PHAR: 6504
Mastering Reproducible Science

COVID-19 Protocols Remain in Place

Spring 2021
Credit Hours: 1

<table>
<thead>
<tr>
<th>Meeting Type</th>
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<tr>
<td>Presentation and Discussion Sessions</td>
<td>Online</td>
<td>Tuesday</td>
<td>5:00pm-5:50pm</td>
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</tbody>
</table>

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We, Professors Roman and Nuxoll, would like to hear from anyone who has a disability that might require some modification of the seating, testing, or other class requirements. Please notify Professor Roman during the first week of class so that we may work with the Office of Student Disability Services to make appropriate arrangements. The Office of Student Disability Services is located in 3100 Burge Hall and the phone number is 335-1462.
**Course Instructors:**

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Course Description

This course focuses on the concepts and tools behind conducting modern scientific inquiries in a rigorous and reproducible manner. Reproducible research is founded on the ideal that fundamental experimental design, disclosure, methods, data analyses, and more generally, scientific claims, are published in a manner that is not only reproducible by others in the field, but that the scientific inquiry itself is conducted in a rigorous manner so that the data generated, and the interpretation of that data strongly supports the conclusions presented. The need for reproducibility is increasing dramatically as modes and methods of experimentation and data analysis become more complex, involving more specialized techniques that may not have widespread expertise. Scientific rigor and reproducibility have major implications for the credibility of science we conduct in our laboratories. It is important to be aware that the majority of issues regarding rigor and reproducibility do not stem from unethical, intentional, or deliberate nefarious motivations, but rather from an absence or insufficiently high standards for good practices in experimental planning, execution, and data analysis. This course will focus on the planning, design, execution, interpretation and reporting of scientific studies in a rigorous and reproducible manner.

This course will address a number of issues, presented by experts in a given area, through lecture and discussion sessions. An example of topics that will be covered, such as: variability of materials, composition and validation of reagents; use of organisms and cells in culture, which can change over time or have insufficient provenance, lack of adequate controls, and interpretation of data issues such as confirmation bias. We will also explore how biomedical data, particularly large data sets related to genetics, genomics, and high throughput screening are curated and processed, as well as measures implementing quality controls during data analysis. Specific topics that will be covered include: Transparency, defining and using biological and technical replicates, self-assessment of rigor and evolution of practices of rigor and reproducibility, cell lines: reproducibility, authentication, provenance and replicates, Analytical methods to enhance rigor & reproducibility – HPLC, mass spectrometry, Assessing structural models (NMR, crystallography and CryoEM), Target validation and reproducibility with antibody-mediated labeling and detection (WB, ELISA, IHC, IF), reproducibility, data curation and analysis in high throughput screening – large datasets, statistical methods for testing in silico docking, modeling, and screening/structure methods, Modern methods to ensure Rigor and Reproducibility in Genetics and Genomics, addressing rigor and reproducibility in clinical studies, considerations for rigor and reproducibility in animal studies (mice), assessing chemical identity and purity, experimental design: sample size, outliers, and exclusion criteria, and additional resources for rigorous experimental design.

Methods of Instruction

Class meetings will be held via Zoom Tuesdays from 5:00-5:50pm. Course instructors will provide reading materials for class, and will communicate any pre-reading material before the course meeting. The course will be active, guided discussion, not merely passive lectures.
**Instruction Materials**

In addition to the materials provided by individual instructors, please reference the following materials which are available through the ICON website.

- Fostering Integrity in Research (2017), National Academies Press

**Personal Recordings of Lectures**

Students must request permission from the instructor prior to creating a personal lecture recording. Permission should be sought in advance of the lecture. In cases where personal recordings are allowed, these recordings may only be used for private study - they are not to be distributed.

**Class Schedule and Lecture Description**

All class meetings will occur through ZOOM or the online meeting platform of the instructor’s choice. Meeting details will be posted on the ICON course website.

**All Class meetings are Tuesday at 5:00-5:50PM**

January 26 – Introduction to the Course, and Transparency Module (D. Roman)

February 2 – Rigorous Experimental Design: Biological and Technical Replicates (D. Quelle)

February 9 – Self-assessment of rigor, evolution of practices of rigor and reproducibility (K. Rice)

February 16 - Cell Lines - Reproducibility, Authentication, and Replicates (J. Fiegel)

February 23 – Designing a Reproducible Experimental Study using Analytical methods in biological experiments – HPLC, mass spectrometry (J. Doorn)

March 9 - Assessing structural models (NMR, crystallography and CryoEM) (E. Fuentes)

March 16 - Target validation and reproducibility with antibody-mediated labeling and detection (WB, ELISA, IHC, IF, etc) (E. Anderson)

March 23 - Reproducibility in high throughput screening - in vitro plate-based approaches (M. Wu)

March 30 - Stress Testing Structure Based Drug Discovery Methods- statistical methods for testing in silico docking and screening/structure methods (A. Spies)

April 6 - Modern methods to ensure Rigor and Reproducibility in Genetics and Genomics (M. Gaine)
April 13, 2021 - Aspects of Rigor and Reproducibility in the Clinical Sciences (N. Brogden)

April 20, 2021 - Rigor and reproducibility in experimental approaches using mice (M. Anderson)

April 27, 2021 - Chemical Identity and Chemical Purity: How do you know the identity and purity of compounds you use in experiments (R. Kerns)

May 4, 2021 – Part I. Resources for Rigorous Experimental Design Part II. Sample Size, Outliers, and Exclusion Criteria (D. Roman)

**Evaluation of Student Performance**

This course is graded on a Pass/Non-Pass Basis. Your grade is determined by three components:

1. Class Attendance
2. Active Class Participation
3. Completion of Instructor Assignments
4. Completion of End Of Course Whitepaper/Report

**Expectations and Course Policies**

**Expectations for attendance and participation**

**Students are expected to attend all course meetings.**

**Course Communication Expectations:**

E-mail is an official communication mechanism at the University of Iowa. All students are required to maintain an official University of Iowa email address.

We will answer any e-mails with questions, comments, or concerns as soon as possible.

In case the instructor needs to make a general announcement outside of normal lecture times, this course will utilize the established class mailing list. It is the student’s responsibility to ensure that their current e-mail is included on that list. For general information and course announcements, please check the course ICON home page regularly.

**Electronic Communication Expectations**

Please keep in mind that all electronic interactions (e-mail, chats, discussion forums, etc.) are an extension of our classroom and should be treated as such. That is, expectations for classroom civility are the same for web-based courses as they are for traditional classroom activities.

**Late or missed assignments:**

A penalty may be used for late assignments as prescribed by the instructor. Missed assignments will receive no points for credit.
Absences:
Students are expected to observe a policy of consistent, timely attendance. It is the student’s obligation to notify the instructor promptly of any absences. Students may be asked to provide documentation to verify reasons for absence using the “Explanatory Statement for Absence from Class” form from the Office of the Registrar (http://registrar.uiowa.edu/absence-class). It is the student’s responsibility to notify the course coordinator if s/he will be absent from class or miss a scheduled examination for any reason. It is also the student’s obligation to contact the instructor in order to make up any work which may have been missed during the absence. The course coordinator is responsible for deciding whether to excuse an absence and/or allow make up of assignments, quizzes, and/or examinations. If the student is unable to reach the instructor or the course coordinator, or the student will be likely to miss a number of classes, the Office of Academic Affairs may be contacted and they will relay a message from a student to the coordinator. Students must still contact the coordinator directly when they are able.

What to do in case of illness:
Please contact the course coordinator or individual instructors if an illness has affected your ability to attend lectures.

Classroom civility:

Any student whose behavior during lecture is distractive OR destructive to the learning environment will be asked to leave.

Learning and the exchange of ideas may take place in many settings, including the formal classroom. When students and faculty come together, the expectation is always that mutual respect and civility will prevail to ensure that every student has the optimum opportunity to learn and that each faculty member has the best opportunity to teach. Disruptions of any kind affect the atmosphere of civility that is expected and interfere with the opportunity for learning and growth to which both faculty and students are entitled.

Differences of opinions or concerns related to the class should be welcomed if presented in a mutually respectful manner. The challenging of viewpoints is part of the academic experience, but should occur in a manner that opens up dialogue and does not threaten any member of the learning community.

Student behavior or speech that disrupts the instructional setting or is clearly disrespectful of the instructor or fellow students will not be tolerated. Disruptive conduct may include, but is not limited to:
1. Rude or disrespectful behavior
2. Unwarranted interruptions
3. Failure to adhere to instructor’s directions
4. Vulgar or obscene language, slurs or other forms of intimidation
5. Physically or verbally abusive behavior

Academic Honesty
Students are subject to the Code of Conduct. Violations of the Code of Conduct will result in consequences, including an F-grade for the course, disciplinary probation or recommendation for expulsion.
Code of Conduct Highlights

There will be no differences in the treatment of persons because of race, creed, color, national origin, age, sex, disability, sexual orientation, gender identity, or any other classification that deprives the person of consideration as an individual.

Educational Environment Civility:
Any student who demonstrates a pattern of blatant disregard for the Standards of Professional Decorum is in violation of the Code of Conduct.

Sexual Harassment:
Sexual harassment and unwelcome sexual behavior is especially serious when it threatens relationships between teacher and student or supervisor and subordinate. If you believe you are the victim of discrimination or sexual harassment or unwelcome sexual behavior, please visit one of the websites below for information about how to get help:

- http://www.uiowa.edu/~eod/policies/index.html
- http://www.sexualharassment.uiowa.edu/
- http://www.uiowa.edu/~ombud/

Depending on the circumstances, additional College of Pharmacy or University of Iowa policies may apply. These policies are available on the web, and students are responsible for being familiar with them.

- College of Pharmacy Doctor of Pharmacy program policies
- The University of Iowa Policies and Regulations Affecting Students

Sexual Misconduct/Sexual Harassment and Class Accommodations

The University of Iowa prohibits sexual misconduct, dating/domestic violence, and stalking in any form, including sexual assault or sexual harassment, and any form of nonconsensual sexual conduct. Students should be able to live, study, and work in an environment free from all forms of sexual misconduct, dating/domestic violence, and stalking.

Incidents of sexual misconduct can be reported to the Office of Sexual Misconduct Response Coordinator (OSMRC) or to the Department of Public Safety. If you are uncertain if what you have experienced from a student is sexual misconduct, view the Sexual Misconduct, Dating/Domestic Violence, or Stalking Involving Students policy. If you are uncertain if what you experienced from a faculty or staff member is sexual harassment, view the Sexual Harassment policy.

Students impacted by a Title IX issue (sexual misconduct, dating/domestic violence, or stalking) may be eligible to request an academic accommodation. Contact the Office
of Sexual Misconduct Response Coordinator for assistance, definitions, and the full University of Iowa policy.

If you or someone you know experiences sexual assault, sexual harassment, dating/domestic violence, stalking, or any other behaviors prohibited under this policy, you are strongly encouraged to seek assistance and support. Information about confidential resources (see the Confidential Resources: Where to Start video for an explanation) can be found here, Confidential Resources for Students.

Problems or Disputes

If a problem or dispute arises in connection with faculty actions in this course, you should take the following actions in order:

1. Contact the faculty member and attempt to resolve the issue directly.
2. If your complaint is still not resolved, contact the course coordinator, if applicable.*
3. If your complaint is still not resolved, you may contact the appropriate Department Chair.
4. If your complaint is still not resolved, you may contact the Associate Dean for Academic Affairs.
5. If your complaint is still not resolved, you may contact the Dean of the College of Pharmacy.

*If your complaint concerns accommodation for a disability and it is not resolved after contacting the course coordinator, you should then contact the Associate Dean for Academic Affairs.

Federal Credit Hour Definition: A credit hour is an amount of work represented in intended learning outcomes and verified by evidence of student achievement that is an institutionally-established equivalency that reasonably approximates not less than: (1) one hour of classroom or direct faculty instruction and a minimum of two hours of out-of-class student work each week for approximately fifteen weeks for one semester or trimester hour of credit, or ten to twelve weeks for one quarter hour of credit, or the equivalent amount of work over a different amount of time; or (2) at least an equivalent amount of work as required in paragraph (1) of this definition for other activities as established by an institution, including laboratory work, internships, practica, studio work, and other academic work leading toward the award of credit hours.