

Phase I Non-Clinical Elective Description

Campus: Northeast (GF)

Elective Title: Introduction to Clinical Trials

Location of Elective: Online

Preceptor(s): Ashley Snyder

Period(s) Offered: Summer II

Number of students per period: Unlimited

Department: Population Health

Course Number: PH 9601

Course Prerequisites: None

Curriculum Phase: 1

Elective Length in weeks: 4

Estimated # of Hours Required per Week: 40 Hours

Will any Face-to-Face/Zoom hours occur on Weekends? Yes _____ No X

Will any Face-to-Face/Zoom hours occur on after 5pm? Yes _____ No X

Purpose: This course provides an introduction to clinical trials, including types of clinical trials, basic set-up of clinical trials, and examples of FDA documents and regulations regarding the conduct of clinical trials. Clinical trials provide necessary evidence for drug, procedure, and other treatment development and FDA approval.

Objectives: Following successful completion of this elective, the student will be able to:

1. Summarize several types of clinical trials (Competency 1.1, 1.3)
2. List the steps required for basic study set up for clinical trials and other clinical research (Competency 1.1, 1.3)
3. Identify resources on institutional policies and government laws related to conducting clinical trials (competency 5.9)
4. Summarize the importance of conducting ethical and safe clinical trials for medically underserved populations (competency 1.9, 2.8, 5.5)
5. State the critical importance of evidence in advancing public health knowledge (competency 1.8, 2.8)
6. Classify quantitative and qualitative data collection methods appropriate for a given public health context (Competency 1.8, 1.9)
7. Demonstrate the ability to analyze quantitative and qualitative data using biostatistics, informatics, computer-based programming, and software, as appropriate (Competency 1.9)
8. Generate interpretation of results of data analysis for public health research, policy, or practice (Competency 1.9, 2.8)
9. Define communication strategies for different audiences and sectors (Competency 4.1, 4.2)

Instructional Activities: During this elective, the student will be involved in/experience:

1. Online asynchronous lectures; topics include:

- Types of Clinical Trials
- Participant Selection and Randomization
- Blinded Studies
- Types of Data and Organizing Data Collection
- Ethical Issues
- Overview of Statistics for Clinical Trials
- Quality Control
- Patient-Reported Outcome Measures
- Grants and Budgeting
- FDA Regulations
- International Regulations
- Multicenter Trials and Clinical Trial Networks
- Limitations and Reporting Results
- Options for Collaboration to Produce Clinical Trials
- Putting It All Together—Examples of Trials from Start to Finish
- *The Cure*, and Further Considerations About Why We Do Clinical Trials

2. Four online asynchronous exams

- Each worth 25 points (25% of the grade)
- Multiple-choice questions
- Unlimited time to complete exams as long as they are completed by the deadlines

3. Textbook readings from three books

- Geeta Anand. *The Cure: How a Father Raised \$100 Million--and Bucked the Medical Establishment--in a Quest to Save His Children*. William Morrow; 2006. ISBN-13: 978-0-06-073439-8
- Allan Hackshaw. *A Concise Guide to Clinical Trials*. 2nd ed. Wiley Blackwell; 2024. ISBN: 9781119502807
- Joseph P. Stalder. *Project Management for Drug Developers*. CRC Press; 2023. ISBN: 978-1-032-12920-4

Grading for this elective is Satisfactory/Unsatisfactory. A Satisfactory grade will be 80% or higher on exams cumulatively (so 80 or more points out of 100 total for the course).

Criteria for Grading: During and following this elective, the preceptor will:

1. Utilize the standardized UNDSMHS phase I elective evaluation form.
2. By direct review of performance on the asynchronous exams evaluate the student's knowledge related to the objectives for the course (Objectives 1-9)