Edward Via College of Osteopathic Medicine

MED 8164
Research Distinction Elective

Ramu Anandakrishnan, PhD
Research Administrator and Instructor
Phone: 703-403-0234
ranandakrishnan@vt.vcom.edu

Research Administration

Kenny Brock, DVM, MS, PhD
Associate Dean for Biomedical Affairs and Research – Auburn Campus
Phone: 334-442-4001
kbrock@auburn.vcom.edu

David Eagerton, PhD, F-ABFT
Associate Dean for Biomedical Affairs and Research – Carolinas Campus
Phone: 864-327-9831
deagerton@carolinas.vcom.edu

Jim Mahaney, PhD
Associate6çÜ`Zá€ Ë ™ ³{'Y2¥…Uƒ Ç•¶‹YóF ž

I. Course

V. Requirements for Successful Completion

A. Requirements and Grading

- CITI Training:
  -

complete, click “Next.”

- Select Curriculum: In this section, select the following courses: Protection of Human Research Subjects, OSHA Bloodborne Pathogens, Research Study Design, Conflicts of Interest, Laboratory Safety, and Biomedical Responsible Conduct of Research. If you wish to add other courses, you may at any time; however, these are the only training courses required. Note that some

- Submission of an IACUC application is required for all research projects that include animal subjects.

¾ Submit a Research Project Proposal that includes the

VII. Grading Scale

6. Records-Based Research
   Online Module: Records-Based Research
   Learning Objectives:
   i. Discuss the risks associated with conducting records-based research.
   ii. Identify the types of review that apply to records-based research.

7. Genetic Research in Human Populations
   Online Module: Genetic Research in Human Populations
   Learning Objectives:
   i. Discuss the risks associated with genetic and genomic research.
   ii. Describe the difference between privacy and confidentiality with genetic and genomic research.
   iii. List the information in genetic and genomic research that should be disclosed to subjects during the consent process.
   iv. Identify the risks and regulatory issues relevant to research using biospecimens.

8. Populations in Research Requiring Additional Considerations and/or Protections
   Online Module: Populations in Research Requiring Additional Considerations and/or Protections
   Learning Objectives:
   i. Describe the different sources of vulnerability.
   ii. Distinguish between vulnerable populations in research who are specifically protected in the federal regulations and those who are not.
   iii. Identify additional protections for vulnerable populations who are not specifically protected in the federal regulations.
   iv. Explain the effect on autonomy, beneficence, and justice that may arise due to research on vulnerable individuals or groups.

9. Research Involving Prisoners
   Online Module: Research Involving Prisoners
   Learning Objectives:
   i. Describe the regulatory definition of a prisoner.
   ii. List the categories of research permitted with prisoners.
   iii. Identify the IRB membership requirements required for approval of research with prisoners.
   iv. Describe the items the IRB must determine in order to approve research involving prisoners.

10. Research Involving Children
    Online Module: Research Involving Children
    Learning Objectives:
    i. Describe the major historical events that influenced how research with children as subjects is currently conducted.
    ii. Identify the types of research with children permitted under 45 CFR 46, Subpart D.
    iii. Discuss the assent and informed consent requirements for different types of studies involving children.
    iv. Reco(hi)p5 ((e)-3001 Tc -0.001 Tw -12.54 -1.1d [(R)-5 (e)-3(v)-1e)-3 (nt)2 (l)-1

11. Research Involving Pregnant Women, Fetuses, and Neonates
    Online Module: Research Involving Pregnant Women, Fetuses, and Neonates
    Learning Objectives:

B. CITI Training: OSHA Bloodborne Pathogens
OSHA Bloodborne Pathogens is designed as initial training or annual retraining to meet the requirements of the U.S. Occupational Safety and Health Administration's (OSHA) Bloodborne Pathogen Standard. Directed at researchers, employees, and students who hand or have contact with human blood, tissues, bodily fluids, or other potentially infectious materials. Students must complete the OSHA Bloodborne Pathogens CITI Training Course and submit their certificate of completion to CANVAS.

1. OSHA Bloodborne Pathogens Standard
   Online Module: OSHA Bloodborne Pathogens Standard
   Learning Objectives:
   i. Describe the overall requirements for employers and their responsibilities for workers who have occupational exposure to bloodborne pathogens.
   ii. Discuss the topics required to train employees who have occupational exposure to human blood or OPIM.
   iii. Describe an Exposure Control Plan and its required contents.

2. Hepatitis B Virus (HBV) Vaccination: Routes of Exposure and Routes of Transmission
   Online Module: Hepatitis B Virus (HBV) Vaccination
   Learning Objectives:
   i. Describe how the Occupational Safety and Health Administration (OSHA) Bloodborne Pathogens Standard requirements pertain to the HBV vaccine.
   ii. Explain the HBV vaccine administration schedule.
   iii. Differentiate between workplace exposures and general exposures to bloodborne pathogens outside of work.

3. Labels and Engineering Controls
   Online Module: Labels and Engineering Controls
   Learning Objectives:
   i. Recognize the required color and configuration of the universal biohazard symbol.
   ii. Describe the equipment and containers that require labeling with the biohazard symbol.
   iii. Discuss a few of the common engineering controls and examine the recommended work practices associated with their use.

4. Universal Precautions and Work Practices
   Online Module: Universal Precautions and Work Practices

5. Emergency Response Procedures
   Online Module: Emergency Response Procedures
   Learning Objectives:
   i. Recognize various emergency incident and exposure response situations.
   ii. Demonstrate how to respond to minor laboratory spills involving biological materials.
   iii. Assemble a biohazard spill response kit for a work area.

C. CITI Training: Research Study Design

This peer-reviewed course provides you with an understanding of how to improve study design, collect and analyze data, and promote reproducible research. You will be provided with a detailed overview of scientific inquiry, examples of various research designs, introductions to data management methods and statistical analysis. This in-depth course is comprised of 11 modules. Students must complete the Research Study Design CITI Training Course and submit their certificate of completion to CANVAS.

1. Introduction to Scientific Research
   Online Module: Introduction to Scientific Research
   Learning Objectives:
   i. Introduce the steps involved in scientific research, including how to formulate a research question and the steps associated with developing a hypothesis.
   ii. Understand the committees that may be involved in the review of research.

2. Observational Research
   Online Module: Observational Research
   Learning Objectives:
   i. Understand different types of observational research designs
   ii. Determine the best designs to fit with intended research activities.
   iii. Discuss the strengths and limitations of the designs.

3. Interventional Research
   Online Module: Interventional Research
   Learning Objectives:
   i. Identify the different types of interventional studies and designs, including special considerations associated with interventional research designs.

4. Quantitative Research: Statistical Reasoning and Hypothesis Testing Part 1
   Online Module: Quantitative Research Part 1
   Learning Objectives:
   i. Outline statistical reasoning, hypothesis testing, and research design.
   ii. Explore how researchers develop research questions, generate research hypotheses, understand variability, and develop methods for explaining variability to the extent possible.

5. Quantitative Research: Statistical Reasoning and Hypothesis Testing Part 2
   Online Module: Quantitative Research Part 2
   Learning Objectives:
   i. Expand on the fundamentals of statistics
   ii. Explore how statistics are used to make research decisions.

6. Survey Research: Designing the Instrument
   Online Module: Survey Research: Designing the Instrument
   Learning Objectives:
      i. Introduction to survey research design
      ii. Focus on developing and pilot testing the survey instrument.

7. Survey Research: Conducting the Research
   Online Module: Survey Research: Conducting the Research
   Learning Objectives:
      i. Discuss key areas associated with conducting survey research, including ways to adapt surveys for new populations, different samples and sampling techniques, and ways to administer surveys.

8. Qualitative Research Methods
   Online Module: Qualitative Research Methods
   Learning Objectives:
      i. Learn an overview of qualitative research and differences among the major qualitative research designs.
      ii. Understand critical issues to consider when designing a qualitative study.

9. Mixed Methods Research
   Online Module: Mixed Methods Research
   Learning Objectives:
      i. Understand mixed methods research and the rationale for using a mixed methods design.
      ii. Discover the different mixed methods designs and the major design decisions to consider.

10. Data Management
    Online Module: Data Management
    Learning Objectives:
       i. Identify the steps, concepts, and importance of data management throughout a research study.
       ii. Describe institutional support services that can help manage your research data.
       iii. Evaluate methodological, technological, and regulatory considerations that affect data management practices.
       iv. Explain the documentation needed to facilitate accessibility and reproducibility of research findings.
       v. Recognize ethical and compliance issues relating to data ownership, sharing, and protection.

11. Reproducibility of Research Results
    Online Module: Reproducibility of Research Results
    Learning Objectives:
       i. Discusses factors that contribute to the lack of reproducibility and the resulting problems that can emerge.
       ii. Describe the stakeholders affected by reproducibility problems
       iii. Discuss a collection of reproducibility initiatives
       iv. Learn strategies that can mitigate or prevent irreproducibility.

D. CITI Training: Conflicts of Interest

Federal agencies have specific regulations on financial conflicts of interest (FCOIs) to promote objectivity in research. As a researcher, you must be familiar with the regulations and VCOM's policies regarding conflicts. This module is to recognize and understand such conflicts for those who will have responsibility for the design, conduct, or reporting of research. This course is comprised of three modules, each will take about 120 minutes to complete. Students must complete the Conflicts of Interest CITI Training Course and submit their certificate of completion to CANVAS.

1. Financial Conflicts of Interest: Overview, Investigator Responsibilities, and COI Rules
   Online Module: Overview, Investigator Responsibilities, and COI Rules
   Learning Objectives:
   i. Describe how PHS regulations relate to FCOIs.
   ii. Recognize various forms of FCOIs in research.
   iii.

E. CITI Training: Laboratory Safety (if applicable)

All students who plan to or may work in a laboratory setting as part of their Research Distinction elective must complete Laboratory Safety Training. This course provides a comprehensive introduction to biosafety and is comprised of five modules. Students who meet this requirement must complete the Laboratory Safety CITI Training Course and submit their certificate of completion to CANVAS.

1. Biosafety Course Overview
   Online Module: Biosafety Course Overview
   Learning Objectives:
   i. Receive an introduction to biosafety and training for researchers handling Risk Group 1 agents.
   ii. Understand Biosafety Level 1 (BSL-1) containment.

2. Risk Management: Work Practices
   Online Module: Risk Management: Work Practices
   Learning Objectives:
   i. Learn how administrative and work practice controls reduce the risk of occupational exposure and laboratory-acquired infections.
   ii. Recognize good work practices by laboratory personnel.
   iii. Understand the foundational work practice controls in biosafety and best work practices for specialized tasks.

3. Work Safely with Sharp Instruments
   Online Module: Work Safely with Sharp Instruments
   Learning Objectives:
   i. Review how to safely handle sharp instruments when working with biohazards.
   ii. Discuss safe work practices with disposable and reusable sharps.

4. OSHA Bloodborne Pathogens Standard
   Online Module: OSHA Bloodborne Pathogens Standard
   Learning Objectives:
   i. Describe the overall requirements for employers and their responsibilities for workers who have occupational exposure to bloodborne pathogens.
   ii. Discuss the topics required to train employees who have occupational exposure to human blood or OPIM.
   iii. Describe an Exposure Control Plan and its required contents.

5. Universal Precautions and Work Practices
   Online Module: Universal Precautions and Work Practices
   Learning Objectives:
   i. Understand the universal precautions concept where all blood and other potentially infectious materials are treated as if infectious for HIV, HBV, and HCV.
   ii. Extend universal precautions to all sharps and patients.
   iii. Review best practices, guidelines, and precautions to be used in a laboratory setting.

F. CITI Training: Biomedical Responsible Conduct of Research

Responsible conduct of research (RCR) is defined by the NIH as "the practice of scientific investigation with integrity. It involves the awareness and application of established professional norms and ethical principles for all activities related to scientific research." RCR comprises the ethics of research practice and regulatory compliance. It fosters a research environment that enables collaboration and promotes public confidence in scientific knowledge and progress. If research is not conducted ethically and responsibly, results can erode the public's trust and support of science and damaging respect among the scientific community. By the end of this course, you should be able to: explain why RCR is important for every researcher, regardless of discipline or career stage; describe the standard RCR topic areas; and discuss key concepts and principles related to proper research practice. This course is comprised of 10 modules, most modules will take about 10-20 minutes to complete. Students must complete the Biomedical Responsible Conduct of Research CITI Training Course and submit their certificate of completion to CANVAS.

1. Using Animal Subjects in Research
   Online Module: Using Animal Subjects in Research
   Learning Objectives:
   i. Identify the ethical perspectives in animal research.
   ii. Discuss the U.S. regulations governing animal research.
   iii. Describe the roles of the Institutional Official (IO), the Institutional Animal Care and Use Committee (IACUC), and the Attending Veterinarian (AV) in animal care and use programs.
   iv. Recognize the ethical responsibilities of the principal investigator (PI) and members of the research team who work with laboratory animals.
   v. Describe how to report incidents of animal abuse and regulatory noncompliance at your organization.

2. Research Involving Human Subjects
   Online Module: Research Involving Human Subjects
   Learning Objectives:
   i. Recognize (e)11 (ar)e r( )Tj 4 (g)is.

8. Data Management
   Online Module: Data Management
   Learning Objectives:
      i. Identify the steps, concepts, and importance of data management throughout a research study.
      ii.

2. Developing a Hypothesis