

Ensure Students Are Learning: Faculty Descriptions of Innovative Teaching Practices

Learning Every Facet of Clinical Research Trials

Innovative Teaching Practice Description:

The mock clinical trial is a research project that takes place over two semesters (the clinical research class has two parts). During the spring semester, students select a specific disease or condition to study, propose an intervention, and design a research project to carry out in the fall semester. Since this is a mock trial, students go through all of the steps of the trial, but they do not use real patients or real medications.

In the spring semester, students work on developing their mock trial by moving through four graded assignments: 1) an outline of the disease or illness and a rationale for their choice; 2) a paper describing their proposed intervention; 3) a description of their research design and chosen methodology; and 4) an outline of the clinical trial itself, including a timeline and milestones. Each phase of the process requires students to engage in research and submit a corresponding written assignment.

During the fall semester, students carry out their mock clinical trial. This particular course is a hybrid course—50% of the course is online and the other half is face-to-face. The online portion of the course consists of online modules completed outside of class time that cover topics such as confidentiality, recruitment, funding, budget management, and more. In addition to carrying out the mock clinical trial, students must demonstrate mastery across three areas:

1) informed consent, 2) seeing and communicating with patients, and 3) data management. For informed consent, students submit a copy of the documents they will use and a paper outlining how they provide information to patients, how they ensure patient understanding, and how they maintain documentation. The mock trial is then carried out by dividing the class into two groups where one group serves as the patients and the others as the researchers. Halfway through the class, students reverse roles so that each student has an opportunity to engage in their trial. As they are going through this process, the instructor observes each student to assess whether they are communicating with patients effectively by keeping them informed of each step, and collecting data such as symptoms, vital signs, and pain levels. Students must also provide written proof of their documentation process by presenting mock files to the instructor. As part of the clinical trial, students also learn about and demonstrate mastery of data management by entering their data into REDCAP (Research Electronic Data Capture), a web-based data management system offered to educational partners at a lower cost. Students will practice analyzing data in a subsequent course, but for the purposes of this course, they only need to demonstrate that they can use the system to collect and manage their data.

The trial concludes with a portfolio that is submitted to the professor for grading. The portfolio is both written and electronic. The written portion consists

of charts and notes, while the electronic portfolio contains all of the trial documents, progress reports, and a tabulation of their data.

Although students do not go through the IRB process, guest speakers are invited to class at the beginning of the semester to provide students with information about the process and demonstrate what the process looks like. Students complete a questionnaire that addresses many of the items covered in an IRB application.

How to Ensure Participation in This Innovative Teaching Practice:

The course is entirely hands on, requiring students to serve as patients and researchers, so participation is a central component of the course. The fact that the instructor maintains a hands-on approach and observes each person when they are engaging with their patients further encourages participation.