Clinical Trials

Certificate Program in Clinical Trials

NOTE: This certificate program may be completed entirely online!

OVERVIEW

Clinical Trials are a key tool in the evaluation of new strategies for prevention and treatment of disease. This certificate program focuses primarily on the design and analysis of randomized clinical trials for evaluation of licensed and non-licensed medical products and other health interventions, the regulatory framework for the conduct and evaluation of data from clinical trials, and ethical principles for the conduct of clinical trials.

EDUCATIONAL OBJECTIVES

After completing the certificate, students will be able to:

1. Summarize the history of clinical trials and describe the role they play in evaluation of health interventions;
2. Explain the key differences, advantages and disadvantages of experimental versus observational study designs;
3. Develop a protocol, consent statement, monitoring plan and data collection plan for a clinical trial;
4. Review and critique manuscripts presenting the results of clinical trials using CONSORT guidelines; and
5. Explain the key ethical principles regarding the design, conduct and analysis of clinical trials

SPONSORING DEPARTMENT

Epidemiology (https://www.jhsph.edu/departments/epidemiology/)

CONTACT INFORMATION

Certificate Program Contact
Sheila Small
ssmall2@jhu.edu

Faculty Sponsor
Janet Holbrook (https://www.jhsph.edu/faculty/directory/profile/922/janet-holbrook/)

ELIGIBILITY

The certificate program is open to graduate students currently enrolled in any division of the Johns Hopkins University, with the exception of MAS students, who are not eligible to apply until they have completed their primary degree program. It is open to individuals who are not enrolled in degree programs at JHU.

ADMISSIONS PROCESS

All applicants must review the General Certificate Guidelines page (http://e-catalog.jhu.edu/public-health/certificates/#newitemtext), which provides important information about how to apply to a certificate program.

APPLYING TO THE CERTIFICATE PROGRAM AS A JHU GRADUATE STUDENT

Applicants must submit a letter of interest, CV/resumé, and anticipated course schedule (http://e-catalog.jhu.edu/public-health/certificates/clinical-trials/)

AnticipatedCourseScheduleforCompletionofCertificateProgram_Coursework_6517_.pdf

Program Contact (ssmall2@jhu.edu) prior to starting coursework. Because of the requirement to work with a faculty mentor to complete the program, only a limited number of students will be accepted.

Start term: It is possible to begin the certificate program only in term 1.

APPLYING TO THE CERTIFICATE PROGRAM AS A NON-DEGREE STUDENT

Students who are not currently enrolled in a graduate program at JHU are required to apply to certificate programs using SOPHAS Express (https://sophasexpress.liaisoncas.com/applicant-ux/#/login). All non-degree applicants should review the general Certificates Admissions (http://e-catalog.jhu.edu/public-health/certificates/#newitemtext) page for instructions on how to apply to a certificate program and application deadlines.

Start terms: It is possible to begin the certificate program only in terms 2, 3, and the Summer Institutes

TOEFL/IELTS: Required.

Prerequisites or special requirements: None

REQUIREMENTS FOR SUCCESSFUL COMPLETION

The certificate program requires at least 18 credit units that consist of core courses in clinical trials, epidemiology, and research ethics, as well as elective courses focusing on specific issues in the design, conduct and analysis of clinical trials. The required courses in clinical trials include introductory courses in epidemiology, clinical trials design and interpretation and clinical trials methodology. Students are also required to take at least 2 additional courses relating to clinical trials and 1 course in research ethics.

Each student will be required to develop a protocol and plan for obtaining consent, e.g., prototype statement, for a randomized clinical trial. The protocol will be 8 to 12 pages long and accompanied by consent statement(s) or other materials appropriate for obtaining consent for the proposed trial. Most students should be able to complete this requirement as part of class project, e.g., 340.648 or 340.861. Alternatively, the student may sign up for 1 to 2 credits of independent study for this project with a mentor. The credits for an independent study to work on the protocol can be counted towards the 18 credits required for the certificate program.

Students are strongly encouraged to participate in the seminars, research in progress meetings, journal club and other activities sponsored by the Center for Clinical Trials.

All required and elective courses must be taken for a letter grade; a minimum grade of C is required in all certificate coursework and students must maintain a 2.75 or better overall GPA for all certificate coursework. The certificate program length is flexible; it varies from student to student, however, the program must be completed within three years.

The student should review the section of the website that addresses completion (http://e-catalog.jhu.edu/public-health/certificates/#courserequirementstext) before completing certificate program requirements. The student’s transcript will not indicate that the certificate was earned until the Notification of Completion has been
submitted, verified by the certificate program, and processed by the Registrar.

**COURSE OF STUDY**

Students should check the JHSPH course directory (https://www.jhsph.edu/courses/) to confirm when the courses are offered. Students should also check for prerequisites and whether instructor consent is required.

<table>
<thead>
<tr>
<th>Code</th>
<th>Title</th>
<th>Credits</th>
</tr>
</thead>
<tbody>
<tr>
<td>PH.550.860</td>
<td>Academic &amp; Research Ethics at JHSPH (All students are required to complete this noncredit course in their first term of study)</td>
<td></td>
</tr>
</tbody>
</table>

Core Clinical Trials Coursework: Students must complete 3 required courses: (340.601 or 340.721), 340.645, and (340.633 OR 340.861), and 340.694

Complete either 340.601 OR 340.721

<table>
<thead>
<tr>
<th>Code</th>
<th>Title</th>
<th>Credits</th>
</tr>
</thead>
<tbody>
<tr>
<td>PH.340.601</td>
<td>Principles of Epidemiology</td>
<td>5</td>
</tr>
<tr>
<td>PH.340.721</td>
<td>Epidemiologic Inference in Public Health I</td>
<td>5</td>
</tr>
</tbody>
</table>

Students must complete the following 2 courses

<table>
<thead>
<tr>
<th>Code</th>
<th>Title</th>
<th>Credits</th>
</tr>
</thead>
<tbody>
<tr>
<td>PH.340.645</td>
<td>Introduction to Clinical Trials</td>
<td>3</td>
</tr>
<tr>
<td>PH.340.694</td>
<td>Power and Sample Size for the Design of Epidemiological Studies</td>
<td>1</td>
</tr>
</tbody>
</table>

Students must complete all courses in either Sequence A or Sequence B

**Sequence A**

<table>
<thead>
<tr>
<th>Code</th>
<th>Title</th>
<th>Credits</th>
</tr>
</thead>
<tbody>
<tr>
<td>PH.340.861</td>
<td>Clinical Trials: Procedures, Design, and Interpretation of Results</td>
<td>3</td>
</tr>
</tbody>
</table>

**Sequence B**

<table>
<thead>
<tr>
<th>Code</th>
<th>Title</th>
<th>Credits</th>
</tr>
</thead>
<tbody>
<tr>
<td>PH.340.633</td>
<td>Data Management in Clinical Trials</td>
<td>3</td>
</tr>
<tr>
<td>PH.340.648</td>
<td>Clinical Trials Management</td>
<td>3</td>
</tr>
</tbody>
</table>

Students must complete one of the following Ethics courses

<table>
<thead>
<tr>
<th>Code</th>
<th>Title</th>
<th>Credits</th>
</tr>
</thead>
<tbody>
<tr>
<td>PH.390.673</td>
<td>Ethical and Regulatory Issues in Clinical Research</td>
<td>3</td>
</tr>
<tr>
<td>PH.550.600</td>
<td>Living Science Ethics - Responsible Conduct of Research</td>
<td>1</td>
</tr>
<tr>
<td>PH.700.621</td>
<td>Ethics in Clinical Practice: Fundamentals, Problems and Approaches</td>
<td>3</td>
</tr>
</tbody>
</table>

Students must complete 2 other Clinical Trials Courses

<table>
<thead>
<tr>
<th>Code</th>
<th>Title</th>
<th>Credits</th>
</tr>
</thead>
<tbody>
<tr>
<td>PH.140.611</td>
<td>Statistical Reasoning in Public Health I</td>
<td>3</td>
</tr>
<tr>
<td>PH.140.633</td>
<td>Biostatistics in Medical Product Regulation</td>
<td>2</td>
</tr>
<tr>
<td>PH.140.642</td>
<td>Design of Clinical Experiments</td>
<td>3</td>
</tr>
<tr>
<td>PH.223.662</td>
<td>Vaccine Development and Application</td>
<td>4</td>
</tr>
<tr>
<td>PH.223.664</td>
<td>Design and Conduct of Community Trials</td>
<td>4</td>
</tr>
<tr>
<td>PH.223.672</td>
<td>Data Mgmt Methods in Health Research Studies</td>
<td>5</td>
</tr>
<tr>
<td>PH.223.690</td>
<td>The Design and Analysis of Cluster Randomized Trials</td>
<td>2</td>
</tr>
<tr>
<td>PH.223.705</td>
<td>Good Clinical Practice: A Vaccine Trials Perspective</td>
<td>4</td>
</tr>
<tr>
<td>PH.340.606</td>
<td>Methods for Conducting Systematic Reviews and Meta-Analyses</td>
<td>4</td>
</tr>
<tr>
<td>PH.340.616</td>
<td>Epidemiology of Aging</td>
<td>3</td>
</tr>
<tr>
<td>PH.340.660</td>
<td>Practical Skills in Conducting Research in Clinical Epidemiology and Investigation</td>
<td>3</td>
</tr>
<tr>
<td>PH.340.676</td>
<td>Bayesian Adaptive Trials</td>
<td>2</td>
</tr>
<tr>
<td>PH.340.682</td>
<td>Pharmacoepidemiology Methods</td>
<td>3</td>
</tr>
</tbody>
</table>

PH.340.686 | Introduction to Systematic Reviews and Meta-Analysis          | 2       |

PH.340.840 | Special Studies and Research Epidemiology (Note: Students interested in pursuing this option should contact a faculty member before registering) | 1 - 22 |

PH.390.631 | Principles of Drug Development                                 | 2       |

PH.390.750 | Introduction to Clinical Research                              | 2       |

One of the following courses, but not both, may be counted towards the certificate program

<table>
<thead>
<tr>
<th>Code</th>
<th>Title</th>
<th>Credits</th>
</tr>
</thead>
<tbody>
<tr>
<td>AS.410.649</td>
<td>Introduction to Regulatory Affairs</td>
<td>4</td>
</tr>
<tr>
<td>AS.410.676</td>
<td>Food And Drug Law</td>
<td>4</td>
</tr>
</tbody>
</table>

One of the following courses, but not both, may be counted towards the certificate program

<table>
<thead>
<tr>
<th>Code</th>
<th>Title</th>
<th>Credits</th>
</tr>
</thead>
<tbody>
<tr>
<td>AS.410.649</td>
<td>Introduction to Regulatory Affairs</td>
<td>4</td>
</tr>
<tr>
<td>AS.410.676</td>
<td>Food And Drug Law</td>
<td>4</td>
</tr>
</tbody>
</table>