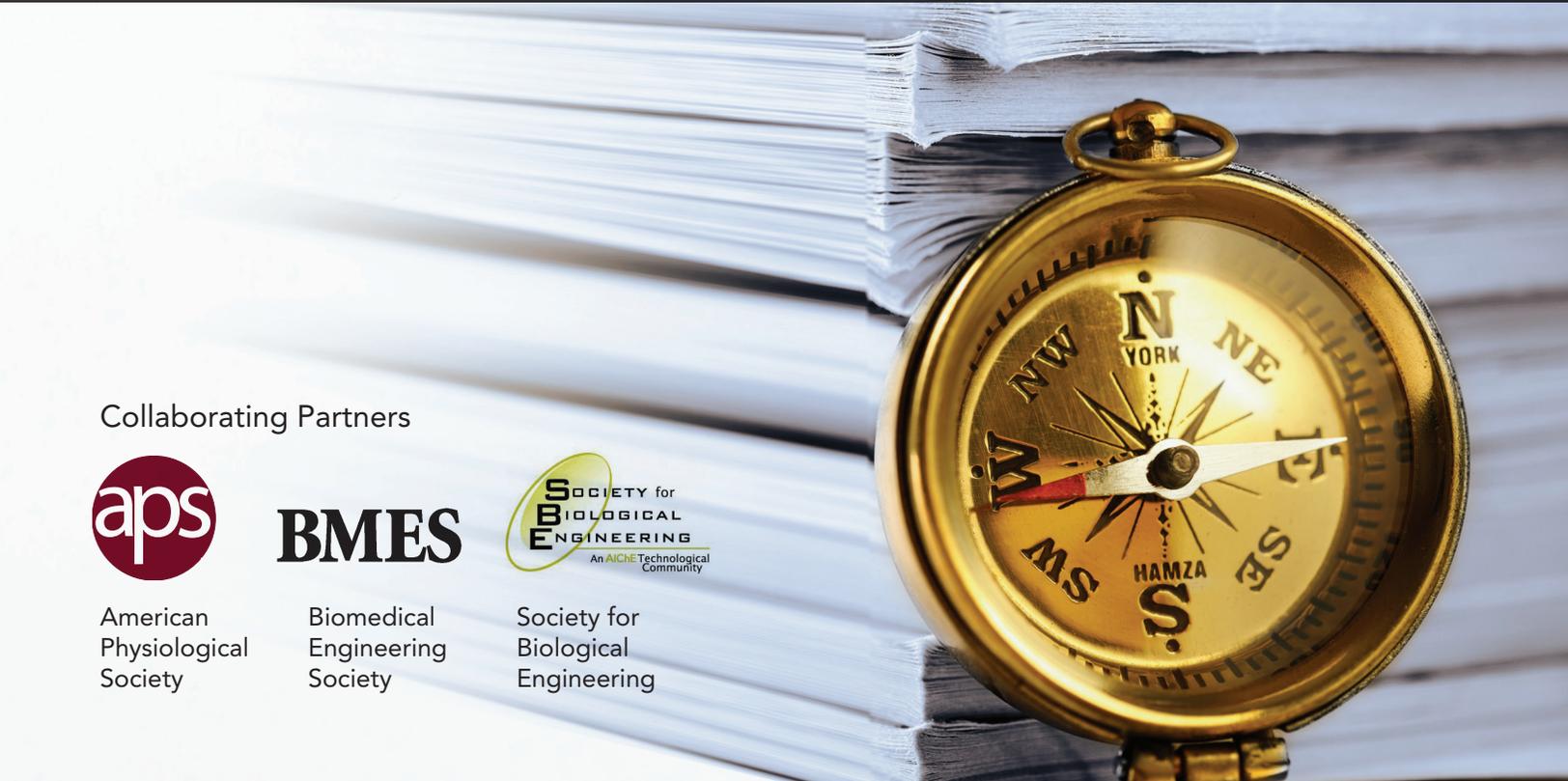




PROFESSIONAL INTEGRITY: BEST PRACTICES FOR PUBLISHING YOUR RESEARCH

Considerations for Animal and Human Studies

Christina N. Bennett, PhD and Marsha Lakes Matyas, PhD



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Animal and Human Studies Considerations

Christina N. Bennett, Ph.D.
Associate Publisher, Ethics and Policy
and

Marsha Lakes Matyas Ph.D.
Director of Education Programs
American Physiological Society

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This module is part of a series of seven teaching modules designed to promote best practices in publication ethics for life scientists and biomedical engineers who publish research papers. All materials in this module have been peer-reviewed by both the Advisory Board (below) and a panel of Responsible Conduct of Research (RCR) course instructors. They also were field-tested with graduate students in physiology. The modules were developed with support from the National Science Foundation (NSF) (#SES -1238368) and in collaboration with staff and members of the American Physiological Society (APS), Biomedical Engineering Society (BMES), and Society for Biological Engineering (SBE). The modules represent the views of the authors and do not necessarily represent the views of NSF, APS, BMES, or SBE. The information in these modules is designed to represent a summary of best practices and advice at the time of publication. They are not meant to serve as legal advice or publisher policy and do not in any way guarantee protection from professional ethics charges. For more information on how the materials were developed and tested, please contact the authors: Marsha Lakes Matyas: education@the-aps.org; Christina N. Bennett: apsethics@the-aps.org, American Physiological Society, 9650 Rockville Pike, Bethesda, MD 20814, www.the-aps.org.

Project Staff

Principle Investigators

Marsha Lakes Matyas, Ph.D., APS
Christina N. Bennett, Ph.D., APS
Jerry Collins, Ph.D., BMES
June C. Wispelwey, SBE/AICHe

Society Directors

Martin Frank, Ph.D., Executive Director, APS
Edward L. Schilling, III, Executive Director, BMES
June Wispelwey, Executive Director, AICHe

Project Advisory Board

Kim E. Barrett, Ph.D., U. of California, San Diego
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Hannah V. Carey, Ph.D., U. of Wisconsin
Lydia Contreras, Ph.D., U. of Texas at Austin
Jane Zimmer Daniels, Ph.D., JZD Consulting
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Charles H. Lang, Ph.D., Penn State Coll. of Med.
Rudy M. Ortiz, Ph.D. U. of California, Merced
Thomas A. Pressley, Ph.D., Texas Tech U. HSC-Lubbock
Gary C. Schoenwolf, Ph.D., U. of Utah
Annie Whitaker, Ph.D., Louisiana State U. HSU-New Orleans

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Animal and Human Studies Considerations Module

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I. Pedagogy

This module is designed to promote best practices in publication ethics for life scientists and biomedical engineers who publish research papers. The goal is for students to not only understand professional standards of practice in research manuscript development but also to be able to apply these standards to their own work AND to be prepared to teach them to their own students in the future. Toward that end, this module employs student-centered learning strategies that engage students across the spectrum of Bloom's taxonomy (see below). For best impact, students should not simply sit and listen or read and answer questions. Instead, we encourage you to use multiple teaching methods and activities that engage students in actively exploring the topic. Some suggestions you will find in this module include:

- **Interactive Lecture:** The lecture slides and notes include a number of places to stop and engage students in working out a problem, discussing a policy, or reviewing a case study.
- **Think/Pair/Share:** Often part of an Interactive Lecture, students are given a problem to address first on their own, and then they are asked to share their responses with a partner, followed by sharing with the whole class.
- **Voting Cards:** Particularly when discussing ethics issues, students prefer not to raise their hands to indicate their answer to a group question. Consider using voting cards with a simple large-print "Yes" on one side and "No" on the other. Everyone raises their hands and votes and you can quickly visualize the class response. An alternative is "thumbs up/thumbs down" but this is harder to see.
- **My Best Practice Checklists:** These are working documents each student develops to use now and in the future as their personal checklists of best practice in publication ethics.
- **PASS IT ON:** As part of their My Best Practice Checklists, students should make a plan for teaching publication ethics to their future trainees.

Instructors can pick and choose which activities and resources they want to use from the module. However, we encourage you to consider using the Learning Cycle approach because of its rich opportunities for student-centered learning. Alternatively, the Homework/Interactive Lecture/Activities (HILA) approach can be used when class time is limited. Both approaches are outlined below.

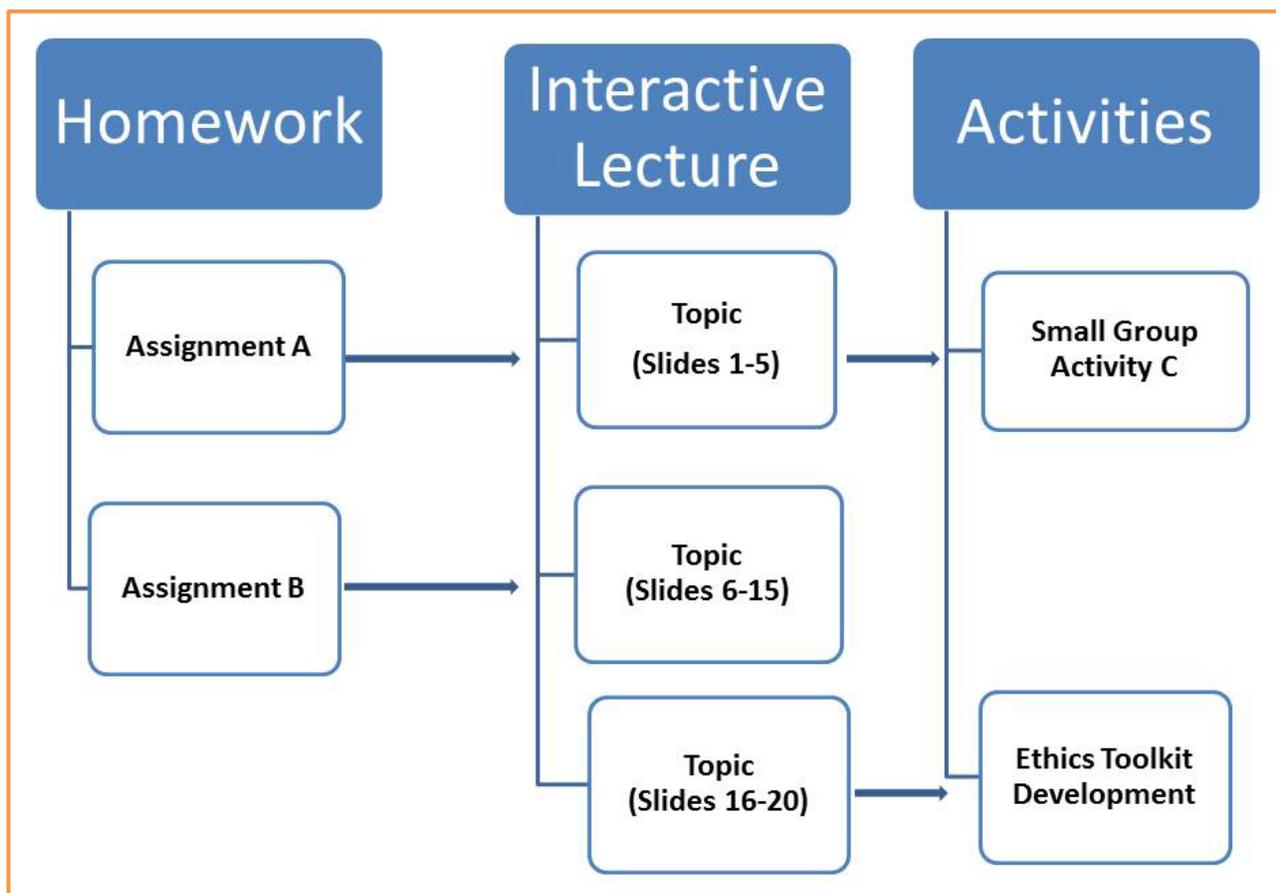
Learning Cycle

- **Engage:** Piques students' interest in the topic and poses questions or issues that capture their thinking. *Examples:* News articles on ethics violations and examples of manipulated figures.
- **Explore:** Students explore and ask questions, investigate via inquiry, make observations, and test hypotheses. Students should generate additional questions by the end of the exploration phase. *Examples:* Case study that students must try to resolve individually or in groups without additional information on professional standards of practice (these would be readdressed in the elaborate phase below), compare CV's of researchers, interpret letters from editors including comments/questions from reviewers, or write a letter to the editor describing figure manipulation in a manuscript to be submitted.

- **Explain:** Students and instructors use questioning/discussion, reference materials (print and online), expert presentations, and other resources to gain a better understanding of the key principles of the lesson and how they apply to the questions raised by students in the explore phase.
- **Elaborate:** Students apply what they have learned to real scenarios. *Examples:* Students revise their response to the explore phase case study using the principles and knowledge gained in the explain phase, and then do the same for a new case study or, ideally, their own work. Create a personal action plan or checklist for professional standards to use in the future.
- **Evaluate:** Evaluation occurs through each phase, with evidence collected of both student understanding of key principles and information and their ability to apply it to new situations and problems. *Examples:* Changes in approach to case study before and after the explain phase. Personal action plan/checklist addresses the key principles of professional practice. Key principles are applied appropriately to new case studies. Can also include quizzes or tests of content knowledge of professional standards of practice.

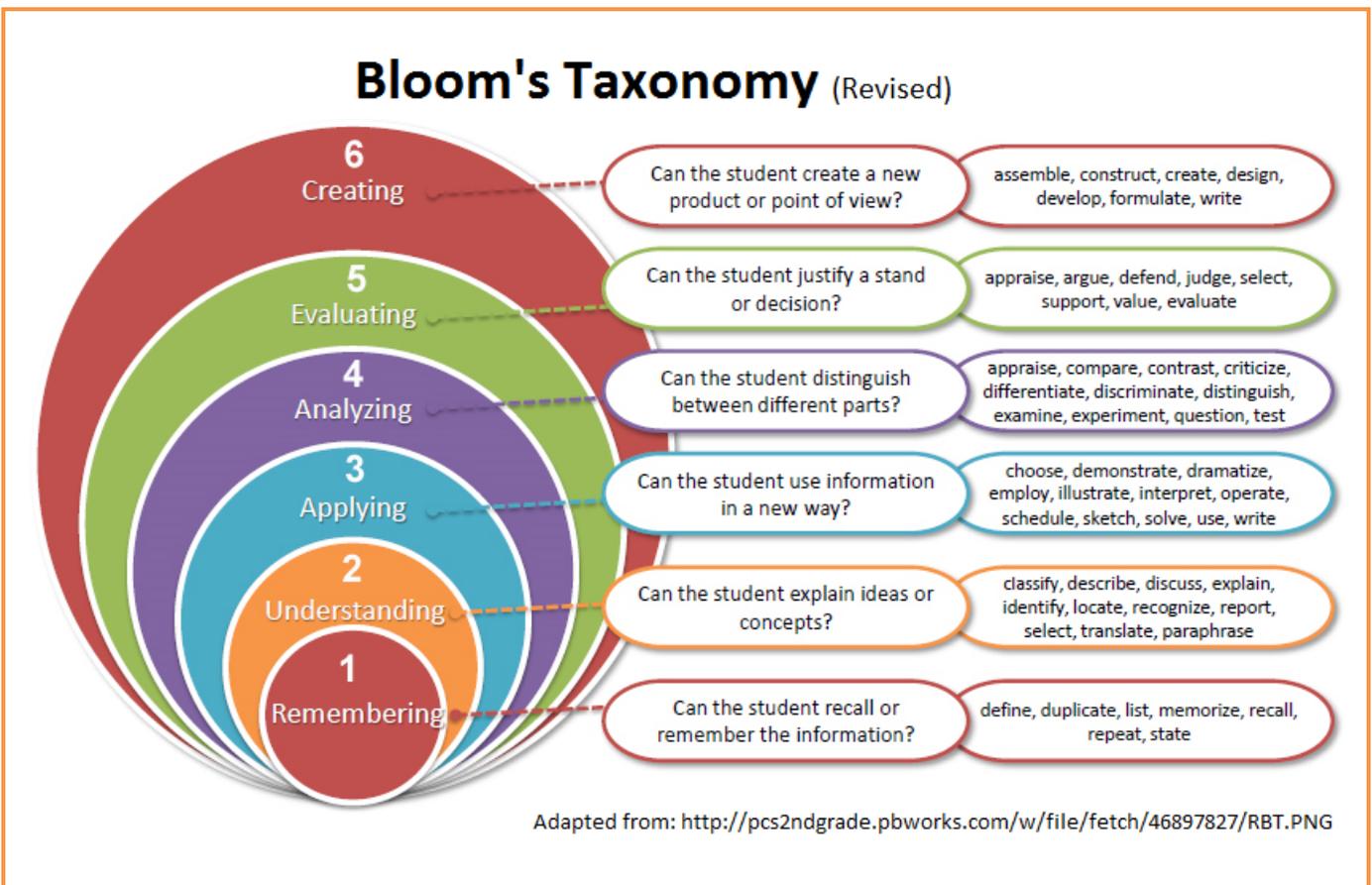
Homework/Interactive Lecture/Activities (HILA)

Homework activities are discussed either during the Interactive Lecture or during follow up activities.



Bloom's Taxonomy

Bloom's Taxonomy (established 1956, revised 2001) helps educators more effectively structure their teaching, student learning, and assessment of skills and knowledge. Organizing learning objectives by Blooms Taxonomy helps educators assure that lessons do not focus solely on memorizing basic knowledge but also challenge students to apply what they learn, evaluate new situations, and create solutions to challenging problems. Higher level objectives engage students in learning situations that are more complex and abstract. Overall, the professional ethics lessons in this series of seven modules focus strongly on the higher Bloom's levels (5 – Evaluating (20%) and 6 – Creating (21%)) in addition to including objectives for basic knowledge (Level 2 – Understanding (30%)) and application (Level 3 – Applying (14%)).



Student Handouts

The student section of this guide is formatted for easy duplication. This guide is also available as an MS Word (.doc) file (See References). We encourage you to provide both printed and .doc formats to students. The lessons are designed to help students create a personalized guide for their future work; developing their notes and best practices plans in a .doc format will help students use as well as modify their plans in the future.

II. Module Objectives

Students will be able to:	Bloom's Levels
1. Describe the history of animal and human subject study regulations.	2
2. Interpret the roles and importance of the Institutional Review Board (IRB) and Institutional Animal Care and Use Committee (IACUC) at their institutions.	3
3. Indicate the information that should be included in manuscripts submitted to scientific journals concerning animal and human studies. Explain the rationale for use of a particular model system, good experimental design, and IACUC or IRB review and approval	2, 5
4. Assess whether animal and human studies have reported sufficient information for the work to be considered ethical and reproducible.	5
5. Discuss why the stakeholders in animal and human research can be much broader than just the research community.	4

III. Instructor Guide

Target Audience

This module can be used with both graduate students and undergraduate students. It was initially designed for early career graduate students in biological science, medical science, or biological engineering graduate programs. Graduate students are likely to be somewhat aware of the academic publishing process but may not have had first-hand experience. Undergraduate students engaged in research and scientific writing may also find the materials useful.

Instructor Tips

- 1) Select the objectives and related activities that you want to address. Edit the PowerPoint Presentation to include the activities and objectives selected.
- 2) The script/key points for the presentation are in the notes section of the PowerPoint slides.
- 3) We encourage you to share 1-2 minute personal stories, when appropriate. Keep the stories positive (i.e., “I had a dilemma and I utilized a best practice...dilemma resolved”).
- 4) Allow students to reach conclusions on their own. You are their guide through this class. Facilitate discussion to keep them on task and within time limits.
- 5) **Be sure to include the “My Checklist” activity in each unit. This is the major “take away” lesson through which students integrate what they have learned in order to develop: 1) their personal checklists for ethical writing; and 2) their plans for teaching publication ethics best practices to their future trainees.**

Teaching Approaches

Learning Cycle and Homework/Interactive Lecture/Activities (HILA) approaches are outlined below.

Evaluation Rubrics and Test Questions

Evaluation rubrics for assignments and test questions are available on request from the authors (email: education@the-aps.org).

Animal and Human Studies Considerations Learning Cycle

Engage

- Complete **Activity A**: Tell Me About Your Research.

Explore

- Complete **Activity B**: Worksheet for Animal and Human Subject Studies.

Explain

- Present **Interactive Lecture**.

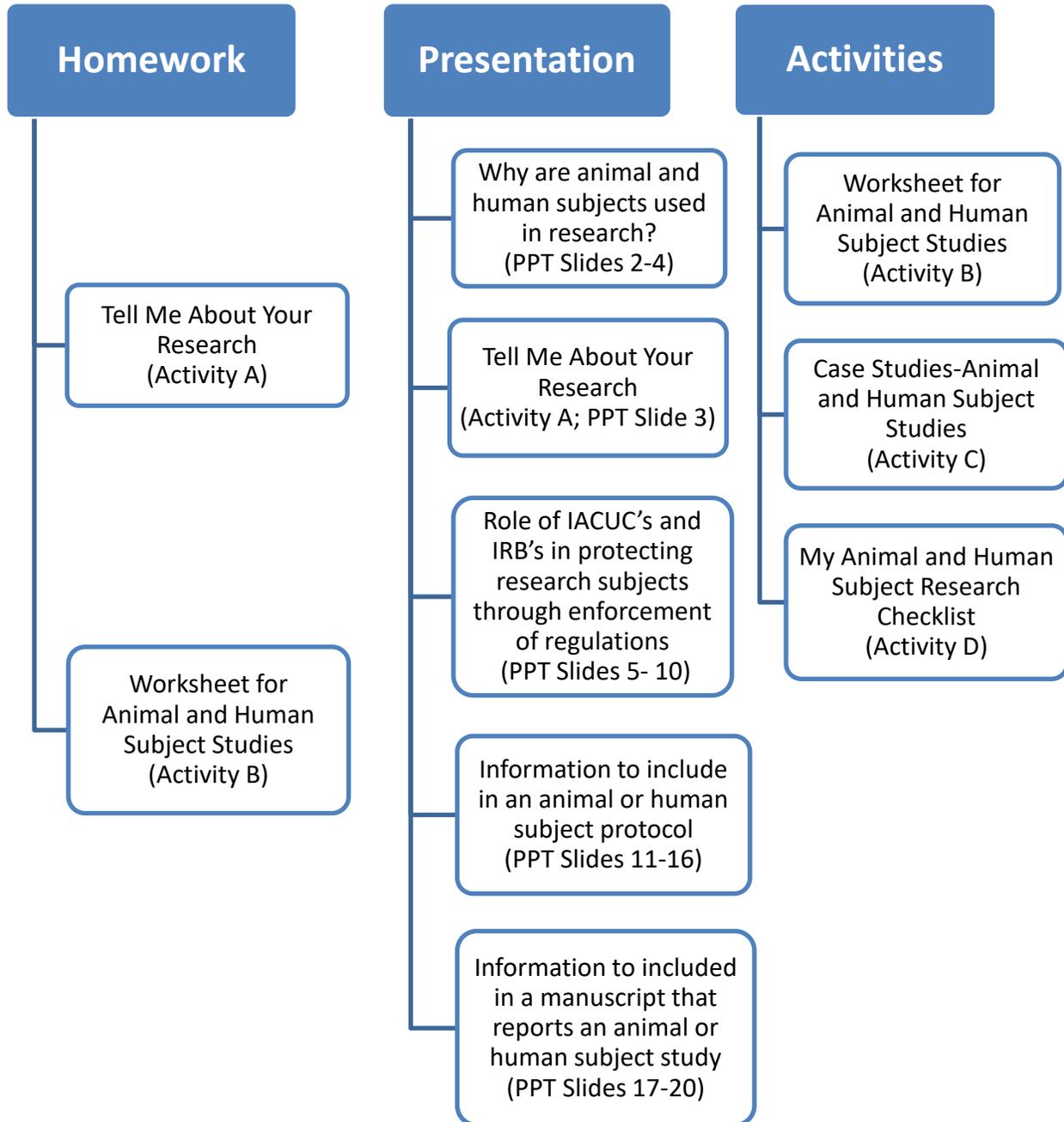
Elaborate

- Complete **Activity C**: Case Studies-Animal and Human Subject Studies.

Evaluate

- Complete **Activity D**: My Animal and Human Subject Research Checklist individually; should be reviewed by instructor.
- Quiz/test questions and answer keys are available from the authors.

Animal and Human Studies Considerations Homework/Interactive Lecture/Activities



Activity A

Tell Me about Your Research

Purpose This activity will help students consider how non-scientists view animal and human research. After completing this activity, students will be able to decide when and how they would describe their research to friends and family.

Objective 5. Discuss why the stakeholders in animal and human research can be much broader than the research community.

Procedure **Learning Cycle:** Students complete Activity A as an Engage activity. Instructor discusses their responses during the Interactive Lecture.
HILA: Students complete Activity A as homework before the Interactive Lecture. Instructor discusses their responses during the Interactive Lecture.

The activity includes two readings:

- Harmon, A. (2010, April 21). Indian Tribe Wins Fight to Limit Research of Its DNA. *New York Times*, <http://www.nytimes.com/2010/04/22/us/22dna.html?pagewanted=all&r=0> (Accessed March 9, 2017).
- American Physiological Society (APS). 2001. *Animal research: finding cures, saving lives*. Bethesda, MD: APS. <http://www.the-aps.org/mm/SciencePolicy/AnimalResearch/Publications/animals> (Accessed March 9, 2017).

The activity asks students how they would describe their research to friends and family, and how they would respond to common questions from non-scientists.

REMINDER: Encourage students to note ideas they want to add to their *My Animal and Human Studies Considerations Checklist*.

Activity B

Worksheet for Animal and Human Subject Studies

Purpose In this activity, students use a checklist to identify key information that should be included in the methods section of animal and/or human studies. After completing this activity, students will be able to identify the information that should be included in manuscripts submitted to scientific journals concerning animal and human subject studies.

- Objectives**
3. Indicate the information that should be included in manuscripts submitted to scientific journals concerning animal and human subject studies. Explain the rationale for use of the particular model system, good experimental design, and IACUC or IRB review and approval.
 4. Assess whether animal and human studies have reported sufficient information for the work to be considered ethical and reproducible.

Procedure **Learning Cycle:** Students should complete the activity in the Explore phase and review answers with the instructor in class.
HILA: Students should complete Step 1 as homework and be prepared to discuss in class.

1. Ask students to select and print out a journal article that reports on an animal or human subjects study and bring it to class.
2. Provide students with a copy of the Animal/Human Study Checklist. Hint: Duplicate the form two-sided so students have a copy of both forms to use as needed.
3. Students should evaluate the human subjects and animal use descriptions reported in their journal article using the Checklist form.
4. After 10 minutes, have students pair with a classmate and share their findings.
5. After 5 minutes, have the class come together to report their overall impression of how well authors report descriptions of animal and human subjects used in research. Have students consider which details are necessary and which are most often missing.

REMINDER: Encourage students to note ideas they want to add to their *My Animal and Human Studies Considerations Checklist*.

Activity C

Case Studies - Animal and Human Subject Studies

Purpose These case studies provide examples of common scenarios that students may encounter regarding animal and human subject use. After completing the activity, students will be able to identify and address concerns about the information that is needed to determine whether research will be considered ethical and reproducible.

- Objectives**
2. Interpret the roles and importance of the Institutional Review Board (IRB) and Institutional Animal Care and Use Committee (IACUC) at their institutions.
 3. Indicate the information that should be included in manuscripts submitted to scientific journals concerning animal and human subject studies. Explain the rationale for use of the particular model system, good experimental design, and IACUC or IRB review and approval
 4. Assess whether animal and human studies have reported sufficient information for the work to be considered ethical and reproducible.

Procedure **Learning Cycle:** This activity should be done in the Elaborate phase following the Interactive Lecture.

HILA: Should be done in class after the Interactive Lecture.

In small groups, one student should read the scenario to the group. After each section, the group should discuss the question. At the end of the activity, students should write down their answers and be prepared to share with the whole class.

Answers for the Instructor are provided in *italics*.

Case Study 1: Animal Protocol Concerns

Instructor Notes: This case study provides an example of an animal study that does not appear to protect the welfare of the animals or abide by journal guidelines.

A. Reviewer reads in an article

“Mice were fasted until their body temperature reached 30 degrees C. That is, the length of the fast for each overweight animal was not exactly the same but ranged between 22 and 33 days. The experiments were done in accordance with the rules of “Non-US Country” on animals and the experiments were approved by the ethics committee of “Non-US Research Institution.”

1. Should the reviewer raise concerns about this protocol?

Yes. Once a reviewer raises a concern, journals seek to address the problem before it is published. Some reviewers will refuse to finish the review until they know that the study is appropriate and free from ethics concerns.

2. What details in the protocol are of concern?

The prolonged fast is very concerning. It is surprising that the protocol for this study was approved.

3. What information is missing?

It is not clear whether mice were harmed by such a long fast. No information was included regarding monitoring of animals for pain and distress. Other possible aspects to consider: Was water provided and did any mice die during the course of the fast? This seems particularly important.

B. Journal contacts the author for clarification

“During the course of review, a concern was raised about the fasting protocol in your manuscript. First, has this specific fasting protocol, including the length of the fast, been approved by your animal care ethics committee? If so, please provide the protocol number and approval date. Second, what were the criteria you used to determine if any of the animals experienced pain or distress as a result of the fasting protocol? Third, what did you do to minimize pain and distress of the mice used in this study, and did any experience pain or distress? Fourth, why was such an extended regimen required for the study? Fifth, why did you use body temperature as an end point for the fasting period, rather than a percentage of body mass loss, which is more reflective of potential adverse effects on animal health? Finally, why wouldn’t a shorter fasting period serve the same purpose?”

C. Response from author

“Yes, we received approval for these studies on July 20, 2014 (protocol #389764). The idea of exposing mice to long-term fasting originated from my ‘curiosity’.... The current study may also be considered to be the first instance that mice with excess weight can survive the loss of over 50% body weight and refeeding can reestablish the original body mass without obvious ill effects. As for the distress and pain, we did not observe any sign of increased stress. Rather, they became calmer during the day and their body core temperature remained in the normal range.”

4. Does the author’s response address the journal’s concerns?

No, it is even more concerning since this study was done out of curiosity rather than based on scientific rationale.

5. Should this study be published as is?

No, it does not meet the criteria of general ethics principles found in NAS’s “Guide for the Care and Use of Laboratory Animals.”

6. Has the welfare of the animals been protected in this study?

It does not appear so. Mice were likely harmed, and even if they were not harmed, the public may perceive that they were. This seems to be an unnecessarily stressful study for the animals.

D. Journal’s response to author:

“Although no mice were ‘harmed’ as a result of the prolonged fast, it is journal policy to publish

animal studies that abide by the rules set forth by the *Guide for the Care and Use of Laboratory Animals*. Thus, the objective when these studies are being planned and executed should be to use the least restriction necessary to achieve the scientific objective while maintaining animal well-being. However, your study does not appear to meet this ethical standard, since there is no indication that the prolonged period of food deprivation used is the minimal necessary to achieve your scientific goals. Therefore, I am recommending that the associate editor reject your paper on ethical grounds.”

7. What could the researcher have done differently to avoid this outcome?

- *The researcher could have done more background research to better design the study so that it addressed an appropriate scientific question, one that does not cause unnecessary pain and distress to the animals.*
- *The researcher could have reviewed the guidelines of the journals before starting this line of study to be sure that the experiments are in line with publication standards.*
- **Instructor Note:** *Be sure to note that journals do not have to accept animal studies that do not meet basic standards. Also, it is important to emphasize that international collaborators may have different standards for animal studies. Be sure to ask whether your collaborators have approval to do the study from their institution.*

Case Study 2: Photographs of Animals in Manuscripts

Instructor Notes: This case study addresses concerns regarding the use of photographic images of animals in publications. It helps students recognize that the public may find photographic images of animals or humans in research environments to be disconcerting. The goal is to identify alternative ways to present photographic images, of animals or humans, in research publications.

A. Cover letter to Journal Editor

“Dear Editor,

We are pleased to submit our manuscript to your prestigious journal. We have identified a new technique to assess whether nonhuman primates prefer an easy task or a complex task. The techniques and experimental setup are novel. They are fully described in the Methods section and in the results reported in Figure 7.

Sincerely,

Excited Author”

B. Email from Journal Staff Member to Journal Editor

“Hi Dr. Editor,

I am checking in this manuscript that was just submitted. Take a look at the photo in Figure 7. Is it necessary? Do you think they have approval to take photos of the animals used in the study?

I will wait to process this until I hear from you.

Journal Staff Member”



Figure 7: Picture of Subject #3 used in the study.

Source: Clipart.com

1. Why would the journal staff member be concerned about the image?

It may appear to show an animal in a distressed condition. When journal staff members, who are usually nonscientists, raise concerns, editors take it seriously because likely other members of the general public would react similarly.

2. Are researchers permitted to take photographs of animals for publication?

Yes and no. Some IACUCs do not allow photographs of animals used in experiments. Check with your IACUC.

3. What types of images of animals should be avoided?

Researchers should avoid using photos of anything that appears to show animals in pain or extended restraint beyond short-term handling. One should always avoid using pictures showing blood or open wounds.

C. Journal Contacts Author

“Dear Author,

Your paper has been received. However, before it can go out for review please remove the photograph in Figure 7 or replace it with a diagram. We are concerned that the image will draw unnecessary attention from animal rights groups.

Sincerely,

Editor in Chief”

D. Author responds to Journal

“Dear Editor,

We really like the photo, but we can understand that it is not necessary for the publication. The photo in Figure 7 has been removed. Please let me know if you need anything else.

Thank you,

Excited Author”

4. Do you think a diagram could serve the same purpose in this instance?

Yes, in this instance it could.

Case Study 3: Source of Human Samples

Instructor Notes: This case study addresses concerns regarding sources of human tissues for research. It will help raise awareness that tissues used in research must be acquired under appropriate ethical standards.

A. Email from Reviewer to Journal Editor

“Dear Editor,

I was asked to review this article entitled “Stem cells detected in cultures of extracted primary teeth” and was excited by the potential for a new source of stem cells. However, the authors report that the teeth came from children between 4-5 years of age. There is no statement of IRB approval or declaration of written informed consent. I am concerned about the source of the teeth, particularly since children generally do not lose teeth until after age 6. I will not complete my review until I am assured that the study was performed under appropriate conditions.

Sincerely,
Reviewer”

1. Has the reviewer raised a relevant concern?

Yes. Institutional and Ethics approval was not reported. Moreover, it is not clear how the teeth were obtained.

2. Which authors’ replies would resolve the reviewer’s concerns?

Authors’ reply to the Editor	Yes/No	How should the Editor reply to the author?
“We simply forgot to include the information. The teeth were extracted by dentists who were approved to participate in the collection. All parents signed consent to donate the extracted teeth for research. Teeth were collected from 5 year olds who injured their teeth from falls or other trauma. Since the teeth aren’t loose, dentists have to pull the ones that are too damaged to repair.”	YES	<i>Request the author to revise the manuscript and declare the institutional and ethics approval. The authors also must note that they received written consent from the parents.</i>
“No approval was needed. We just asked several dentists affiliated with our University to send us teeth that were extracted from 5 year olds. The teeth would have been discarded if we had not used them in our research.”	NO	<i>Request more information. How do they know that approval was not needed? Did they ask their institution about this arrangement?</i>
“We did not ask our institution for approval because we bought the teeth from a company. They claim that the teeth were extracted within the past 24 hrs. I do not know how the company acquires the teeth.”	NO	<i>The article cannot proceed. There is not enough information to be assured that the extraction and processing was done ethically.</i>

“We did seek IRB approval. The teeth came from a dental tissue bank that arranges transfer of teeth from dentists to researchers. Parents’ of the patients consented to allow the leftover tissue to be used for research. We received no identifying information about the patient, only age and reason for extraction.”

YES

Request the author to revise the manuscript and declare the institutional and ethics approval. The authors also must note the source of the tissues and that informed consent was obtained.

REMINDER: Encourage students to note ideas they want to add to their My Animal and Human Studies Considerations Checklist.

Activity D

My Animal and Human Studies Considerations Checklist

Purpose Students will develop a checklist based on course material that they can use now and in the future to guide ethical text preparation in terms of animal and human studies. They should use materials from the activities, readings, and Interactive Lecture. After completing the activity, students should have a checklist for animal and human studies considerations AND a plan for teaching these best practices to their students.

- Objectives**
2. Interpret the roles and importance of the Institutional Review Board (IRB) and Institutional Animal Care and Use Committee (IACUC) at their institutions.
 3. Indicate the information that should be included in manuscripts submitted to scientific journals concerning animal and human subject studies. Explain the rationale for use of the particular model system, good experimental design, and IACUC or IRB review and approval.
 4. Assess whether animal and human studies have reported sufficient information for the work to be considered ethical and reproducible.

Procedure **Learning Cycle:** Complete in the Evaluate phase. Students should do this individually but will want to share their lists in class or with the instructor.
HILA: Should be done after the interactive lecture. Students should do this individually but will want to share their lists in class or with the instructor.

The following provides an outline of the material from the module that students may want to include in their checklist in some format. Students should create a checklist that works for THEM not simply recreate this list. Encourage them to include the three definitions and five general topics below.

Definitions and Resources to Remember	
A. IACUC	<i>Institutional Animal Care and Use Committee. Reviews and approves animal studies.</i>
B. IRB	<i>Institutional Review Board. Reviews and approves human subject studies.</i>
C. "The Guide"	<ul style="list-style-type: none"> • The Guide for Laboratory Animal Facilities and Care (National Academy of Sciences) • Serves as the standard for proper care of animals in research and for compliance of animal research facilities • https://www.nap.edu/catalog/12910/guide-for-the-care-and-use-of-laboratory-animals-eighth

D. Human Subjects Decision Charts	<ul style="list-style-type: none"> • Health and Human Services Office for Human Research Protections • Guide for IRBs, investigators, and others to help identify whether an activity is research that must be reviewed by an IRB; • The review may be performed by expedited procedures; and • Informed consent or its documentation may be waived. • https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts/#c1
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My Best Practices Checklist	
I. Animal Subjects – Important information to include	
A. Rationale	
B. Technique	
C. Expertise	
D. Other	
E. PASS IT ON	My ideas for teaching good practices for ethical text preparation on studies using animals to MY students:
II. Human Subjects – Important information to include	
A. Rationale	
B. Technique	
C. Expertise	
D. Other	
E. PASS IT ON	My ideas for teaching good practices for ethical text preparation on studies using humans to MY students:

Presentation Slides

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PROFESSIONAL INTEGRITY: BEST PRACTICES FOR PUBLISHING YOUR RESEARCH

Animal and Human Studies Considerations

You will be able to:

- Describe the history of animal and human subject study regulations
- Interpret roles and importance of (ACUC's) and IRB's
- Indicate the information to include in manuscripts to fully describe animal and human studies
- Assess whether animal and human studies have reported sufficient information regarding ethics and reproducibility
- Discuss why animal and human research affects those outside of the research community



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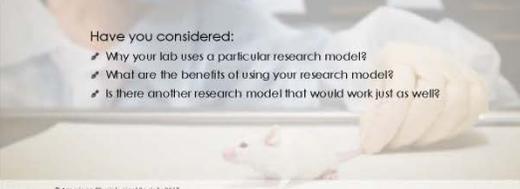
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Professional Integrity: Best Practices for Publishing Your Research
Animal and Human Studies Considerations

Why Use Animals and Human Subjects in Your Studies?

Have you considered:

- Why your lab uses a particular research model?
- What are the benefits of using your research model?
- Is there another research model that would work just as well?



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Professional Integrity: Best Practices for Publishing Your Research
Animal and Human Studies Considerations

Animals and Human Subjects Must Be Respected and Protected



DISCUSS

- How do you describe your research to family, friends and non-scientists?
- Did you find it difficult to describe your research in a way that non-scientists could understand it?

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Professional Integrity: Best Practices for Publishing Your Research
Animal and Human Studies Considerations

Animal and Human Subject Studies Enable Better Understanding of Biology and Function



Hoff et al., Cheng et al., et al., doi:10.1177/journal.pone.0132161

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Professional Integrity: Best Practices for Publishing Your Research
Animal and Human Studies Considerations

Approval First

Review and Approval Takes Time. Weeks to Months. Plan Ahead!

Before starting any animal or human subject experiment, Principal Investigator must seek approval



- Institutional Animal Care and Use Committee (IACUC) reviews and approves animal studies
- Institutional Review Board (IRB) reviews and approves human subject studies

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Professional Integrity: Best Practices for Publishing Your Research
Animal and Human Studies Considerations

IACUC Review



- Each U.S. institution that conducts animal research has its own IACUC (and some have more than one).
- An IACUC panel includes at least 5 members. Among these must be a laboratory animal veterinarian, an animal research scientist, a nonscientist (from within or outside the institution), and someone with no affiliation with the institution.
- What are they looking for in an animal use protocol?
 - Appropriate rationale and methods
 - Appropriate species for study
 - Minimum animal numbers for statistically robust studies
 - Pain/distress/analgesia: euthanasia methodology
 - Animal and surgical training for research personnel

<http://www.nap.edu/catalog/1210/guide-for-the-care-and-use-of-laboratory-animals-eighth>

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Protection of Animals Used in Laboratory Research

The Guide for Laboratory Animal Facilities and Care
 - Replaces the 1963 Guide published for animal care in research and for biomedical research facilities.

U.S. Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research and Training
 - Recommended to increase the number of vertebrate animals used and better protected.

1963 **1966** **1985** **1986**

U.S. Animal Welfare Act (AWA)
 - Regulates only when laboratory animals are transported, sold, purchased, leased, loaned, or otherwise disposed of by research facilities.

Public Health Service Policy on Human Care and Use of Laboratory Animals
 - This policy, which covers research, research training, experimentation, education, testing, and other uses, is in the Guide, U.S. Government Department of Health.

http://www.fda.gov/abbott/animal_welfare.html

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IRB Review

- Research protocols that propose to use human subjects are reviewed by Institutional Review Boards.
- An IRB panel consists of at least 5 members. The panel must be diverse and competent and include a scientist, a nonscientist, and someone with no affiliation with the institution.
- What are they looking for in a human subject protocol?
 - All research subjects are protected from harm.
 - Risks to research subjects are minimized and reasonable.
 - Research subjects are fully informed of procedure and risks.
 - Research subjects consent to the research (signed form).
 - There is appropriate oversight, and all regulations are followed.

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Protection of Human Subjects Participating in Research

Nuremberg Code
 - Required informed consent.
 - Required scientific objectives.
 - Necessary and performed by qualified personnel.

1947 **1964** **1974** **1979**

Declaration of Helsinki
 - Clinical studies involving human subjects require approval by an independent ethics committee.
 - Research on human subjects must be based on a sound scientific basis.
 - Research on human subjects must be conducted in accordance with ethical principles and standards.

Regulations for the Protection of Human Subjects of Biomedical and Behavioral Research (HHS, 45 CFR 46)
 - Subject to Secretary approval or program approval and blanket approval.
 - Subject to Secretary approval or program approval.

The Belmont Report
 - Ethical principles and guidelines for the protection of human subjects of research.
 - Applied to research.
 - Applied to practice.
 - Applied to education.

http://www.fda.gov/abbott/animal_welfare.html

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Is Your Study Exempt?

- Data sources can determine the type and level of review and exemptions that apply.
- Data from various sources are subject to different restrictions:
 - Classroom data
 - Public databases
 - Samples from previous projects

http://www.fda.gov/abbott/animal_welfare.html

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Protocols Should Describe Rationale, Techniques, and Expertise

Rationale	Techniques	Expertise
<ul style="list-style-type: none"> What is the experimental question? Rationale? What is the most appropriate model system to address the question? 	<ul style="list-style-type: none"> How will you perform the study? What techniques will you use? 	<ul style="list-style-type: none"> Who will perform the experiments? Are they properly trained? Is this a collaborative study? Are the collaborators following similar animal and human subject guidelines?

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What Is a Reasonable Sample Size?

Same Experiment Different Sample Sizes

N = 3 N = 3 N = 8 N = 8

N = 12 N = 12 N = 25 N = 25

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"The Rate of Passage of Inert Materials Through the Digestive Tract" by Frederick Hoelzel Published in 1929

Reprinted from 1929, a series of meals (bread, etc.), showing their rate of passage through the digestive tract of rats proportional to their specific gravity.

Kind of substance	Specific gravity	Time of passage (hours)	Time of passage (hours)	Time of passage (hours)
Water (D ₂ O)	1.0	100	100	100
Food	1.0	100	100	100
Barium meals	1.6	125	100	100
Carbon compounds	1.6	100	100	100
Mercury meals	1.6	100	100	100
Organic acids	1.6	100	100	100
Other meals	1.6	100	100	100
Aluminum	1.6	100	100	100
Mercury meals	1.6	100	100	100
Other meals	1.6	100	100	100

* The rate of passage of gas was estimated, as explained in the text. The rate of passage of food materials was judged by the rate of passage of carbon compounds (barium meals) and those problems that were recognized for solving the food.

† The differences related above have varied somewhat in specific gravity.

F. Hoelzel, American Journal of Physiology, October 1929.

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"The Rate of Passage of Inert Materials Through the Digestive Tract" by Frederick Hoelzel Published in 1929

"A large part of the foregoing investigation would have been impossible without the convenience of living in the laboratory."

F. Hoelzel, American Journal of Physiology, October 1929.

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Should an Animal or Human Subjects Protocol Be Narrow or Broad in Scope?

Mouse Model A

60 mice

Drug X

Protocol C

Mouse lacking Gene X
(Mouse Model A or Mouse Model B)

60 - 90 mice

Inhibitor of Metabolism
Drug X, Y or A.A.

Protocol C or D
depending on mouse model

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"Indian Tribe Wins Fight to Limit Research of Its DNA"

"Members of the tiny, isolated tribe had given DNA samples to university researchers starting in 1970, in the hope that they might provide genetic clues to the tribe's devastating rate of diabetes. But they learned that their blood samples had been used to study many other things, including mental illness and theories of the tribe's geographical origins that contradict their traditional stories."

by Amy Harmon New York Times, April 21, 2016

Stakeholder perspectives:

Scientist	Tribe
Permission was obtained to study behavioral and medical disorders.	Studies were outside scope of agreement.
Blood is source of DNA.	Blood is spiritually meaningful.
Results from the studies are of great interest to the research community.	Results could change tribe's history and damage its future.

<http://www.nytimes.com/2016/04/21/us/indian-tribe-wins-fight-to-limit-research-of-its-dna.html>

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Protocol Details Should Be Included in the Methods Section of Associated Research Articles

Reviewers will check for:

- Statements of protocol approval and other national/local approvals
- Considerations for animal and human subject safety
- Specific details about the animals used (e.g. number, sex, age, treatment groups, interventions)
- Health details about human subject participants (e.g. sex, age, weight, interventions)

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Example: Animal Study Methodology

MATERIALS AND METHODS

Animals

Male C57 (Leptin^{fl/fl} and Lepr^{fl/fl}) and Sprague-Dawley rats were purchased from Harlan (Indianapolis, IN). Rats were housed in controlled animal care facilities that were kept at a consistent humidity (60 ± 3%), temperature (24 ± 1°C), and light cycle (14h/10h). Rats were given free access to tap water and standard rat chow (LabDiet 5053 or Purina 5053). Lean and obese rats were housed separately, with rats housed 2-4 in a cage. Experiments were performed on age-matched female (17-18 wk old) Zucker rats, adult (15-17 wk old) Zucker rats, and Sprague-Dawley rats.

All experiments were performed in accordance with the National Institutes of Health's Guide for Care and Use of Laboratory Animals and the American Physiological Society's "Guiding Principles in the Care and Use of Vertebrate Animals in Research and Teaching." The animal protocols were reviewed and approved by the Institutional Animal Care and Use Committee of University of North Texas Health Science Center and Medical College of Georgia.

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Example: Human Subject Study Methodology

METHODS
Ethical approval
 Participants were recruited from the University of Alberta and the general population and each provided written, informed consent. This study was approved by the University of Alberta Health Research Ethics Board (Biomedical Panel) and conformed to the standards set by the Declaration of Helsinki.

Participant description
 fourteen healthy men were recruited (age: 24.6 ± 1.1 yr, height: 177.0 ± 2.1 cm, weight: 85.8 ± 3.5 kg, waist mass: 49.2 ± 3.1 kg, BMI: 27.1 ± 1.1). All subjects were free from cardiovascular disease and had normal ECG-biopsy pressure response during a standard 12-lead ECG during a 60s max test (Vmax system; VIASYS Products).

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Missing Approvals Can Delay Publication

Journal will delay publication if IACUC or IRB approval is not reported in the manuscript

- ✦ If no approval was given, paper will not be published
- ✦ Institution may be informed
- ✦ More regulations for all researchers at institution

Even if IRB or IACUC approval is noted, the journal editors may seek additional clarification if they view the experiments as questionable in terms of appropriate use of test subjects.

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Small Group Discussion

Your instructor will provide directions for these activities



DISCUSS

- ✦ These activities will help you APPLY what you have learned so far to common scenarios

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End of Presentation. Open Discussion.

- ✦ Access more APS Professional Skills Training Courses at www.the-aps.org/csl
- ✦ This module is part of a series of seven teaching modules designed to promote best practices in publication ethics for life scientists and biometric engineers who publish research papers. The modules were developed with support from the National Science Foundation (NSF) (EES-1328368) and in collaboration with staff and members of the APS, BMES, and SBE. The modules represent the views of the authors and do not necessarily represent the views of NSF, APS, BMES, or SBE. The information in these modules is designed to represent a summary of good practices and advice at the time of publication; they are not meant to serve as legal advice or publisher policy and do not in any way guarantee a protection from professional ethics charges.
- ✦ For more information on how the materials were developed and tested, please contact the author.

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Presentation Slide Text

Slide #	Text
1	<p>This presentation is part of the professional skills training series on professional integrity best practices for publishing your research.</p> <p>Today we will review best practices for animal and human subject studies. This presentation will help you to:</p> <ul style="list-style-type: none"> • Describe the history of animal and human subject study regulations • Interpret roles and importance of IACUC's and IRB's • Indicate the information to include in a manuscript to fully describe animal and human studies • Assess whether animal and human studies have reported sufficient information regarding ethics and reproducibility AND • Discuss why animal and human research affects those outside of the research community
2	<p>Do you use animals and human subjects in your work? If so, have you considered WHY your lab uses a particular model system such as mice, rats, sheep, dogs or humans? "We've always done it" is not a sufficient answer!</p> <p>You should consider the research benefits of the model system you are currently using compared to alternative systems. Is there another model system that would work just as well? For example, would using fish, flies, or worms as a model system provide similar findings to using rats, mice, or primates? If so, these alternative models may be less expensive and/or easier to use.</p> <p>It is important to understand the research benefits provided by working with a specific animal species or a particular group of human subjects. This information can help you fully describe the value of your work to those in, and outside of, your research field.</p>
3	<p>As you know, not everyone supports animal and human subject research. However, by sharing your research experience with your family and friends, you can provide them with a good example of animal or human subject research that is beneficial, important, and well-regulated. In fact, every time you discuss your research involving animals and human subjects, be sure that you share your work respectfully. That is, be sure that you take into consideration how others might interpret your comments especially if they are not familiar with the model system or fully understand how research is performed. Casual comments about your work may give the wrong impression about how valued animals and human subjects are in research.</p>

	<p>As part of your homework for Activity A: Tell Me About Your Research, you were asked to write down a description of your research that you might share with a non-scientist. Did you find it difficult to describe your research in a way that non-scientists could understand?</p> <p>If you are watching this presentation as a group, at this time, pause the presentation and spend a few minutes reading, or listening to the descriptions written by your colleagues and comment on whether you think the statement would be understood by a non-scientist. Discuss what portions of the description could be changed to make it more accessible to non-scientists.</p> <p>If you are working independently, pause the presentation and read some of the descriptions provided at the course site. Use these as models to edit and improve your own research description.</p>
<p>4</p>	<p>Researchers use animals and human subjects in experiments because they provide a means to understand the function of the organism. Specifically, they allow the researcher to test how an organ system or whole body functions in response to a stimulus or challenge. Different animals are used in different types of studies. For example, fruit flies are a great model to study genetics while rats are used for many different types of research including studies on learning and memory.</p> <p>Over your career, you will likely use different research models to advance your understanding of a particular research problem. For example, you might use immortalized cell lines in your initial explorations of whether a particular gene or treatment affects the cell's function. Your results may lead you to explore whether the gene or drug has the same effect on the same types of cells in a living organism. That, of course, requires using a more complex model system such as fruit flies, fish or rodents. This may provide a good opportunity to work with collaborators who have expertise in those animal models.</p>
<p>5</p>	<p>Using animals or humans in experiments requires considerable planning time. The research design and experimental protocol or procedure must not only be written in detail but also must be approved by a governing body at your academic institution. The protocol is prepared by the principal investigator and submitted for review and approval by your institution's Institutional Animal Care and Use Committee (commonly called an IACUC) or Institutional Review Board (called an IRB). IACUCs review animal research protocols, and IRBs review human subject protocols.</p> <p>These reviews take time, as the committees may only review protocols once every month or two. Thus, you have to plan ahead if you want these studies to start on your time schedule. However, going through IACUC and IRB review is not meant to restrict your research. Their goal is to ensure that you do the best quality research to get the</p>

	<p>best results.</p> <p>Writing protocols is a balance between detailed descriptions and research flexibility. Principal investigators write protocols so that they are broad enough to allow some flexibility in how they perform the studies. On the other hand, the protocols have to provide adequate detail so that it is clear that the experiments have been carefully designed and the number and type of animals have been considered. If you are writing a protocol for the first time, it is important to seek input from more experienced researchers.</p>
<p>6</p>	<p>Every academic institution that performs animal research must have an IACUC, that is, a committee that reviews and approves animal research protocols. The IACUC also inspects the institution’s animal facilities to assure that the national standards for animal care are met.</p> <p>There are at least 5 members on an IACUC including a veterinarian, a research scientist, a non-scientist, and someone not affiliated with the university. It is a good idea to find out who is on the IACUC at your institution. The members of the committee are a great resource for animal-related questions, and one might be in your department.</p> <p>Why would you have a community member and non-scientist on the committee? These committee members help to ensure that the studies approved are likely to be considered ethical and beneficial by the general public. This is an important check since scientists who are familiar with animal research may have different perspectives about using animals than do non-scientists.</p> <p>What do IACUC’s look for in a protocol? They want to ensure that the study is well designed with an appropriate rationale and methods, that the species used is a good match for the study, that the experiments minimize pain and distress to the experimental subjects, that the study does not duplicate previously published work, and that personnel are qualified to perform the experiments. However, they do not perform a scientific review of the study like that done by a grant study section or journal manuscript reviewers.</p>
<p>7</p>	<p>Concerns about the treatment of animals in laboratory research have been an issue for as long as researchers have needed test subjects. However, two large scandals in the 1960’s raised the profile of the issue and resulted in additional federal regulations of animal research. Both scandals involved pet dogs that disappeared and were likely sold to dog dealers who then went on to sell the pets to research laboratories. As a result of these instances several guidelines were enacted.</p> <p>The Guide for Laboratory Animal Facilities and Care was first published in 1963 by the National Academy of Sciences. It is still in use today, now titled the “Guide for the Care</p>

	<p>and Use of Laboratory Animals”. It is THE standard for how research animal facilities should be maintained in order to best protect and care for the animals in the facilities.</p> <p>In 1966, the US Animal Welfare Act established standards on how animals, kept by animal dealers and laboratories, should be treated including guidance on their care, handling, transportation, and housing. Animals protected by the US Animal Welfare Act included dogs, cats, non-human primates, hamsters, rabbits and guinea pigs BUT it did not include mice and rats. This act established the requirement for IACUCs.</p> <p>The US Animal Welfare Act has been revised a number of times and has broadened protection to all warm-blooded animals and requires the same standards for government agencies as for private institutions.</p> <p>In 1985, the Food Security Act, subtitle F Animal Welfare, defined the guidelines for humane care including ventilation, sanitation and housing. As such, the IACUC’s role is to support minimizing pain and distress in animals in the laboratory by using anesthesia, analgesia, and euthanasia.</p> <p>And in 1986 the US Public Health Service issued a policy that protects all live vertebrates used in any aspect of research and training. Those who receive US government grant money to do research must comply with these policies.</p> <p>These policies are still in effect today and help guide IACUC reviews.</p>
<p>8</p>	<p>Like IACUCs, Institutional Review Boards consist of a panel of 5 or more members. They review and monitor research that involves human subjects.</p> <p>The panel’s role is to ensure that: the research subjects will not be harmed, risks are minimized, and all participants are fully informed about and consent to the study. IRBs also confirm that there will be appropriate oversight and that all regulations, including local, state and federal regulations related to the particular study, are followed.</p>
<p>9</p>	<p>If you completed a Responsible Conduct of Research (or RCR) training, you probably learned that human research subjects were not always well protected. Examples such as the medical experiments run during World War Two and the Tuskegee syphilis experiments led to the establishment and continued refinement of codes and regulations that serve to protect human research subjects.</p> <p>After World War Two, the Nuremberg Code was released. It stated that those participating in research studies must CONSENT to being a participant. The research must be SCIENTIFICALLY NECESSARY and performed by QUALIFIED PERSONNEL.</p> <p>The Declaration of Helsinki, instituted in 1964 and revised seven times in the past 50</p>

	<p>years, provides additional protection. Clinical studies should be based upon results identified in the lab or in animal models. Again, they state that human subjects should be informed about the study and provide consent. This policy also states that, if the research does not comply with these ethical guidelines, the results SHOULD NOT be published.</p> <p>The 1974 US federal regulations for the protection of human subjects (45 CFR 46) defined that human subject research requires IRB approval. That is, an Institutional Review Board must approve the study before it can be performed. The regulation also provides special research protection to pregnant women and their fetuses, to prisoners, and to children.</p> <p>The 1979 Belmont Report was written by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. They identified the basic ethical principles that should be followed in human subject research. The principles include respect for persons, beneficence or kindness, and justice.</p>
<p>10</p>	<p>In some instances, you may not be sure whether or not your study requires IRB approval. There are specific types of studies that are exempt from IRB review or that require additional types of approval. This is usually dependent upon the source and type of data you will be gathering or using in your study.</p> <p>For example, what if you are using data from a public database? Or using tissue samples that were from a previously approved project? Or collecting data on student learning in a classroom?</p> <p>The Office for Human Research Protections in the US Department of Health and Human Services provides guidance to determine what reviews and approvals will be required for your studies. They provide both text and decision flow charts for easier interpretation of the guidelines. You may want to bookmark these pages for future use.</p>
<p>11</p>	<p>In summary, the regulations for animal and human subject research that guide IACUC and IRB reviews ensure that researchers have considered not only the experimental details of their studies but also the ethical considerations of their work. While writing protocols and working with IACUCs and IRBs requires additional time, their input can help you develop more robust research designs and protocols and can prevent ethical issues as you seek funding for your work and seek publications of your results.</p> <p>Let's explore some of the practical aspects of writing animal and human protocols. Here we list some of the essential questions you should be considering throughout the research project, from planning and implementation to manuscript development.</p>

	<p>First, you must have a clear rationale or logic for the studies: What is the experimental question? What is the rationale for your approach? What is the most appropriate model system to address the question?</p> <p>Second, you must identify effective methodologies for conducting the planned studies: How will you perform the study? What techniques will you use?</p> <p>Finally, you must have personnel with the expertise to conduct the studies: Who will perform the experiments? Are they properly trained? Is this a collaborative study? Are the collaborators following the same animal or human subject guidelines?</p> <p>The last question is particularly important for international collaborations. Be sure that those who are performing animal or human subject studies have complied with their country's regulations and that their regulations align with the ethical guidelines of your country. If you are not approved to do a study at your institution because of ethical concerns, it is not appropriate to perform the study in a country with less rigorous ethical guidelines.</p>
12	<p>Sample size is a major consideration when preparing animal and human subject protocols.</p> <p>How many animals or human subjects are needed to properly evaluate the experimental question?</p> <p>Too few samples may just capture random changes rather than a true experimental effect. This is illustrated in the first series of experiments shown here. The researchers initially ran the experiment with a sample size of 3 subjects per treatment group. Results indicated a significant difference between the groups. However, doing the experiment with a larger sample size of 8 indicated no difference between the groups.</p> <p>Alternately, collecting too many samples can waste time and resources and may not provide any more information than would have been discovered by using fewer samples. In the second example, the results were similar in experiments using 12 subjects and 25 subjects. Therefore, the use of additional subjects was not needed.</p> <p>How do you know how large your sample size should be? Researchers often consult with biostatisticians to determine the likelihood of seeing an experimental effect in a particular sample size. By calculating the numbers of individual samples one will need to see a specific effect size, researchers reduce their chances of running an experiment that uses too few or too many resources.</p>

13	<p>For example, in this paper, published in 1929, Dr. Hoelzel studied how long it took for inert materials, seeds and non-food products, to pass through the digestive system.</p> <p>As reported in the article, “Observations were made on 16 rabbits, 7 guinea pigs, 50 rats, 8 mice, 4 dogs, 2 cats, 1 monkey, 3 pigeons, 1 chicken, and the writer.”</p>
14	<p>The picture on the left is Dr. Hoelzel before starting the study and the picture on the right is Dr. Hoelzel at the end of a 15-day fast to clean out his GI system thoroughly before he began ingesting inert materials including seeds, cellulose knots, glass beads, gravel, steel, and silver.</p> <p>Did the author use appropriate model systems and sample sizes for each model system? Was the experimental design well-crafted? Do you think it would pass an IRB or IACUC review today?</p> <p>The answers to these questions are likely yes and no. Use of a number of model systems may be acceptable. However, modern IACUCs would likely require a more defined plan for the selection of inert materials and for the animal numbers needed. Likewise, Dr. Hoelzel would need to request approval by an IRB before taking part in the study as a research subject.</p>
15	<p>Another major consideration in preparing an animal or human subject protocol is whether the scope should be broad or narrow. That is, should you describe your ideal experiment or leave room for potential variations in the experimental design.</p> <p>On one hand, the goals for the study, and what resources and techniques will be needed, should be clearly defined. On the other hand, the reagents used, subject numbers needed, and overall experimental design, should be flexible enough so that you do not have to contact the review board every time a reagent is discontinued or more samples are needed.</p>
16	<p>For example, the readings assigned in Activity A: Tell Me About Your Research describe how researchers from a university collected DNA samples from a small Native American tribe in Arizona to help determine the genetic factors contributing to the tribe’s high incidence of diabetes.</p> <p>However, the DNA was also used to study a number of other genetic questions, questions outside the scope of diabetes. The Havasupai tribe considered the non-diabetes research to be a violation of their initial agreement and disrespectful of their community. However, the researchers designed the agreement to be intentionally broad in order to have the opportunity to expand their research focus. There was a clear miscommunication between the researchers and the tribe regarding what studies would be performed.</p>

	<p>When these types of situations occur, it raises alarms throughout the research community and the public. To protect your professional integrity AND, more importantly, to protect the safety of the public, it is important to consider your work in a broader context, particularly from the perspective of all the stakeholders involved, AND adhere to the guidelines set forth by your university and by federal, state, and local regulations. Likewise, one wonders whether the IRB had sufficient diversity on its panel to properly consider the unique perspective of the subjects being tested.</p>
17	<p>Once experiments are complete, be sure to write up the study as it was performed. It is important to include enough detail in the Methods section of your journal manuscripts so that your work can be compared to other published studies and can be repeated by other research laboratories. Many of the details included in the IACUC or IRB protocol should be described in the Methods section of your journal article that reports on the study.</p> <p>Reviewers will check the Methods section to see if statements of protocol approval and other national and local approvals are included.</p> <p>Likewise, they will look for statements about animal and human subject safety as well as specific details about the subjects used. For animal studies, these details may include animal numbers, sex, age, treatment groups and other interventions. For human studies, you may need to report general health details such as sex, age, weight and other interventions.</p>
18	<p>Here is an example of a section in the Methods that describes the animals used in the study. Pause the presentation to read the description.</p> <p>Note that the authors provide details about the type of animal used in the study, the facilities and environment, and food sources. They also highlight the ethical standards followed and the institution that approved the IACUC review.</p>
19	<p>Next is an example of a section in the Methods that describes the human subjects that participated in a study. Pause the presentation to read the description.</p> <p>Note that the authors provide details such as the institution providing ethics approval and the written informed consent provided by study participants.</p> <p>In addition, the description of the participants details not only the number of participants, but also their age, height, weight, and general health.</p>
20	<p>What if the authors do not report IACUC or IRB approval in a manuscript that includes animal or human studies?</p>

	<p>The journal will stop review and inquire. If the authors report that they do not have IACUC or IRB approval, then the paper will not be published. Performing animal or human subject experiments without your institution's approval is a serious offense. Likely, the institution will be informed, and serious violations will result in more regulations for all researchers at an institution.</p> <p>On the other hand, a reviewer may read a Methods section, that notes IACUC or IRB approval, but have serious doubts that any ethics committee would approve the study as described. The reviewer will notify the editor and the journal will contact the authors for more information to ensure that the experiments, as reported, were approved and are ethical. Journals have the right to elect to not publish a manuscript based on the ethical concerns even if the research had IACUC or IRB approval.</p>
<p>21</p>	<p>The remaining activities in this module will help you to APPLY what you have learned so far to common scenarios and to your own work.</p> <p>BE SURE to add notes from this presentation to your "My Checklist" document.</p>
<p>22</p>	<p>Thank you for listening to this presentation. To access more information about APS Professional Skills Training Courses visit www.the-aps.org/pst.</p>

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<http://www.hhs.gov/ohrp/humansubjectss/guidance/belmont.html>.
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11. Yates, B. and Barrett, K. E., Reporting of studies using animal and human subjects in APS journals: how the society protects authors from ethical minefields, *The Physiologist*, 55(1):8-10, 2012 Feb. Retrieved from: <http://the-aps.org/mm/Publications/Journals/Physiologist/2010-present/2012/February.pdf>.

Course Resources

Each of the **Professional Skills Training Courses on Best Practices for Publishing Your Research** has multiple resources to accompany the Instructor Guide. All of the following resources are available at www.the-aps.org/pst/ethics.

1. PowerPoint (.ppt) files for the Interactive Lecture. These slides are editable.
2. Instructor and Student Guides are available as editable .doc files.
3. Request form for assessment tools (quizzes and key).
4. Links to video versions of the Interactive Lecture on YouTube.
5. Links to online, on demand version of the module.

Publication Ethics Community

In addition, APS hosts a Publication Ethics Community on the Life Science Teaching Resource Community. The community posts ethics cases for comment by participants and experts. See www.lifescitrc.org and click on My Community.

Ethics CORE (Collaborative Online Resource Environment)

This website is coordinated by the National Center for Professional and Research Ethics. The site provides resources for Responsible Conduct of Research courses and seeks to create communities of responsible research and professional practice. It is an excellent source of case studies, simulations, role-play scenarios, videos, and lectures. See <https://nationalethicscenter.org>.

We welcome your questions and feedback on these materials.
Email us at education@the-aps.org.

Animal and Human Studies Considerations Module

Student Handouts



These activities will help you:

1. Describe the history of animal and human subject study regulations.
2. Interpret the roles and importance of the Institutional Review Board (IRB) and Institutional Animal Care and Use Committee (IACUC) at their institutions.
3. Indicate the information that should be included in manuscripts submitted to scientific journals concerning animal and human studies. Explain the rationale for use of a particular model system, good experimental design, and IACUC or IRB review and approval
4. Assess whether animal and human studies have reported sufficient information for the work to be considered ethical and reproducible.
5. Discuss why the stakeholders in animal and human research can be much broader than just the research community.

This module is part of the series, *“Professional Integrity: Best Practices for Publishing Your Research”* developed by:

American Physiological Society www.the-aps.org

Biomedical Engineering Society www.bmes.org

Society for Biological Engineering www.aiche.org/sbe

For information on the other modules or to take an online, interactive version of one or more modules, go to www.the-aps.org/pst.

About Your Publication Ethics Checklists

In these modules, you will be encouraged to create your OWN checklists for preparing manuscripts using ethical and professional standards of practice for researchers.



WRITE

Why do I need a checklist?

As your training progresses, your research and writing skills develop along with your knowledge of the field, your professional network, and your independence as a professional. This also means that understanding and following best practices for professional behavior, including research and publication ethics, increasingly rests on your shoulders. YOU become the person who is setting the standards for your laboratory group. YOU are the person who must establish protocols for assuring ethical behavior. And YOU are the person who has to teach standards and protocols to every trainee in your lab and, sometimes, to those with whom you collaborate. You cannot assume that they come with an understanding of best practice...you must inform, guide, and monitor their adherence to best practices.

What should I include in the checklist?

You are investing time and effort to learn best practice for publication ethics through this module (and possibly the other modules in this series). **This activity is the big “take away” from this module.** It is YOUR checklist of things to remember about publication ethics. In each module in this series, you will add a checklist of the things you want to remember from that module. You also will add notes on how you would teach this to your students in the future. For most modules, we encourage you to add three sections to your checklist:

- 1. Definitions to Remember Table:** Consider adding the terms and definitions from the lecture. Also add the links for professional standards you want to access later (e.g., ICMJE criteria for authorship). Remember to add the source of your definition or text if you are copying it.
- 2. My Best Practices Checklist:** What are the things you want to check as you develop or revise your manuscripts?
- 3. PASS IT ON:** How will you teach this to YOUR trainees in the future? How will you share this with those with whom you collaborate?

When you are done with these modules, we encourage you to make a copy of your checklists and keep them handy for use as you develop manuscripts in the future.

Activity A

Tell Me About Your Research

Purpose This activity will help you consider how non-scientists view animal and human research. After completing this activity, you will be able to decide when and how you would describe your research to friends and family.

Procedure Read the following articles/webpages. On the APS website, be sure to read the questions and answers for each topic (bottom of the page):



READ

- Harmon, A. (2010, April 21). Indian Tribe Wins Fight to Limit Research of Its DNA. *New York Times*, <http://www.nytimes.com/2010/04/22/us/22dna.html?pagewanted=all&r=0> (Accessed March 9, 2017).
- American Physiological Society (APS). 2001. *Animal research: finding cures, saving lives*. Bethesda, MD: APS. <http://www.the-aps.org/mm/SciencePolicy/AnimalResearch/Publications/animals> (Accessed March 9, 2017).



WRITE

Answer the following questions.

1. How would you describe your research to family, friends, and non-scientists? Do you discuss the animal or human subjects you use in your work? If so, how do you describe that aspect of your work? Are there details that you are careful to not discuss?
2. Consider the example of the Hacasupai Indians. Would you agree with Dr. Markow's claims that she was doing "good science" and that her actions were ethical? Why/why not?

Activity B

Worksheet for Animal and Human Subject Studies

Purpose In this activity, you will use a checklist to identify key information that should be included in the methods section of animal and/or human studies. After completing this activity, you will be able to assess whether animal and human studies have reported sufficient information for the work to be considered ethical and reproducible. You also will be able to identify the information that should be included in manuscripts submitted to scientific journals concerning animal and human subject studies.

- Procedure**
1. Select a journal article that reports on an animal or human subject study. PRINT a copy and bring it to class.
 2. Use the Animal/Human Study Worksheet to evaluate the human subject or animal use descriptions reported in your journal article using the Checklist form.
 3. After 10 minutes, pair with a classmate and share your findings.
 4. After 5 minutes, be prepared to report to the class your overall impression of how well authors report descriptions of animal and human subjects used in research. Be sure to consider which details are necessary and which are most often missing.



DISCUSS



WRITE

REMEMBER: Note ideas that you want to add to your My Animal and Human Studies Checklist.

Animal Study Worksheet		
Does the Methods section of the animal study include:	Yes/No	Comments
IACUC approval from authors' institution(s)?		
Animal type (species, strain, sex, numbers used)?		
Housing environment (temp, # animals/cage, light/dark cycle, humidity, etc.)?		
Food (source, type, etc.)?		
Ethics guidelines (NAS Guide for Care and Use of Laboratory Animals, etc.)?		
Other relevant details included in the description? Please describe.		
Missing information? Please describe.		
Ethics concerns? Please describe.		

Human Study Worksheet		
Does the Methods section of the human study include:	Yes/No	Comments
IRB approval from authors' institution(s)?		
Written informed consent from participants?		
Details about the participants in study (number, sex, selection criteria)?		
Participant health details (age, weight, height, BMI, etc.)?		
Adherence to ethics guidelines (Declaration of Helsinki, etc.)?		
Other relevant details included in the description? Please describe.		
Missing information? Please describe.		
Ethics concerns? Please describe.		

Activity C

Case Studies - Animal and Human Subject Studies

Purpose These case studies provide examples of common scenarios that you may encounter regarding animal and human subject use. After completing the activity, you will be able to identify and address concerns about the information that is needed to determine whether research will be considered ethical and reproducible.

Procedure In small groups, one student should read the scenario to the group. After each section, the group should discuss the question.



DISCUSS

At the end of the activity, students should write down their answers and be prepared to share with the whole class.

Case Study 1: Animal Protocol Concerns

A. Reviewer reads in an article

“Mice were fasted until their body temperature reached 30 degrees C. That is, the length of the fast for each overweight animal was not exactly the same but ranged between 22 and 33 days. The experiments were done in accordance with the rules of “Non-US Country” on animals and the experiments were approved by the ethics committee of “Non-US Research Institution.”

1. Should the reviewer raise concerns about this protocol?
2. What details in the protocol are of concern?
3. What information is missing?

B. Journal contacts the author for clarification

“During the course of review, a concern was raised about the fasting protocol in your manuscript. First, has this specific fasting protocol, including the length of the fast, been approved by your

animal care ethics committee? If so, please provide the protocol number and approval date. Second, what were the criteria you used to determine if any of the animals experienced pain or distress as a result of the fasting protocol? Third, what did you do to minimize pain and distress of the mice used in this study, and did any experience pain or distress? Fourth, why was such an extended regimen required for the study? Fifth, why did you use body temperature as an end point for the fasting period, rather than a percentage of body mass loss, which is more reflective of potential adverse effects on animal health? Finally, why wouldn't a shorter fasting period serve the same purpose?"

C. Response from author

"Yes, we received approval for these studies on July 20, 2014 (protocol #389764). The idea of exposing mice to long-term fasting originated from my 'curiosity'.... The current study may also be considered to be the first instance that mice with excess weight can survive the loss of over 50% body weight and refeeding can reestablish the original body mass without obvious ill effects. As for the distress and pain, we did not observe any sign of increased stress. Rather, they became calmer during the day and their body core temperature remained in the normal range."

4. Does the author's response address the journal's concerns?

5. Should this study be published as is?

6. Has the welfare of the animals been protected in this study?

D. Journal's response to author:

"Although no mice were 'harmed' as a result of the prolonged fast, it is journal policy to publish animal studies that abide by the rules set forth by the *Guide for the Care and Use of Laboratory Animals*. Thus, the objective when these studies are being planned and executed should be to use the least restriction necessary to achieve the scientific objective while maintaining animal well-being. However, your study does not appear to meet this ethical standard, since there is no indication that the prolonged period of food deprivation used is the minimal necessary to achieve your scientific goals. Therefore, I am recommending that the associate editor reject your paper on ethical grounds."

7. What could the researcher have done differently to avoid this outcome?

Case Study 2: Photographs of Animals in Manuscripts

A. Cover letter to Journal Editor

“Dear Editor,

We are pleased to submit our manuscript to your prestigious journal. We have identified a new technique to assess whether nonhuman primates prefer an easy task or a complex task. The techniques and experimental setup are novel. They are fully described in the Methods section and in the results reported in Figure 7.

Sincerely,
Excited Author”

B. Email from Journal Staff Member to Journal Editor

“Hi Dr. Editor,

I am checking in this manuscript that was just submitted. Take a look at the photo in Figure 7. Is it necessary? Do you think they have approval to take photos of the animals used in the study?

I will wait to process this until I hear from you.

Journal Staff Member”



Figure 7: Picture of Subject #3 used in the study.

Source: Clipart.com

- 1. Why would the journal staff member be concerned about the image?**
- 2. Are researchers permitted to take photographs of animals for publication?**
- 3. What types of images of animals should be avoided?**

C. Journal Contacts Author

“Dear Author,

Your paper has been received. However, before it can go out for review please remove the photograph in Figure 7 or replace it with a diagram. We are concerned that the image will draw

unnecessary attention from animal rights groups.

Sincerely,
Editor in Chief”

D. Author responds to Journal

“Dear Editor,

We really like the photo, but we can understand that it is not necessary for the publication. The photo in Figure 7 has been removed. Please let me know if you need anything else.

Thank you,
Excited Author”

4. Do you think a diagram could serve the same purpose in this instance?

<p>“We did seek IRB approval. The teeth came from a dental tissue bank that arranges transfer of teeth from dentists to researchers. Parents’ of the patients consented to allow the leftover tissue to be used for research. We received no identifying information about the patient, only age and reason for extraction.”</p>		
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REMEMBER: Note ideas that you want to add to your My Animal and Human Studies Checklist.

WRITE

Activity D

My Animal and Human Studies Considerations Checklist

Purpose You will develop a checklist based on course material that you can use now and in the future to guide ethical text preparation for animal and human studies. You should use materials from the activities, readings, and Interactive Lecture. After completing the activity, you should have a checklist for animal and human studies considerations AND a plan for teaching these best practices to your future students.

Procedure This activity is the big “take away” from this module. It is YOUR checklist of things to remember about publication ethics. In this activity, add the things to your checklist that you want to remember about the ethical use of animals and/or humans in research and preparing manuscripts based on that research. You also will add notes on how you would teach this to YOUR students in the future.

1. Definitions/Resources to Remember Table

Consider adding the terms IACUC and IRB as well as links for “The Guide” and the Human Subjects Decision Charts. Remember to add the source of your definition, if you are copying it.

2. My Best Practices Checklist

- a. **Animal Subjects:** Consider adding information on rationale, techniques, expertise and be sure to add info on how you will pass this on to your future students
- b. **Human Subjects:** Consider adding information on rationale, techniques, expertise and be sure to add info on how you will pass this on to your future students.

Sample tables are provided below. You can recreate the tables in your word processing program.

Definitions and Resources to Remember	
A. IACUC	
B. IRB	
C. “The Guide”	
D. Human Subjects Decision Charts	

My Best Practices Checklist

I. Animal Subjects – Important information to include

A. Rationale	
B. Technique	
C. Expertise	
D. Other	
E. PASS IT ON	My ideas for teaching good practices for ethical text preparation on studies using animals to MY students:

II. Human Subjects – Important information to include

A. Rationale	
B. Technique	
C. Expertise	
D. Other	
E. PASS IT ON	My ideas for teaching good practices for ethical text preparation on studies using humans to MY students:

Student Slide Handout

aps BMES

PROFESSIONAL INTEGRITY: BEST PRACTICES FOR PUBLISHING YOUR RESEARCH

Animal and Human Studies Considerations

You will be able to:

- Describe the history of animal and human subjects study regulations
- Interpret roles and importance of IACUC's and IRB's
- Indicate the information to include in manuscripts to fully describe animal and human studies
- Assess whether animal and human studies have reported sufficient information regarding ethics and reproducibility
- Discuss why animal and human research affect those outside of the research community

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Professional Integrity: Best Practices For Publishing Your Research
Animal and Human Studies Considerations

Why Use Animals and Human Subjects in Your Studies?

Have you considered:

- Why your lab uses a particular research model?
- What are the benefits of using your research model?
- Is there another research model that would work just as well?

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Professional Integrity: Best Practices For Publishing Your Research
Animal and Human Studies Considerations

Animals and Human Subjects Must Be Respected and Protected

DISCUSS

- How do you describe your research to family, friends and non-scientists?
- Did you find it difficult to describe your research in a way that non-scientists could understand it?

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Professional Integrity: Best Practices For Publishing Your Research
Animal and Human Studies Considerations

Animal and Human Subject Studies Enable Better Understanding of Biology and Function

Published by: Cheng XE, et al. doi:10.1371/journal.pone.0132101
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Professional Integrity: Best Practices For Publishing Your Research
Animal and Human Studies Considerations

Approval First.

Review and Approval Takes Time. Weeks to Months. Plan Ahead!
Before starting any animal or human subject experiment, Principal Investigator must seek approval

- Institutional Animal Care and Use Committee (IACUC) reviews and approves animal studies
- Institutional Review Board (IRB) reviews and approves human subject studies

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Professional Integrity: Best Practices For Publishing Your Research
Animal and Human Studies Considerations

IACUC Review

- Each U.S. institution that conducts animal research has its own IACUC (and some have more than one).
- An IACUC panel includes at least 5 members. Among these must be a laboratory animal veterinarian, an animal research scientist, a nonscientist (from within or outside the institution), and someone with no affiliation with the institution.
- **What are they looking for in an animal use protocol?**

- Appropriate rationale and methods
- Appropriate species for study
- Minimum animal numbers for statistically robust studies
- Pain/discomfort minimized; euthanasia methodology
- Animal and surgical training for research personnel

<http://www.nap.edu/catalog/12710/guide-for-the-care-and-use-of-laboratory-animals-eighth>
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Animal and Human Studies Considerations

Is Your Study Exempt?

- Data sources can determine the type and level of review and exemptions that apply.
- Data from various sources are subject to different restrictions:
 - Classroom data
 - Public databases
 - Samples from previous projects

<http://www711.aps.org/jahp/resolutions-and-policies/decisions-chart/#1>

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Animal and Human Studies Considerations

Protocols Should Describe Rationale, Techniques, and Expertise

Rationale	Techniques	Expertise
<ul style="list-style-type: none">What is the experimental question? Rationale?What is the most appropriate model system to address the question?	<ul style="list-style-type: none">How will you perform the study?What techniques will you use?	<ul style="list-style-type: none">Who will perform the experiments? Are they properly trained?Is this a collaborative study? Are the collaborators following similar animal and human subject guidelines?

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Animal and Human Studies Considerations

What Is a Reasonable Sample Size?

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Animal and Human Studies Considerations

"The Rate of Passage of Inert Materials Through the Digestive Tract" by Frederick Hoelzel Published in 1929

Reproduced from table 4, summary of results (Hoelzel, 1929), showing that materials passed through the digestive tract at rates proportional to their specific gravity.

Kind of material	Specific gravity	Time in hours	Time in minutes	Time in seconds	Time in tenths of seconds
Case (20%)				2 to 4*	
Food				10 to 15	
Flour				15 to 20	
Flour and seeds	0.75	100	100	100	0.8 to 1.6
Flour and seeds	0.80	100	100	100	1.00
Milk and seeds	0.85	100	100	100	1.20
Orange seeds	0.90	100	100	100	1.40
Flour and seeds	0.95	100	100	100	1.60
Flour and seeds	1.00	100	100	100	1.80
Flour and seeds	1.05	100	100	100	2.00
Flour and seeds	1.10	100	100	100	2.20
Flour and seeds	1.15	100	100	100	2.40
Flour and seeds	1.20	100	100	100	2.60
Flour and seeds	1.25	100	100	100	2.80
Flour and seeds	1.30	100	100	100	3.00
Flour and seeds	1.35	100	100	100	3.20
Flour and seeds	1.40	100	100	100	3.40
Flour and seeds	1.45	100	100	100	3.60
Flour and seeds	1.50	100	100	100	3.80
Flour and seeds	1.55	100	100	100	4.00
Flour and seeds	1.60	100	100	100	4.20
Flour and seeds	1.65	100	100	100	4.40
Flour and seeds	1.70	100	100	100	4.60
Flour and seeds	1.75	100	100	100	4.80
Flour and seeds	1.80	100	100	100	5.00
Flour and seeds	1.85	100	100	100	5.20
Flour and seeds	1.90	100	100	100	5.40
Flour and seeds	1.95	100	100	100	5.60
Flour and seeds	2.00	100	100	100	5.80
Flour and seeds	2.05	100	100	100	6.00
Flour and seeds	2.10	100	100	100	6.20
Flour and seeds	2.15	100	100	100	6.40
Flour and seeds	2.20	100	100	100	6.60
Flour and seeds	2.25	100	100	100	6.80
Flour and seeds	2.30	100	100	100	7.00
Flour and seeds	2.35	100	100	100	7.20
Flour and seeds	2.40	100	100	100	7.40
Flour and seeds	2.45	100	100	100	7.60
Flour and seeds	2.50	100	100	100	7.80
Flour and seeds	2.55	100	100	100	8.00
Flour and seeds	2.60	100	100	100	8.20
Flour and seeds	2.65	100	100	100	8.40
Flour and seeds	2.70	100	100	100	8.60
Flour and seeds	2.75	100	100	100	8.80
Flour and seeds	2.80	100	100	100	9.00
Flour and seeds	2.85	100	100	100	9.20
Flour and seeds	2.90	100	100	100	9.40
Flour and seeds	2.95	100	100	100	9.60
Flour and seeds	3.00	100	100	100	9.80
Flour and seeds	3.05	100	100	100	10.00
Flour and seeds	3.10	100	100	100	10.20
Flour and seeds	3.15	100	100	100	10.40
Flour and seeds	3.20	100	100	100	10.60
Flour and seeds	3.25	100	100	100	10.80
Flour and seeds	3.30	100	100	100	11.00
Flour and seeds	3.35	100	100	100	11.20
Flour and seeds	3.40	100	100	100	11.40
Flour and seeds	3.45	100	100	100	11.60
Flour and seeds	3.50	100	100	100	11.80
Flour and seeds	3.55	100	100	100	12.00
Flour and seeds	3.60	100	100	100	12.20
Flour and seeds	3.65	100	100	100	12.40
Flour and seeds	3.70	100	100	100	12.60
Flour and seeds	3.75	100	100	100	12.80
Flour and seeds	3.80	100	100	100	13.00
Flour and seeds	3.85	100	100	100	13.20
Flour and seeds	3.90	100	100	100	13.40
Flour and seeds	3.95	100	100	100	13.60
Flour and seeds	4.00	100	100	100	13.80
Flour and seeds	4.05	100	100	100	14.00
Flour and seeds	4.10	100	100	100	14.20
Flour and seeds	4.15	100	100	100	14.40
Flour and seeds	4.20	100	100	100	14.60
Flour and seeds	4.25	100	100	100	14.80
Flour and seeds	4.30	100	100	100	15.00
Flour and seeds	4.35	100	100	100	15.20
Flour and seeds	4.40	100	100	100	15.40
Flour and seeds	4.45	100	100	100	15.60
Flour and seeds	4.50	100	100	100	15.80
Flour and seeds	4.55	100	100	100	16.00
Flour and seeds	4.60	100	100	100	16.20
Flour and seeds	4.65	100	100	100	16.40
Flour and seeds	4.70	100	100	100	16.60
Flour and seeds	4.75	100	100	100	16.80
Flour and seeds	4.80	100	100	100	17.00
Flour and seeds	4.85	100	100	100	17.20
Flour and seeds	4.90	100	100	100	17.40
Flour and seeds	4.95	100	100	100	17.60
Flour and seeds	5.00	100	100	100	17.80
Flour and seeds	5.05	100	100	100	18.00
Flour and seeds	5.10	100	100	100	18.20
Flour and seeds	5.15	100	100	100	18.40
Flour and seeds	5.20	100	100	100	18.60
Flour and seeds	5.25	100	100	100	18.80
Flour and seeds	5.30	100	100	100	19.00
Flour and seeds	5.35	100	100	100	19.20
Flour and seeds	5.40	100	100	100	19.40
Flour and seeds	5.45	100	100	100	19.60
Flour and seeds	5.50	100	100	100	19.80
Flour and seeds	5.55	100	100	100	20.00
Flour and seeds	5.60	100	100	100	20.20
Flour and seeds	5.65	100	100	100	20.40
Flour and seeds	5.70	100	100	100	20.60
Flour and seeds	5.75	100	100	100	20.80
Flour and seeds	5.80	100	100	100	21.00
Flour and seeds	5.85	100	100	100	21.20
Flour and seeds	5.90	100	100	100	21.40
Flour and seeds	5.95	100	100	100	21.60
Flour and seeds	6.00	100	100	100	21.80
Flour and seeds	6.05	100	100	100	22.00
Flour and seeds	6.10	100	100	100	22.20
Flour and seeds	6.15	100	100	100	22.40
Flour and seeds	6.20	100	100	100	22.60
Flour and seeds	6.25	100	100	100	22.80
Flour and seeds	6.30	100	100	100	23.00
Flour and seeds	6.35	100	100	100	23.20
Flour and seeds	6.40	100	100	100	23.40
Flour and seeds	6.45	100	100	100	23.60
Flour and seeds	6.50	100	100	100	23.80
Flour and seeds	6.55	100	100	100	24.00
Flour and seeds	6.60	100	100	100	24.20
Flour and seeds	6.65	100	100	100	24.40
Flour and seeds	6.70	100	100	100	24.60
Flour and seeds	6.75	100	100	100	24.80
Flour and seeds	6.80	100	100	100	25.00
Flour and seeds	6.85	100	100	100	25.20
Flour and seeds	6.90	100	100	100	25.40
Flour and seeds	6.95	100	100	100	25.60
Flour and seeds	7.00	100	100	100	25.80
Flour and seeds	7.05	100	100	100	26.00
Flour and seeds	7.10	100	100	100	26.20
Flour and seeds	7.15	100	100	100	26.40
Flour and seeds	7.20	100	100	100	26.60
Flour and seeds	7.25	100	100	100	26.80
Flour and seeds	7.30	100	100	100	27.00
Flour and seeds	7.35	100	100	100	27.20
Flour and seeds	7.40	100	100	100	27.40
Flour and seeds	7.45	100	100	100	27.60
Flour and seeds	7.50	100	100	100	27.80
Flour and seeds	7.55	100	100	100	28.00
Flour and seeds	7.60	100	100	100	28.20
Flour and seeds	7.65	100	100	100	28.40
Flour and seeds	7.70	100	100	100	28.60
Flour and seeds	7.75	100	100	100	28.80
Flour and seeds	7.80	100	100	100	29.00
Flour and seeds	7.85	100	100	100	29.20
Flour and seeds	7.90	100	100	100	29.40
Flour and seeds	7.95	100	100	100	29.60
Flour and seeds	8.00	100	100	100	29.80
Flour and seeds	8.05	100	100	100	30.00
Flour and seeds	8.10	100	100	100	30.20
Flour and seeds	8.15	100	100	100	30.40
Flour and seeds	8.20	100	100	100	30.60
Flour and seeds	8.25	100	100	100	30.80
Flour and seeds	8.30	100	100	100	31.00
Flour and seeds	8.35	100	100	100	31.20
Flour and seeds	8.40	100	100	100	31.40
Flour and seeds	8.45	100	100	100	31.60
Flour and seeds	8.50	100	100	100	31.80
Flour and seeds	8.55	100	100	100	32.00
Flour and seeds	8.60	100	100	100	32.20
Flour and seeds	8.65	100	100	100	32.40
Flour and seeds	8.70	100	100	100	32.60
Flour and seeds	8.75	100	100	100	32.80
Flour and seeds	8.80	100	100	100	33.00
Flour and seeds	8.85	100	100	100	33.20
Flour and seeds	8.90	100	100	100	33.40
Flour and seeds	8.95	100	100	100	33.60
Flour and seeds	9.00	100	100	100	33.80
Flour and seeds	9.05	100	100	100	34.00
Flour and seeds	9.10	100	100	100	34.20
Flour and seeds	9.15	100	100	100	34.40
Flour and seeds	9.20	100	100	100	34.60
Flour and seeds	9.25	100	100	100	34.80
Flour and seeds	9.30	100	100	100	35.00
Flour and seeds	9.35	100	100	100	35.20
Flour and seeds	9.40	100	100	100	35.40
Flour and seeds	9.45	100	100	100	35.60
Flour and seeds	9.50	100	100	100	35.80
Flour and seeds	9.55	100	100	100	36.00
Flour and seeds	9.60	100	100	100	36.20
Flour and seeds	9.65	100	100	100	36.40
Flour and seeds	9.70	100	100	100	36.60
Flour and seeds	9.75	100	100	100	36.80
Flour and seeds	9.80	100	100	100	37.00
Flour and seeds	9.85	100	100	100	37.20
Flour and seeds	9.90	100	100	100	37.40
Flour and seeds	9.95				

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"Indian Tribe Wins Fight to Limit Research of Its DNA"

"Members of the tiny, isolated tribe had given DNA samples to university researchers starting in 1990, in the hope that they might provide genetic clues to the tribe's devastating rate of diabetes. But they learned that their blood samples had been used to study many other things, including mental illness and theories of the tribe's geographical origins that contradicted their traditional stories."
 by Amy Hamon New York Times, April 21, 2016

Stakeholder perspectives:

Scientists	Tribe
Permission was obtained to study behavioral and medical disorders	Study was outside scope of agreement
Blood is a source of DNA	Blood is spiritually meaningful
Results from the studies are of great interest to the research community	Results could damage tribe's history and damage its future

<http://www.nytimes.com/2016/04/21/us/politics/indian-tribe-says-researchers-took.html>

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Protocol Details Should Be Included in the Methods Section of Associated Research Articles

Reviewers will check for:



- ✓ Statements of protocol approval and other national/local approvals
- ✓ Considerations for animal and human subject safety
- ✓ Specific details about the animals used (e.g. number, sex, age, treatment groups, interventions)
- ✓ Health details about human subject participants (e.g. sex, age, weight, interventions)

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Example: Animal Study Methodology

MATERIALS AND METHODS

Animals

Male C57BL/6J (Lepr^{fl/fl}), Lepr^{fl/fl} and Lepr^{fl/fl} and Sprague-Dawley rats were purchased from Taconic (Indarapolis, IN). Rats were housed in conventional core facilities that were kept at a consistent humidity (60 ± 5%), temperature (24 ± 1°C) and light cycle (12h/12h). Lepr^{fl/fl} and obese rats were housed separately with rats housed 2-4h a cage. Experiments were performed on age-matched females (6-7 wk old Zucker rats, 6-17 wk old Zucker rats, and Sprague-Dawley rats).

All experiments were performed in accordance with the National Institutes of Health's Guide for Care and Use of Laboratory Animals and the American Physiological Society's "Guiding Principles in the Care and Use of Vertebrate Animals in Research and Training." The animal protocols were reviewed and approved by the Institutional Animal Care and Use Committees of University of North Texas Health Science Center and Medical College of Georgia.

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Example: Human Subject Study Methodology

METHODS
Ethical approval
Participants were recruited from the University of Alberta and the general population and each provided written, informed consent. The study was approved by the University of Alberta Health Research Ethics Board (Biomedical Panel) and conformed to the standards set by the Declaration of Helsinki.

Participant description
Fourteen healthy men were recruited (age: 24.6 ± 1.1 yr, height: 177.0 ± 2.1 cm, weight: 85.8 ± 5.8 kg, $\dot{V}O_2$ max: 49.2 ± 3.1 ml $\text{kg}^{-1} \text{min}^{-1}$). All subjects were free from cardiovascular disease and had normal ECG-blood pressure response during a standard 12-lead ECG during a $\dot{V}O_2$ max test (Vmax system; VIASYS Products).

DOI: 10.1152/ajpregu.00472.2013
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Missing Approvals Can Delay Publication

Journal will delay publication if IACUC or IRB approval is not reported in the manuscript

- ✦ If no approval was given, paper will not be published
- ✦ Institution may be informed
- ✦ More regulations for all researchers at institution

Even if IRB or IACUC approval is noted, the journal editors may seek additional clarification if they view the experiments as questionable in terms of appropriate use of test subjects.

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Small Group Discussion

Your instructor will provide directions for these activities



DISCUSS

- ✦ These activities will help you APPLY what you have learned so far to common scenarios

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End of Presentation. Open Discussion.

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- ✓ For more information on how the materials were developed and tested, please contact the authors.

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The time is always right to do the right thing.

—Martin Luther King Jr.

CONSIDERATIONS FOR ANIMAL AND HUMAN STUDIES is one of seven teaching modules designed to promote best practices in publication ethics for life scientists and biomedical engineers who publish research papers. Each module provides information on and principles of the most common publication ethics issues as well as the tools needed to integrate and apply professional standards of practice to real life situations. After finishing each module, students will have a personal checklist to use in the preparation of future manuscripts AND a plan for teaching module principles to their future trainees and collaborators.

Modules are designed to be used by higher education institutions, laboratory groups, individuals, and professional societies. The teaching paradigms used in the modules support various types of learners and were designed to integrate into current Responsible Conduct of Research (RCR) training courses/programs.

Modules were developed with support from the National Science Foundation (NSF) (#SES -1238368) and in collaboration with staff and members of the American Physiological Society, Biomedical Engineering Society, and the Society for Biological Engineers.

Handouts for instructor and students, audio and video resources, and online course links are available at www.the-aps.org/pst for all seven modules:

- Authorship
- Conflicts of Interest
- Considerations for Animal and Human Studies
- Data Fabrication and Falsification
- Data Management and Integrity
- Overlapping Publications
- Text Preparation and Avoiding Plagiarism