Edward Via College of Osteopathic Medicine

MED 8164
Research Distinction Elective
Academic Year 2024 - 2025

COURSE SYLLABUS

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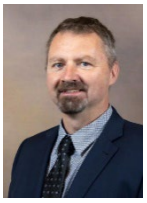

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I. Course Description

VCOM's Research Distinction Elective is designed specifically for those students pursuing the DO with Research Distinction designation upon graduation. Students who are accepted into the DO with Research Distinction Program are those who may want to pursue a career in clinical or translational research. The DO with Research Distinction Program provides students the opportunity to further develop skills in reviewing evidence-based medicine, critical thinking, and writing skills, all while working under the mentorship of VCOM clinical or biomedical faculty. The goal of the program is to provide a well-rounded research experience to students by exposing them to all facets of medical research, which will aid them in future academic and private practice goals.

Because of fourth-year grading requirements, this course must be completed by February 28 of the OMS 4 year. ADPOS students must contact the course director for their due date.

II. Credits

9 credit hours

III. Course Learning Objectives

This program is intended to enrich the medical school experience by enabling the student to work directly with clinical and biomedical research faculty and pursue topics of interest in a wide spectrum of disciplines. Upon successful completion of this course, the student will be able to:

- Complete the components of a research project including identification of health care related scientific questions, participation in data collection and analysis, oral dissemination of scientific information, and written dissemination of scientific information.
- Understand how to critically review scientific literature related to medical outcomes and analyze quality of study design.
- Become familiar with various statistical approaches to data analysis, including systematic reviews and meta-analyses.

IV. Suggested Resources

- VCOM Research Primer Modules under the following pathway- VCOM-CC- Foundations of Clinical Medicine- Research Modules: https://vcom.mediasite.com/mediasite/catalog/catalogs/default
- VLMS Research Matcher
- VCOM Library Contacts:

- Auburn Campus: Hiram Rogers, MLIS, Director for Library Sciences, hhrogers@auburn.vcom.edu
- Carolinas Campus: Bill Nichols, MLS, Medical Librarian, wnichols@carolinas.vcom.edu
- Louisiana Campus: Kristy Hutson, BA, Director for Library Services, khutson@ulm.vcom.edu
- Virginia Campus: Elaine Powers, MSLS, Director for Library Services, epowers@vt.vcom.edu

- VCOM IRB Website

V. Requirements for Successful Completion

A. Requirements and Grading

- **CITI Training:**
  - **Protection of Human Research Subjects**
  - **OSHA Bloodborne Pathogens**
  - **Research Study Design**
  - **Conflict of Interest**
  - **Laboratory Safety**
  - **Biomedical Responsible Conduct of Research**

Students must complete the above CITI courses and submit their certificates of completion to CANVAS before beginning their research project.

If you have already completed this training, confirm that your CITI training is still valid and will be valid throughout the length of your research project. If it is not valid, you will need to complete a refresher course.

- Submit your certificates of completion to Canvas before beginning your research project at: https://canvas.vcom.edu/login/ldap
- If you have any questions about registration or course selection, please contact Eryn Perry, eperry@vcom.edu

For those who have not yet completed CITI training, follow the steps below to create an account affiliated with VCOM, which will allow you to complete CITI Training:

- By following the link below, you will access the CITI Training website where you will register for an account. Once you have reached this link, perform the following actions to create an account affiliated with VCOM:
  - https://www.citiprogram.org and click "Register" on the top right of the page.
  - Under "Select Your Organization Affiliation," type "Edward Via College of Osteopathic Medicine" in the box and choose this selection from the drop-down menu.
    - Check the box to agree to the Terms of Service and Privacy Policy.
    - Check the box to affirm that you are an affiliate of VCOM.
    - Click, "Create a CITI Program account".
  - Complete the Personal Information section and click "Continue to Step 3."

- Create your Username, Password and Security Question and Answer and click "Continue to Step 4."
- If you have an ORCID ID and wish to connect, you may do so, but this is not a requirement and can be done at any time. Enter applicable demographic data into the required fields and click "Finalize Registration."
- Complete CE Credit Status request and then click "Submit" (this will most likely be "No").
- The next page, "Affiliate with an Institution" requests information required by VCOM as part of the member profile affiliation. Once 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 Questions require answers (marked with an asterisk). Once done, click "Submit."
- You will now see the notice that you are enrolled in your selected courses and your registration is complete.
- You will see your "Courses Ready to Begin" list and the "Start Now" button.
- Note that a course does not need to be completed all at one time; your progress will be saved whenever you exit.
- You must achieve an average score of at least 80% on all quizzes to pass the course.
- Once complete, submit your certificates of completion to Canvas before beginning your research project at: https://canvas.vcom.edu/login/ldap
- If you have any questions about registration or course selection, please contact Eryn Perry, eperry@vcom.edu

- **Research Primer Modules**
  Complete all the following 7 VCOM Research Primer Modules. The modules are located on VCOMTV under the following pathway: VCOM-CC > Foundations of Clinical Medicine > Research Modules. A report will be generated from VCOMTV to ensure completion by each student. To be sure you get credit for completion, do not use an external accelerator to view the modules. Viewing through an external accelerator will show as incomplete and you will not receive credit for having completed the modules as required.
  - Background Research and Literature
  - Developing a Hypothesis
  - Developing Your Research Plan With Your Research Mentor
  - How to Write a Scientific Manuscript
  - Scientific Publishing
  - How to Give an Effective Presentation
  - Scientific Meetings

- **Research Manuscript**
  There are many different types of research projects – clinical, basic, educational, sociological, etc. All are potential research projects provided that a suitable hypothesis and project plan can be devised. Such a project should be right-sized to complete the goals for the Research with Distinction Program, with sufficient time to create a publication-quality Research Manuscript. The work must not have been previously published or presented.

  Students wishing to complete a research project must do so under the guidance of a faculty mentor who has an established research program or the skills and ability to conduct a research program.
  - Students must have a mentor that is a VCOM faculty member or a clinician/PhD/PharmD/similarly credentialed individual that is affiliated with VCOM.
  - Meet with your mentor and confirm that they will be providing supervision for your research project.
  - Work with your mentor to identify two additional clinicians, PhD, PharmD, or similarly credentialed individuals, willing to serve on your research committee. They need not be affiliated with VCOM.
    - Committees must include the faculty mentor and the Associate Dean for Biomedical Affairs and Research at the student's respective campus or Dr. Brolinson, or Dr. Anandakrishnan.
    - The initial committee meeting will take place after you have produced your research topic title, hypothesis, and brief abstract/approach with your mentor.
  - Submit the "Research Committee Identification Form".
  - If you need help identifying a mentor or developing a research idea, please contact the Course Director who will assist you.

  A project devised with a mentor can be designed to be completed by several individuals or teams in succession to accomplish the overall project goals. However, such a research project must be organized and broken down into sub-goals. Also, all students are required to submit a research manuscript. Team members can submit the same manuscript, but such a manuscript must contain a section that details the contributions of each team member to the goals/sub-goals of the project.

  Students should follow the format required by the peer-reviewed journal chosen for submission of the research manuscript.

  Research Manuscript Length Requirement: A minimum of 1500 words, excluding the title page, abstract, references, and captions, with a minimum of 30 references, excluding website references.

  In addition, students must be sure that they include all components as indicated in the Research Distinction Manuscript Grading Rubric. The Rubric can be found in CANVAS.

  The following components are required (due dates will be determined by the Associate Dean for Biomedical Affairs):

- Submit the Research Committee Identification Form to Canvas (see requirements for selecting a mentor and committee above).
- In addition to all students completing the CITI Laboratory Safety Course, those students working in a laboratory must contact the lab manager or the Associate Dean for Research on the respective campus for more information about any required training specific to the lab in which they are working.
- Work with the faculty mentor to submit an IRB or IACUC application as needed.
    - Submission of an IRB application is required for all clinical research projects, surveys, or projects that include human subjects. Surveys of students or faculty within the college are not approved for this project.
    - Submission of an IACUC application is required for all research projects that include animal subjects.
- Submit a Research Project Proposal that includes the following sections: Project Title, Project Summary, Significance, Hypothesis, Objectives/Specific Aims, Detailed Approach (Study design and methodology), Preliminary Results, Potential Pitfalls and Alternative Approaches, Expected Results, Investigators' Roles and Responsibilities, and Project Timeline, as agreed to by the student and the mentor. This plan will be reviewed for approval by the Course Director.
- Schedule and present your research project proposal to your research committee. Update your project proposal to incorporate committee member comments.
- Schedule and present your research results to your research committee. Conduct additional research and analysis to address committee member comments.
- Submit your Research Manuscript to your research committees for review. Update the manuscript to address committee member comments.
- Submit your Manuscript to a peer-reviewed journal for publication.
- Submit your Research Manuscript and the Research Distinction Manuscript Grading Rubric to the faculty mentor and Canvas for grading.
    - The faculty mentor must complete grading of the report within 1 week of being provided the manuscript. Students may be required to revise the report based on feedback before receiving a final grade.

VI. Grading

Students must complete all course requirements to pass the course. The Research Manuscript will receive a letter grade, and this grade will also be the grade the student receives for the Research Distinction credit hours.

In accordance with VCOM's grading policy, the College defines satisfactory performance as 70% or above in the course. A final course grade of less than 70% will result in an "F" grade for the course and the student will be brought before the Promotion Board.
The following requirements must be met to pass the course:

Course Item	Contribution to Final Grade
CITI Training: Protection of Human Research Subjects	Pass
CITI Training: OSHA Blood Borne Pathogens	Pass
CITI Training: Research Study Design	Pass
CITI Training: Conflicts of Interest	Pass
CITI Training: Laboratory Safety (if applicable)	Pass
CITI Training: Biomedical Responsible Conduct of Research	Pass
7 Research Primer Modules	Pass
Research Committee Identification Form	Pass
IRB Application	Pass
IACUC Application (if applicable)	Pass
Research Project Proposal	Pass
Research Project Proposal Presentation	Pass
Research Results Presentation	Pass
Manuscript Submission to a Peer-reviewed Journal	Pass
Research Manuscript & Research Distinction Manuscript Grading Rubric	100%

VII. Grading Scale

The paper is graded as Honors, High Pass, Pass, or Fail based on the number of points received on the grading rubric and is non-GPA accountable.

Letter Grade	Points
H – Honors	90 – 100
HP – High-Pass	80 – 89
P - Pass	70 – 79
F - Fail	<70

VIII. Academic Expectations

Grading policies, academic progress, and graduation requirements may be found in the *College Catalog and Student Handbook* at: http://www.vcom.edu/handbooks/catalog/index.html

A. Failure of the Course

If a student fails to complete any portion of the course or fails to earn a C (70%) or better on the Research Manuscript, the student will receive an "F" grade for the course and will be brought before the Promotion Board. If the student is allowed to repeat the course, all components of the course must be repeated. In this case, the "F" grade remains the permanent grade for the initial course and the student will receive a new grade for the repeated course. The grade will be recorded in a manner that designates that it is a repeated rotation (e.g. R-pass).

No grade will be changed unless the Office of Clinical Affairs certifies to the Registrar, in writing, that an error occurred or that the remediation results in a grade change.

IX. Professionalism and Ethics

It is advised that students review and adhere to all behavioral policies including attendance, plagiarism, dress code, and other aspects of professionalism. Behavioral policies may be found in

the College Catalog and Student Handbook at: https://vcom.cld.bz/VCOM-College-Catalog-and-Student-Handbook/index.html

A. VCOM Honor Code

The VCOM Honor Code is based on the fundamental belief that every student is worthy of trust and that trusting a student is an integral component in making them worthy of trust. Consistent with honor code policy, by beginning this exam, I certify that I have neither given nor received any unauthorized assistance on this assignment, where "unauthorized assistance" is as defined by the Honor Code Committee. By beginning and submitting this exam, I am confirming adherence to the VCOM Honor Code. A full description of the VCOM Honor Code can be found in the *College Catalog and Student Handbook* at: http://www.vcom.edu/handbooks/catalog/index.html

X. Syllabus and Rotation Schedule

Please use this syllabus as a guide, paying particular attention to the requirements for each project.

The faculty of the course will make every effort to adhere to the syllabus and rotation schedule; however, the Office of Clinical Affairs reserves the right to make changes to the syllabus; including changes to examinations, quizzes, modules, homework or other assignments; and/or the schedule with as much advance notice as possible. These changes will be communicated to the students in writing via CANVAS or email.

XI. Curriculum

A. CITI Training: Protection of Human Research Subjects

Students must complete the Protection of Human Research Subjects CITI Training Course and submit their certificate of completion to CANVAS.

1. **Belmont Report and Its Principles**
   Online Module: Belmont Report and Its Principles
   Learning Objectives:
   i. Identify the three principles discussed in the Belmont Report.
   ii. Apply the principles to human subjects research.

2. **History and Ethics of Human Subjects Research**
   Online Module: History and Ethics of Human Subjects Research
   Learning Objectives:
   i. Discuss the historical basis for regulations governing human subjects research.
   ii. Identify the ethical principles underlying research involving human subjects.
   iii. Explain how the U.S. federal regulations are designed to implement those ethical principles and preserve the public trust.
   iv. Discuss the current regulatory environment for human subjects research.

3. **Basic Institutional Review Board (IRB) Regulations and Review Process**
   Online Module: Basic Institutional Review Board (IRB) Regulations and Review Process
   Learning Objectives:
   i. Describe the role, authority, and composition of the IRB.
   ii. List the IRB requirements for conducting research involving human subjects.
   iii. Describe the types of IRB review.
   iv. Describe the process of working with the IRB.
   v. Identify other regulations and regulatory groups that require compliance based on the type of research being conducted.

4. **Informed Consent**
   Online Module: Informed Consent
   Learning Objectives:
   i. Describe the requirements for complying with informed consent regulations.
   ii. Describe the process for obtaining informed consent.
   iii. Discuss when subjects may be vulnerable to undue influence or coercion.
   iv. Describe the regulations for waiving informed consent.

5. **Social and Behavioral Research (SBR) for Biomedical Researchers**
   Online Module: Social and Behavioral Research (SBR) for Biomedical Researchers
   Learning Objectives:
   i. Describe some of the areas of study where SBR techniques are used.
   ii. Discuss the types of data collection associated with SBR.
   iii. Identify the risks and benefits that are unique to SBR.

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. Recognize the current efforts by the FDA to ensure the inclusion of children in studies on the safety and efficacy of new drugs.

11. **Research Involving Pregnant Women, Fetuses, and Neonates**
    Online Module: Research Involving Pregnant Women, Fetuses, and Neonates
    Learning Objectives:
    i. Describe the types of research permitted with pregnant women, fetuses, and neonates under federal regulations.
    ii. Identify from whom consent is needed when conducting research with fetuses under 45 CFR 46, Subpart B.
    iii. Discuss the requirements under Subpart B for conducting research with neonates of uncertain viability.

12. **FDA-Regulated Research**
    Online Module: FDA-Regulated Research
    Learning Objectives:
    i. Recognize when an Investigational New Drug (IND) application is and is not necessary.
    ii. Describe the role of Form FDA 1572.
    iii. Define what constitutes a medical device.
    iv. Identify the responsibilities of sponsors and researchers as they relate to FDA-regulated research.

13. **Research and HIPAA Privacy Protections**
    Online Module: Research and HIPAA Privacy Protections
    Learning Objectives:
    i. Summarize HIPAA's additional privacy protections for individually identifiable health data that are used for human subjects research, including authorizations and accountings of disclosures.
    ii. Describe situations where full HIPAA privacy protections are required, and those which can qualify for waivers, alterations, or exemptions with more limited requirements.
    iii. Explain the responsibilities of researchers and organizations for meeting HIPAA's privacy requirements and for appropriate data security protections that are necessary to protect privacy.

14. **Conflicts of Interest in Human Subjects Research**
    Online Module: Conflicts of Interest in Human Subjects Research
    Learning Objectives:
    i. Define interests and relationships that may result in a conflict of interest.
    ii. Distinguish different types of COIs in research.
    iii. Identify federal regulations that govern disclosure and management of individual conflicts of interest.
    iv. Discuss challenges and strategies to manage individual and institutional COIs (ICOIs) in research.
    v. Recognize the ethical concerns associated with COIs in research.

15. **International Studies**
    Online Module: International Studies
    Learning Objectives:
    i. Describe ethical issues that may affect planning research outside the U.S.
    ii. Identify published international research ethics guidelines.
    iii. Describe specific ethical issues that have been raised in international research.
    iv. Describe U.S. government regulations for ethical review of international projects.
    v. Understand the responsibilities of researchers seeking ethical review in host countries.

16. **Avoiding Group Harms - U.S. Research Perspectives**
    Online Module: Avoiding Group Harms - U.S. Research Perspectives
    Learning Objectives:
        i. Discuss what is meant by the term "group" in research.
        ii. Describe how members of groups may be vulnerable in research.
        iii. Identify examples of research practices that have harmed groups.
        iv. Identify strategies that researchers can take to reduce the risk of group harms.

17. **Avoiding Group Harms – International Research Perspectives**
    Online Module: Avoiding Group Harms – International Research Perspectives
    Learning Objectives:
        i. Describe some distinct groups or communities of people who might be vulnerable to group harms.
        ii. Identify examples of research that have caused harm to groups.
        iii. Identify strategies that researchers can take to reduce the risk of group harms.

18. **Students in Research**
    Online Module: Students in Research
    Learning Objectives:
        i. Discuss the historical development of regulations associated with protecting human research subjects.
        ii. Identify considerations in defining what constitutes "human subjects research."
        iii. Describe standard categories of review regarding risks to subjects.
        iv. Review general IRB submission procedures for projects involving human research subjects.
        v. Discuss strategies for best practices in creating an accurate, robust submission and conducting responsible, ethical research.

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 handle 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
   VCOMTV: Occupational Exposure/Needle Stick
   Learning Objectives:
   i. Define universal precautions.
   ii. Recognize the types of PPE used for protection against exposure to bloodborne pathogens and when to select them.
   iii. Identify biomedical wastes and treatment and disposal protocols for the various waste types.

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, and 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-based 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 10-20 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. Identify the research team members who are subject to FCOI requirements.
   iv. Identify the significant financial interests (SFIs) that investigators must disclose to their institutions.
   v. Recognize the ongoing obligations that investigators have relating to FCOIs.

2. **Institutional Responsibilities as They Affect Investigators**
   Online Module: Institutional Responsibilities as They Affect Investigators
   Learning Objectives:
   i. Recognize that institutions receiving funding from the U.S. Public Health Service (PHS) agencies must require their investigators to disclose certain types of financial information.
   ii. Describe how institutions collaborating on research projects identify, review, and manage conflicts of interest (COIs).
   iii. Comprehend the expectations that institutions have as they review and evaluate their investigators' financial interest reports.
   iv. Explain the circumstances under which an investigator's significant financial interest (SFI) or institutional financial interest could affect the objectivity of research.
   v. Recognize why institutions must develop management strategies to address FCOIs.
   vi. Recognize that the U.S. Food and Drug Administration (FDA) requires the sponsor of research to collect and report investigators' financial interests.
   vii. Describe the public accessibility requirement in the PHS regulations.
   viii. Describe the circumstances under which an institution must develop and implement a mitigation report.

3. **VCOM Policy**
   Online Module: VCOM Policy
   Learning Objectives:
   i. Describe how investigators report financial conflicts of interest in research.
   ii. Discuss VCOM's procedures related to assessing and managing financial conflicts of interest in research.
   iii. Understand the reporting requirements of the investigator and VCOM.

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 or 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 ethical issues pertaining to human subjects research.
   ii. Identify the main U.S. regulations governing human subjects research.
   iii. Define the main ethical principles structuring how human subjects research should be conducted.
   iv. Describe the main components of the informed consent process.
   v. Describe the mandate, role, and responsibilities of an Institutional Review Board (IRB).

3. **Authorship**
   Online Module: Authorship
   Learning Objectives:
   i. Describe the primary criteria used to determine who should be listed as an author on a scholarly publication.
   ii. Describe the range of acceptable authorship practices, including different conventions used to determine the order of authors.
   iii. Discuss the circumstances under which an acknowledgment may be appropriate.
   iv. Describe the ethical responsibilities of an author.
   v. Discuss challenging and problematic authorship practices.

4. **Collaborative Research**
   Online Module: Collaborative Research
   Learning Objectives:
   i. Explain the importance of collaborative research and why it is increasingly common.
   ii. Discuss challenges associated with interdisciplinary research collaboration and ways to address them.

iii. Describe ethical and regulatory considerations in international collaborative research and in academic-industry partnerships.
iv. Identify regulations, policies, and ethical guidelines that affect collaborative research.
v. Describe practices for establishing and maintaining effective research collaborations.

5. **Conflicts of Interest and Commitment**
   Online Module: Conflicts of Interest and Commitment
   Learning Objectives:
   i. Define different types of conflicts of interest.
   ii. Define conflict of commitment.
   iii. Explain the reasons why conflicts of interest and commitment can be problematic.
   iv. Discuss U.S. regulations and policies relating to financial conflicts of interest.
   v. Describe strategies that may mitigate or eliminate the impact of conflicts of interest.

6. **Peer Review**
   Online Module: Peer Review
   Learning Objectives:
   i. Discuss the history and evolution of peer review.
   ii. Describe different types of peer review.
   iii. Discuss the value of peer review as it relates to publications and grant awards.
   iv. Identify ethical issues associated with peer review.
   v. Describe the ethical obligations of a peer reviewer.

7. **Research Misconduct**
   Online Module: Research Misconduct
   Learning Objectives:
   i. State how the U.S. federal government has defined research misconduct.
   ii. Differentiate among the three types of research misconduct: fabrication, falsification, and plagiarism.
   iii. Identify factors that can contribute to the occurrence of research misconduct.
   iv. Describe strategies that individuals and organizations might use to prevent or mitigate the occurrence of research misconduct.
   v. Describe how research misconduct allegations should be managed.

8. **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.

9. **Mentoring and Healthy Research Environments**
   Online Module: Mentoring and Healthy Research Environments
   Learning Objectives:
   i. Explain the roles and responsibilities of mentors and mentees.
   ii. Identify challenges that can disrupt or undermine a mentoring relationship.
   iii. Describe practices and strategies that support high-quality mentoring relationships and help prevent or manage conflicts between mentors and mentees.
   iv. Describe leadership behaviors that cultivate a psychologically healthy and supportive work environment.

10. **Plagiarism**
    Online Module: Plagiarism
    Learning Objectives:
    i. Recognize the parameters of plagiarism according to definitions developed by U.S. federal agencies.
    ii. Discuss basic principles of scholarship, such as the use of citations and quotations, as they relate to the issue of plagiarism.
    iii. Describe the distinction between summarizing and paraphrasing.
    iv. Recognize proper paraphrasing skills and use of citations.

C. Research Primer Modules

The modules in the Research Primer will instruct you on the basics of identifying a research idea/hypothesis, conducting background literature studies, conducting the research project, and reporting on the research outcomes. Concepts presented will help you establish a strong skills base in basic and clinical research. The modules are located on VCOMTV under the following pathway: VCOM-CC > Foundations of Clinical Medicine > Research Modules.

1. **Background Research and Literature**
   VCOMTV: Background Research and Literature
   Learning Objectives:
   i. Identify sources of scientific information.
   ii. Recognize features of a good journal and a good paper.

2. **Developing a Hypothesis**
   VCOMTV: Developing a Hypothesis
   Learning Objectives:
   i. Identify a novel and/or interesting idea.
   ii. Devise, clearly and concisely, a hypothesis and its significance.

3. **Developing Your Research Plan with Your Research Mentor**
   VCOMTV: Developing Your Research Plan with Your Research Mentor
   Learning Objectives:
   i. Define the differences between different types of studies.
   ii. Develop a plan for testing your hypothesis.

iii. Clearly formulate your research plan.
iv. Develop a research plan for your OMS 4 paper.

4. **How to Write a Scientific Manuscript**
   VCOMTV: How to Write a Scientific Manuscript
   Learning Objectives:
   i. Select for and evaluate example publications that you can use as models for your manuscript.
   ii. Categorize your information before you start writing.
   iii. Arrange your manuscript beginning with the title, abstract, figures and tables.
   iv. Extend your manuscript to include all important components, and then modify manuscript drafts through many iterations.

5. **Scientific Publishing**
   VCOMTV: Scientific Publishing
   Learning Objectives:
   i. Choose a target journal for your publication and identify predatory journals.
   ii. Distinguish and contrast among the various types of publications and how each differs in its content.

6. **How to Give an Effective Presentation**
   VCOMTV: How to Give an Effective Presentation
   Learning Objectives:
   i. Choose the various presentation types that are best for you and your science.
   ii. Discriminate good from bad presentations.
   iii. Develop high quality presentation materials, either as a projection or a poster.

7. **Scientific Meeting**
   VCOMTV: Scientific Meeting
   Learning Objectives:
   i. Recognize why to attend scientific conferences and who attends them.
   ii. Compare the difference between a conference, symposium, colloquium, and specialty conferences
   iii. Recall what to do before, during and after a conference.
   iv. Identify online tools to search for conferences and attendees.