-6950 if you are using strains of an organism in your research prior to conducting that research.

9. **Conflicts of Interest** (COI). Complete COI forms to disclose relationships or payments that may affect the outcome or interpretation of any research (or if you ask your students to purchase a book you wrote). After disclosure, conflict can often be managed with research conducted under an approved management plan, the simplest of which involves full disclosure to all stakeholders.
Contact: Committee D - Adelia Otero (Main campus 277-0204). <http://research.unm.edu/coi/> or Committee C - A. Marie Barron (HSC 272-6433) <http://hsc.unm.edu/research/coi/index.shtml>.
Institutional Official: The University Provost on main campus is responsible official for COI.

10. **Export Control** rules fall under Industrial Security. Forms should be completed if there are restrictions on publication OR your research includes Intellectual Property, Confidential Information, US-made materials or technology that falls under ITAR regulations or the Commerce Control list, you are working with non-US citizens (foreign nationals), or if you plan to ship anything outside the US.
Contact: 277-0732; Deborah Kuidis, FSO/Mgr Industrial Security & Deborah Cole, Export Control OVRP
<http://research.unm.edu/ExportControl/>

11. **Institutional Animal Care and Use Committee** (IACUC) regulates the use of animals in any kind of research, display, or in the classroom for any purpose.
Contact: Katy Mirowsky-Garcia, 272-0418 and Victoria Sugita, 272-6806, IACUC, Office of Animal Care Compliance (OACC); <http://hsc.unm.edu/som/research/acc/>
Campus Attending Veterinarian: Kevin O'Hair, 272-3936 Institutional Officials: Main Campus - UNM President; HSC Campus - HSC Chancellor.
Two Committees administered by the OACC:

- (1) Health Sciences Center IACUC – Responsible for all vertebrate research conducted at HSC sites.
- (2) Main Campus IACUC – Responsible for all vertebrate research at Main Campus and field study sites.

12. The **Human Research Protections Office** (HRPO) in BMSB basement (272-1129) should be consulted if you are proposing to recruit participants for any study that uses surveys, questionnaires, collects medical information, clinical trials, etc. and will collect any data from living human subjects.

The HRPO website (<http://hsc.unm.edu/som/research/HRRC/>) includes a great many resources to examine. Five IRB committees operate at UNM under the administration of the HRPO:

- (1) 4 committees are for studies involving biomedical procedures broadly defined and are called the Health Sciences Center *Human Research Review Committees* (HRRC); and
- (2) 1 committee is for studies involving subjects in the social, behavioral, educational or other sciences on main campus and is called the main campus *Institutional Review Board*.

Contact: email: HRPO@salud.unm.edu for HSC; or call (272-0880 for main campus & 272-1129 for HSC).

See: <http://hsc.unm.edu/som/research/HRRC/>

Institutional Official: HSC Chancellor is the responsible official for the entire campus.

13. **Research Ethics and Integrity Program** in the UNM main campus Office of the Vice President for Research provides resources and information to foster responsible conduct in research and in responding to federal requirements for ethics training. <http://grad.unm.edu/aire/> email: AIREUNM@unm.edu

Contact: Dr. William Gannon at 505-277-3488 or (wgannon@unm.edu)

14. **Research Misconduct** issues are filed with the Vice President for Research, and if you have questions or concerns contact: 505-277-6128, <http://research.unm.edu/researchethics/> Follow [Policy E40](#)

15. **Fraud, Misconduct, and Retaliation** are serious events if you are exposed to these issues; these can be reported immediately and anonymously to: UNM Hotline 1-888-899-6092

NOTE: Links for items above can also be found at: <http://research.unm.edu/> and <http://hsc.unm.edu/research/>

16. The **Kennedy Institute of Ethics** (KIE) at Georgetown University in Washington, DC is the world's oldest and most comprehensive academic bioethics and research ethics center. The Institute and its library serve as an unequalled resource for those who study ethics, who debate, and who make public policy. The Kennedy Institute is home to an internationally renowned group of scholars who engage in research, teaching, and public service on issues that include protection of research subjects, reproductive and feminist bioethics, end of life care, health care justice, intellectual disability, cloning, gene therapy, eugenics, and other major issues in research and bioethics. KIE scholars figure prominently among the pioneers of the discipline. <http://kennedyinstitute.georgetown.edu/>

17. **Scientific Integrity** (2014; 4th edition) by Francis Macrina is a textbook for graduate and postdoctoral trainees and scientists in the biomedical, behavioral, and life sciences. Its content and design are ideally suited for use in responsible conduct of research courses. It is our textbook. <http://www.scientificintegrity.net/>

18. **Teaching Research Ethics**: The purpose of this site is to provide resources and tools for teachers of research ethics. The goal is to promote best practices and evidence-based research ethics education. <http://research-ethics.net/>

19. **NIH Bioethics Resources on the Web**: Links to a great many ethics sources, including research ethics and RCR sources. Students are encouraged to explore this and some of the other research ethics websites listed above. <http://bioethics.od.nih.gov/>

20. **Public Responsibility in Medicine and Research** (PRIM&R, pronounced prim-er). PRIM&R is an organization of over 3000 professionals (including Dr. Warner) that works to advance the highest ethical standards in the conduct of research. Since 1974, via a wide variety of conferences and courses, PRIM&R has provided well-researched and accurate information on the ethical and regulatory issues affecting research while also offering unparalleled access to certification, networking, and professional development

resources. If you attended only one research ethics conference each year, PRIM&R would be the one.
<http://www.primr.org/>