BIOMED 555: RESPONSIBLE CONDUCT OF RESEARCH (RCR)
Fall 2022

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

I. Course Details

Semester Dates: **October 19th 2022** through **December 14th 2022**

Class day and time: **Every Wednesday, 3:00 – 5:00 PM**

Location: **In person, FITZ Hall (Harvey) Room 309** (see schedule below on page 4).

Course Directors: Rama Gullapalli, MD, PhD (rgullapalli@salud.unm.edu; 272-8249 Office)
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Gregg Banninger (GBanninger@innovations.unm.edu)
Matthew Davis (MDavis@innovations.unm.edu)
Tara G. Konecny (TKonecny@salud.unm.edu)

Teaching Assistant: Julianne Peabody (JPeabody@salud.unm.edu; 272-9945)

II. 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.

III. 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:

(1) human subjects in research;
(2) animal subjects in research;
(6) scientific misconduct;
(7) data management and scientific record keeping;

(3) responsible authorship and publication;
(4) effective mentoring;
(5) conflicts of interest and commitment;
(8) data ownership and intellectual property;
(9) effective collaboration in research; and
(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."

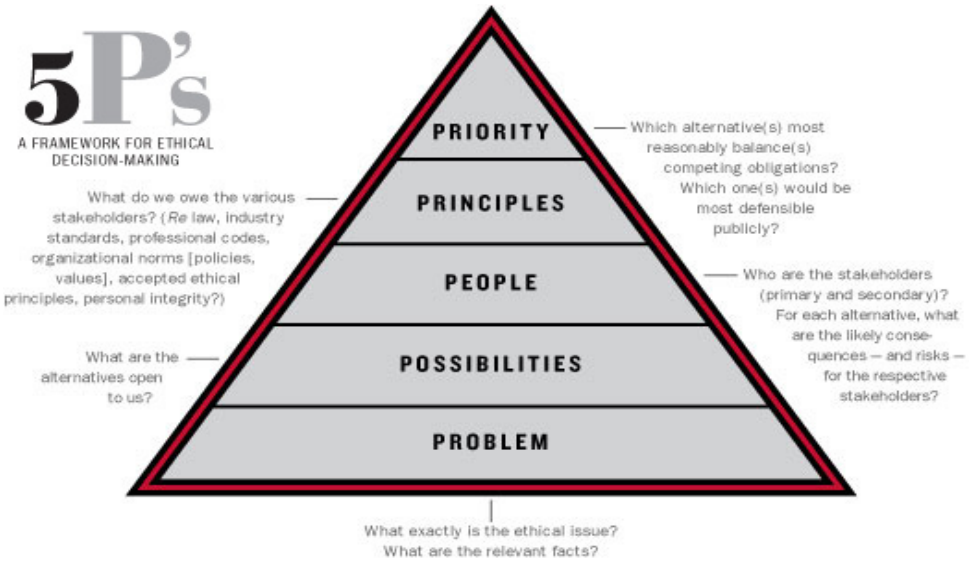
IV. Required Textbook:

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. **Students are expected to turn in brief, and thoughtful responses to the assigned case studies.**
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.

V. 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.

VI. 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, **and turn in written brief case reports on case studies**, and 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.

VII. 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. **Each student is expected to provide the instructor with a written summary response to each assigned case study.**
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.

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.

VIII. 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 and help keep each other on topic. Faculty will help keep students focused.

IX. 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. Buranda/Dr. Gullapalli 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. The written case summary for each session is an indispensable component of the grade. 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.

Fall 2022 Class Schedule:

BIOMED 555 – Responsible Conduct of Research (RCR)
Location: In-person, Harvey Conference Room 309: Wednesday 3:00-5:00 PM

We will 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**
Oct 19th	Rama Gullapalli MD, PhD and Tione Buranda, PhD	Introduction and Course overview: Responsible Conduct of Research (research ethics, rigor and reproducibility, etc.)	Macrina, Chpt 1 & 2 Cases: 2.1 2.2 & 2.8
Oct 26th	Tara G. Konecny, DVM	Animals in Biomedical Experimentation	Macrina, Chpt 6 Cases: **see Appendix**
Nov 2nd	Thomas Byrd, MD	Human Subjects in Research	Macrina, Chpt 5, H.O., and Harry Beecher article **Cases: see Appendix**
Nov 9th	Bryce Chackerian, PhD	Conflicting Interests & Commitments	Macrina, Chpt 7 Cases: 7.4, 7.5 **Case 1: see Appendix**
Nov 16th	Akshay Sood, MD	Mentorship & Collaborative Research	Macrina, Chpt 3 & 8 Cases: 3.1, 3.2 & 3.10
Nov 23rd	**Thanksgiving Week – No Class**		
Nov 30th	Nathalie Adophi, PhD	Authorship (Collaboration) and Peer Review	Macrina, Chpt 4 and ICMJE website Cases: 4.5, 4.9, 4.10
Dec 7th	Gregg Banninger PhD and Matthew Davis	Commercialization of Research and Intellectual Property	Macrina, Chpt 9 Cases: 9.1, 9.6, 9.10
Dec 14th	Natalie M. Salas, MD Martha Carvour, MD	Responsible use of Race in Research – Lab Ethics to Data Analysis	**Materials and Cases; See Appendix**

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

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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: Julie Lovchik 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 - Adelicia 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 OVPR
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: Tara G. Konecny, 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/

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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; 4rd 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 *i*s 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/

BIOMED 555: RESPONSIBLE CONDUCT OF RESEARCH (RCR) –

III. Case Studies by Tara G. Konecny, DVM

Case 1. Pressure to accelerate research with nonhuman primates (NHP)
LabAnimal, Volume 48 Issue 10, October 2019
As the father of a child who succumbed to globoid cell leukodystrophy (Krabbe disease), Dr. Leon Martel was passionate about his research to find a cure for this autosomal recessive neurological disorder, for which there is no satisfactory treatment. Martel's initial gene therapy research at Great Eastern University used mice for modeling the disease, and he found increased longevity, improvement of clinical signs, and no adverse side effects attributed to the therapy. He then progressed to treating affected dogs. Bone marrow transplantation, combined with or without gene replacement therapy, showed similar early indications of success, although some signs of mild liver and neural toxicity were found postmortem in two treated normal control animals.
Martel's work was published and presented at meetings, which eventually led to a phone call from his U.S. senator, who served on the Health, Education, Labor and Pensions Committee. The senator urged Martel and the college dean to push ahead with testing on rhesus monkeys as these nonhuman primates were previously used for Krabbe disease research. The senator's altruistic goal was to have Martel accumulate enough data for the school to apply for accelerated approval of the procedure from the Food and Drug Administration and then begin clinical trials with afflicted human children. Nevertheless, after initial talks between Martel, the dean, and the chair of the IACUC, it became obvious that Martel and the IACUC chair were hesitant to move forward with nonhuman primate studies until more work was done to elucidate the cause of the mild toxicity seen in the dog studies. The dean, under continuing pressure from the senator, argued that the mouse studies showed no toxicity at all and that the mild toxicity in dogs had no overt clinical impact and was found in only two of the twelve control animals. The discussion led to a key question: If affected and non-affected monkeys were to be studied, what clinical signs would be used to determine if there was either improvement or toxicity to the animals? Clinical signs in affected monkeys were known, but clinical signs in normal monkeys subjected to Martel's gene therapy technique were unknown. Martel feared that given the infrequent and mild aberrant findings in dogs and the long life span of rhesus monkeys, there may no simple way for him to determine a clear and meaningful study endpoint.
If you were Martel, how would you deal with the pressure from the dean?

References
1. Baskin, G. B. et al. *Lab Anim Sci.* **48**, 476–482 (1998)

Case Discussion
1. Would you submit a protocol amendment to add monkeys to the study?
2. Should more investigation be conducted before deciding to test NHP? If so what?
3. Legally what authority does the IO and the Senator have? Approval or disapproval of protocol with or without IACUC approvals?
4. If most concerns are resolved but team is still unsure about risks to NHP model, what approach might be taken?

Case 2 - A pain in the eye: what's the category? LabAnimal Volume 48 Issue 4, April 2019 Recording electrical signals from the eye of a living mouse may become a little easier with the use of an electrode mesh that can be injected into an animal's eye. The basic technique, as recently described1, is to perform an intravitreal injection into the rear of the eye where the mesh then unfolds onto the retina. Wires attached to the mesh and an external electrical recording device exit the eye at the lateral canthus.
The new technique was being proposed for use at Great Eastern University where Dr. Tom Villanueva, the attending veterinarian, was presenting the details of the technique to the IACUC. Dr. Brad Collins, an IACUC member, interrupted him to ask if the wires that exit from the eye are painful to the mouse. "I've seen videos of the surgery and aftercare" said Villanueva, "and it doesn't appear to bother them. They don't paw at the eye, they seem to act normally in the cage, they have normal ocular pressure and a normal pupillary reflex."

“That may be true,” said Collins, “but if I had a wire protruding from the corner of my eye, I wouldn’t be a happy camper. I don’t know how much it would hurt, but I’ll bet it would bother me. What pain category is being proposed for this protocol?”
“USDA category D,” responded Villanueva. “The surgery is performed under anesthesia, and we will be giving buprenorphine for three days post-op.”
“Well, I’m still concerned,” Collins said. “If we believe that a procedure that’s painful or distressful to a human is likely to be painful or distressful to a mouse, then I think this should be category E, due to unalleviated distress from the wires attached to its eye and acutely altered vision from the presence of the mesh.”
“I disagree,” Villanueva answered. “As far as I know this procedure has never been performed on humans, so I don’t see how you can make that correlation. The investigator was trained on the technique at a lab where it’s being used and he knows what he’s doing, so I think it’s best to let the committee discuss the protocol and vote on it.”
If you were a member of the Great Eastern IACUC, are there additional questions you would ask? From the information currently available, which pain category do you think is appropriate for this study?
References

1. Animal Welfare Regulations 2012. 9 CFR §2.31
2. USDA Pain levels. https://www.esf.edu/animalcare/documents/USDApainLevels.pdf

Case Discussion

- What determines category
- Are pain categories required in non-USDA species
- If not required what is the utility of considering pain categories
- For novel studies like this that could pose risks of pain, what might help determination of risk

Case 3. Is ‘saving money’ a valid justification? LabAnimal Volume 47 Issue 4, April 2018

One of the guiding principles of using animals for biomedical research is to use the smallest number of animals that may lead to statistically or biologically significant results. Supporting this concept, both the NIH and USDA state that “investigators may use fewer animals than approved. This does not require IACUC approval, notification, consultation, or administrative handling.”[1]
Dr. Ed Stark was an established researcher with a propensity for doing things in a way that just skirted the line between right and wrong. This tendency often caused problems for the school’s IACUC, as exemplified by an incident when Stark decided to reduce the number of animals in one of his IACUC approved experiments. He did this by euthanizing an entire group of negative (untreated) control mice without informing the IACUC. When the IACUC office finally found out what Stark had done, the committee chairman asked him for an explanation because Stark had argued during the initial review of his protocol that the untreated controls were scientifically necessary. But now he said that the findings to date with his experimental groups were trending toward strong statistical significance and the vehicle control mice (those having corn oil mixed in their diet) were adequate controls to complete the study. He added that he wanted to avoid some of his per diem charges, so eliminating an unnecessary group of animals made good sense, and in any case the IACUC had no authority to even question him about how he conducted his experiment as long as there was no protocol noncompliance or animal welfare issues.
Stark’s response did not sit well with the IACUC chairman who discussed the incident at the next full committee meeting. The chair’s position was that there was nothing in the protocol that gave Stark the authority to euthanize an entire experimental group of healthy animals that he originally stated were important to his study. On the other hand, he was aware of the NIH guidance about an investigator being allowed to use fewer animals without informing the IACUC but he did not interpret that guidance as sanctioning the euthanasia of an entire experimental group just to save money.
How do you think the IACUC should resolve the issues raised by its chairman?

References

1. Public Health Service. *Guidance on significant changes to animal activities*. Notice NOT-OD-14-126. (National Institutes of Health, Washington, D.C. 26 Aug. 2014.)

Case Discussion

- Do you think that the IACUC overstepped?
- Is substituting the corn oil “vehicle” diet group as negative control acceptable?
- Is cost alone sufficient to decide to remove controls?
- Would you consider this a valid method for reduction?

BIOMED 555: RESPONSIBLE CONDUCT OF RESEARCH (RCR) –

I. Case Studies by Thomas F. Byrd, M.D.

Please keep the following Principles from the Belmont Report in mind when reviewing these case studies that we will discuss on December 11, 2019:
1) Respect for persons
2) Beneficence
3) Justice

Case 1
You are reviewing a protocol in which the research goal is to determine whether some dentists are avoiding treating patients with cognitive disabilities. The protocol calls for study team members to call dentists offices throughout the state and either portray themselves as a family member attempting to schedule a dental appointment for their cognitively impaired relative, or as someone attempting to schedule an appointment for themselves. The responses from each office will be recorded. What are the factors you should consider when reviewing this protocol?

Case 2
A program is developed in which student athletes enrolling in a college will be mandated to undergo baseline fMRI scans and take a battery of neurocognitive tests prior to participating in college athletics. If the athlete has a concussion they will be asked to repeat these tests. fMRI scans are an unproven modality for assessing cognitive function after a concussion. As part of standard of care, if they suffer a severe concussion and/or have persistent neurocognitive deficits, they will also undergo head CT scanning and be referred to a neurologist by the team physician. Is informed consent required? What additional information do you need to know?

Case 3
A university pharmacy team is proposing a study in which patients with latent tuberculosis identified by either ppd skin testing or Quantiferon TB gold blood testing will be treated for latent tuberculosis by pharmacists in local community pharmacies. The goal is to determine if this mechanism for delivering treatment is effective. The treatment is relatively new, FDA approved, once weekly regimen consisting of the drugs rifapentine and isoniazid for 12 weeks to be dispensed weekly by the community pharmacist. What information regarding risks should be in the human subject consent form?

Case 4
Two anesthesiologists who are pain management specialists and run a pain clinic at a VA hospital have an idea of how to treat low back pain which often is due to osteoarthritis of the facet joints in the lumbar spine. They hypothesize that immobilization of the facet joints by percutaneous injection of methyl methacrylate in the joints will relieve back pain. They propose to enroll subjects in a trial to receive either methyl methacrylate or sham injection to assess the effect on back pain. What are some considerations in reviewing this?

Case 5
An investigator is doing research on brown fat metabolism and wants to obtain brown fat cells from subjects after a period of cold exposure. The investigator proposes to obtain biopsies from deposits of brown fat from normal volunteers which are often located just under the clavicle. Subjects will receive $700.00 to undergo a brown fat biopsy performed by a university interventional radiologist. What are some considerations in the discussion of this protocol?

Case 6
An investigator is proposing to do a study to identify genetic variants associated with obesity. They hope to identify children who are obese and who also have a non-obese sibling and recruit the subjects from a

pediatric clinic. They propose to do comparative whole genome sequencing on the siblings as well as their parents in this study. What are some ethical considerations in conducting this research?

Case 7
Athletes from the community including area high schools and colleges who have had a recent concussion will be recruited by flyers to participate in a study in which they will undergo serial neurocognitive/balance/reaction time tests to determine the effect of the concussion on these functions, and if there are effects, how long they take to resolve. What are some important considerations in assessing this study? Is there a risk to the athletes?

Case 8
A high school teacher has partnered with a university faculty member to study the potential influence of social media on drinking behavior in high school students. The study will deploy trained high school researcher peers who will set up booths in local malls and other venues advertising the study. High school students who are interested in participating will be consented and the student researchers will ask the subject to open snapchat (storyline version) on their cell phones and scroll through the content from the preceding 24 hours. The student researchers will grade and record what they see for alcohol-related content. A high school faculty member will be present in the event any problems arise. What are some considerations in reviewing this study?

Case 9
A group of clinicians submit an industry sponsored study that involves a promising treatment to the IRB. The protocol will randomize subjects to receive standard surgical care for acute spinal cord injury or placement of a neuroscaffold device at the site of injury which is made of material that will be ultimately be replaced and absorbed by the patient's own cells. The title of the informed consent document is - Randomized, Controlled, Single-blind Study of Probable Benefit of a Neuro Scaffold for treatment of acute spinal cord injury compared to Standard of Care. What is an important consideration when reviewing this clinical trial?

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II. Case Study by Bryce Chackerian PhD

From:
https://ori.hhs.gov/rcr-casebook-conflicts-interest

Case 1:

Dr. Bobby Bill was an undergraduate in the lab of one of the first researchers to successfully demonstrate the existence of a "longevity gene" in *c. elegans*, and since then his passion has been the search for the expression of genes uniquely present in genetic variants of organisms that live significantly longer than the mean. He has turned the attention of his NIH-funded lab to drosophila as a model organism, and his research group at a very good Midwestern school in the US has successfully isolated a handful of genes that are highly expressed in fruit flies that live significantly longer than typical.

Dr. Bill was contacted by a large pharmaceutical company, also interested in longevity, to be a professional consultant. Initially, they were interested in establishing a drosophila colony that would include an aged population, and asked Dr. Bill's help in the husbandry of the aged fruit flies. They invited Dr. Bill to their corporate research labs about three times a year, each time paying his travel and a $2,000 honorarium. However, the relationship has evolved and now Dr. Bill is serving a role more like a scientific collaborator than a consultant. He has now been asked to serve on their Scientific Advisory Board and as compensation will be getting some shares in the company stock currently worth about $12,000. Furthermore, they have "gifted" $180,000 to his lab to cover a graduate student for three years to work on a few collaborative projects. Dr. Bill now spends about 15% of his effort on the collaboration and 60% of his effort on his NIH project. The remainder of his time is spent on teaching and committee service. The trips to the company have increased, and sometimes Dr. Bill has to get other faculty members to cover his lectures because of his travel schedule.

At a recent research meeting at the company, Dr. Bill and the Board could clearly see a potentially patentable product emerging from their joint line of inquiry. This product, which stimulates expression of the longevity genes, has the potential of providing a therapy to slow the onset of aging in humans, which is extremely exciting and could be quite lucrative. However, the Scientific Advisory Board would need to decide whether or not to publish their findings, and how to protect the intellectual property rights emerging from this research. The Board asks which parties need to be represented legally as the push to commercialize the product moves forward: Dr. Bill, his graduate student, his institution? Dr. Bill feels that, while his research group contributed to the success of the project, direct experiments related to the product were not performed by any NIH-funded personnel. And, he has spent much effort at night and on weekends on the company's project. Therefore, he feels that it is fair that his intellectual property (IP) interests be represented, but not necessarily the school's interests. Dr. Bill feels as though, since he fulfilled his teaching, service, and research efforts at the school during this time period, all additional efforts he may have made were on his own behalf. Further, Dr. Bill feels that since the graduate student was getting her training on this project, she has not really earned any additional benefit for her participation in the project.

How should Dr. Bill answer the Board's questions about who should be listed on the potential patent?

Discussion Questions

- Does Dr. Bill have either a perceived or real conflict of interest in participating in this project? At what point in this scenario did that happen?

- Does Dr. Bill have a conflict of commitment? How does this concept differ from the concept of a conflict of interest?
- Under NIH Financial Conflict of Interest (FCOI) guidelines, must he report any or all of his travel reimbursements, stocks or direct payments from the company? Does the company have to report their compensation to Dr. Bill?
- When should IP/patent rights be discussed and determined in a collaborative project? By what mechanism does that occur at academic institutions?
- In your opinion, does the school have any IP/patent rights? Why might this be important to the school?
- Are faculty sometimes allowed to serve as outside consultants? If the school has a policy on faculty consultation activities, might that affect their rights in this situation?
- Is collaboration between academia and industry a good thing? What are the pros and cons?
- Has Dr. Bill done anything "wrong" in this scenario? Has the company?
- What special issues might arise for the graduate student whose stipend is paid through a gift from a company, such as in this case?
- Should this research be subjected to peer review through publication, or is the push to help humanity better served by allowing the company to continue along these research lines without the added competition that publication would certainly bring?
- Does the NIH have any IP/patent rights in this scenario? In any scenario?
- Debate Question: Must we avoid all conflicts of interest, or can some be managed?

BIOMED 555: RESPONSIBLE CONDUCT OF RESEARCH (RCR)

IV. Responsible use of Race in Research – Lab Ethics to Data Analysis: Materials and Case Studies developed by Natalie M. Salas, MD Internal Medicine, Infectious Disease UNM, and Martha Carvour, MD, Internal Medicine - Infectious Diseases University of Iowa

By the end of this session attendees will be able to:

- Demonstrate understanding of the impact of unconscious bias in lab operations and the impact this can have on the entire team as well as team members of color in particular
- Identify strategies to respond when members of the team experience subtle or overt racism in the work environment
- Identify institutional resources that are available for trainees who experience racism in the lab
- Identify when data collected about race in human research is used inappropriately as a biological construct
- List 2 different ways to gather and analyze data on race in human subjects that is scientifically responsible.

Session Pre-Reading:

On Racism: A New Standard for Publishing on Racial Health Inequities | Health Affairs

https://www.healthaffairs.org/doi/10.1377/hblog20200630.939347

Cerdeña JP, Tsai J, Grubbs V. APOL1, Black Race, and Kidney Disease: Turning Attention to Structural Racism. Am J Kidney Dis. 2021 Jan 21:S0272-6386(21)00055-X. doi: 10.1053/j.ajkd.2020.11.029. Epub ahead of print. PMID: 33485919.

Case 1:

PhD student Juan Martinez has been working in Lab X for 3 months on a longitudinal research project. He arrives frequently at the lab with his colleagues where they are greeted by a security officer who waves them in. One morning he has car trouble and arrives later than usual, after his colleagues have entered the lab. He realizes he has forgotten his security badge, but has seen his colleagues frequently swiped into the lap by the friendly security officer. He decides he will ask for this, but when he sees the security officer, the man doesn't appear to recognize him without his colleagues. He asks for both his lab security badge and an ID card prior to allowing him entry into the building. Flustered, he calls an Uber to go back home and get his badge - the round trip cost him 25 dollars and 45 mins of time, both resources he's not really sure he has. Fortunately his PI and mentor is very supportive, and he has no further issues getting into the building. He enters and is relieved to see some of his colleagues standing around the entrance of the lab on a coffee break. He begins to approach them, when he meets a woman he does not recognize who flags him down in the hall, smiling.

"Hey, Good morning!," she says pleasantly, "The light in Lab X that has been flickering for weeks has finally gone out - I called maintenance about 20 minutes ago, I'm so glad you arrived!"

Questions:

- How would you describe what occurred to this PhD Student? Is this a microaggression? Macroaggression? Overt racism?
- What is the best way for the student's colleagues and PI to respond?
- How should the student respond? Should he complain about the security officer? About the building administrator?

- Have you ever witnessed this, or has this ever happened to you? How did you respond? What institutional resources are available should you encounter or witness a situation like this?

Resources for Trainees who witness or experience racism:

For the Learning Environment Office (LEO):

- *Contact LEO to report mistreatment of BSGP learners or talk about an incident that you think might be mistreatment*
- Submit an online report (anonymous or not): https://app.smartsheet.com/b/form/8d0b8a0107c14cffa37c996ae2562697
- Reach out to LEO's Director, **Diana Martínez**: deemb@salud.unm.edu or 505-620-6382
- Reach out to LEO's Assistant Director **Emma Naliboff Pettit**: ecpettit@salud.unm.edu or 310-367-9235
- For more information on LEO: www.goto.unm.edu/leo

For the Office of Compliance, Ethics, and Equal Opportunity (CEEO, formerly OEO):

- *Contact CEEO to report discrimination based on race, ethnicity, religion, gender, sexual orientation, disability, age, pregnancy status, etc. Anyone can report discrimination to CEEO (not limited to learners or by program. CEEO serves students, faculty, and staff on main campus and HSC).*
- File a report on the website by clicking on "File Civil Rights/Title IX Report": https://oeo.unm.edu/
- Reach out to the Interim Director of Equal Opportunity, **Heather Jaramillo**: hjarmillo@unm.edu

Case 2:

An interdisciplinary group of biomedical researchers at a large academic institution convenes a COVID-19 Interest Group to discuss ongoing research pertaining to the SAR-CoV-2 virus and/or the COVID-19 pandemic. The group includes clinical and translational researchers and provides opportunities for collaborative discussions about the rapidly emerging science in the field. At a journal club-style session, a postdoctoral scholar presents a pre-print manuscript about the apparent impacts of COVID-19 on a set of immunological markers in a racially diverse, multicenter cohort of patients. The authors of the manuscript describe significant disparities in clinical outcomes for several historically minoritized racial and ethnic groups represented in the cohort--including Black/African American, Native American/Indigenous, Pacific Island Native, and Latino/a/x persons--and propose that immunological mechanisms partially mediate these disparities. A prominent physician researcher in the COVID-19 Interest Group states, "This is a very interesting study--and a great example of why including diverse populations in research is so important! Some racial groups may be more genetically susceptible to COVID-19, and some of the genes responsible may encode important immune functions. By understanding those genetic factors, we can fundamentally change our understanding of how this virus interacts with the immune system. Perhaps we can even identify high-risk genes that we can use to screen patients."

Questions:

- Using the pre-readings for this session as a guide, how might the postdoctoral scholar and other participants in the journal club approach these statements about racial and ethnic health disparities, immunology, and genetics?
- The assertion that the study is "a great example of why including diverse populations in research is so important" appears to affirm the principle of diversity. In context, does it affirm the principles of diversity, equity, and inclusion? Why or why not?
- What factors or dynamics in the journal club session--such as perceived or actual power differentials between participants--might impact the discussion? How can the principles from Case 1 be applied to Case 2?