## Graded Coursework (24 credits)

<table>
<thead>
<tr>
<th>Statistics</th>
<th>Core Methods</th>
<th>Translational Methods</th>
<th>Management &amp; Responsible Conduct</th>
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<tbody>
<tr>
<td>Introduction to Statistical Methods</td>
<td>Principles of Clinical Research</td>
<td>Introduction to Medical Genetics</td>
<td>Research Ethics and the Responsible Conduct of Research</td>
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<tr>
<td>Statistical Analysis</td>
<td>Decision Sciences in Clinical Research</td>
<td>Proteomics and Protein Biology in Medicine</td>
<td>Research Management</td>
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<tr>
<td>Clinical Trials</td>
<td>Health Services Research</td>
<td>Introduction to Immunology in Clinical Research</td>
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<tr>
<td>Systematic Reviews and Meta Analysis</td>
<td>Clinical Research Seminar</td>
<td>Molecular Biology Techniques</td>
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<td>Longitudinal Data Analysis</td>
<td>Patient-Reported Outcomes in Clinical Research</td>
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<tr>
<td>R Programming Boot Camp</td>
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<td>Concepts in Comparative Effectiveness Research</td>
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<td></td>
<td>Implementation and Dissemination of Health Care Research</td>
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## Research Project (12 credits)

**Degree Program: 36 credits total**

*(Two-year minimum to complete the program)*

## Year One

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<th>Fall</th>
<th>Spring</th>
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<td>Research Management</td>
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## Year Two

<table>
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<tr>
<th>Fall</th>
<th>Spring</th>
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<tr>
<td>Electives</td>
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CRP-263 Longitudinal Data Analysis.
The course covers the design, analysis and interpretation of two types of study designs, those that involve questions about systematic change over time and those that involve questions about whether and when events occur. **Credit: 2.**

CRP-264 Introduction to Immunology in Clinical Research.
An introduction to basic concepts of immunology, clinical assessment of immune function, and the fundamental importance of immune mechanisms in human disease are covered. **Credit: 2.**

CRP-265 Molecular Biology Techniques.
Through lectures and hands-on laboratory experiments students are introduced to methods required to perform basic molecular biology techniques. **Credit: 2.**

CRP-266 Concepts in Comparative Effectiveness Research.
Students develop research skills and competencies related to understanding, conducting and interpreting comparative effectiveness research (CER) as applied to existing data sets. **Credit: 2.**

CRP-271 Patient-Reported Outcomes in Clinical Research.
This course provides students with the knowledge necessary to incorporate patient-reported outcomes into observational studies and clinical trials. **Credit: 2.**

CRP-272 R Programming Boot Camp.
This course is an introduction to the use of R and RStudio for data management to enable the student to restructure, clean and otherwise prepare data sets for subsequent analysis. **Credit: 1.**

CRP-273 Implementation and Dissemination of Health Care Research.
This course presents an overview of methods for research and program evaluation within health services organizations and systems, and is recommended for students who will be carrying out policy research, social science research or program impact evaluation within health delivery systems as well as developing and implementing programs to improve health care outcomes. **Credit: 2.**
The Curriculum

Required Degree Courses

CRP-241 Introduction to Statistical Methods.
Fundamental statistical concepts and their use in clinical research. Students are introduced to core concepts and perform basic statistical computations and introductory data analysis using R. Credit: 4.

CRP-242 Principles of Clinical Research.
This course emphasizes general principles and issues in clinical research design, providing a basis for understanding the classification of studies as experimental or observational, prospective or retrospective, case-control, cross-sectional or cohort. Credit: 4.

CRP-245 Statistical Analysis.
This course extends CRP-241 and primarily considers the types of single and multi-predictor statistical models most frequently encountered in clinical research. Credit: 4.

CRP-253 Research Ethics and Responsible Conduct of Research.
This course explores a variety of ethical and related issues that arise in the conduct of medical research and is designed to meet and exceed the NIH requirement for training in Responsible Conduct of Research. Credit: 2.

CRP-254 Research Management.
This course addresses operational issues that arise in the conduct of a clinical research project including administration, data management systems, regulation, good clinical practice [GCP], the Health Insurance Portability and Accountability Act [HIPAA], and sponsorship. Credit: 2.

CRP-270 Research.
An individualized research project under the direction and supervision of the student’s mentor and examining committee forms the basis for this culmination of the program of study leading to the degree. Credit: 12.

Electives

CRP-243 Introduction to Medical Genetics.
Fundamental concepts of human genetics and genetic systems of the mouse and other model organisms. Credit: 2.

CRP-247 Clinical Research Seminar.
This seminar builds on the core courses to provide experience in the development and critique of the methodological aspects of clinical research literature and protocols. Credit: 2.

CRP-248 Clinical Trials.
Fundamental concepts in the design and analysis of clinical trials are examined. Credit: 2.

CRP-249 Health Services Research.
Research methods in health services research are explored. Credit: 2.

CRP-257 Proteomics and Protein Biology in Medicine.
Platform technologies and computational methodologies for protein profiling and interaction analysis are introduced. Credit: 2.

CRP-259 Decision Sciences in Clinical Research.
This course focuses on basic modeling techniques, with an emphasis on decision analysis and cost-effectiveness analysis and the application of these techniques to the student’s own research. Credit: 2.

CRP-262 Systematic Reviews and Meta Analysis.
This course provides a practical foundation for systematic reviews involving quantitative synthesis (quantitative meta analysis). Credit: 2.

"The program definitely improved my ability to create high-quality research proposals, conduct my own research, create a better understanding of the ethics of research and good clinical practice, and to be a critical consumer."

– Yousuf Zafar, MD, MHS
Associate Professor of Medicine
Duke University School of Medicine
MASTER OF HEALTH SCIENCES IN CLINICAL RESEARCH

The Clinical Research Training Program provides clinicians with didactic and practical training in the quantitative and methodological principles of clinical research. Designed primarily for fellows training for academic careers, the program gives students the opportunity to integrate academic training with their clinical training.

Degree Option
Designed for part-time study, the program can be completed in two years and leads to the Master of Health Sciences (MHS) in Clinical Research Degree awarded by the Duke University School of Medicine. Candidates must fulfill the following requirements:

- 24 credits of graded course work plus a research project, which accounts for 12 credits. Courses are taught both on-site and via live video from dedicated remote class sites.
- Five required courses (CRP 241, 242, 245, 253, and 254), constituting a total of 16 credits (see Course Descriptions).
- A clinical research project conducted with human subjects that serves to demonstrate the student’s ability to apply the quantitative and methodological principles of clinical research contained in the curriculum.

Non-Degree Option
Courses in the program are available to qualified individuals seeking to acquire specific skills without pursuing the master's degree. In addition to clinical fellows, such individuals include medical students, faculty members, postdoctoral fellows, and other health professionals seeking to hone their knowledge in specific areas.

Admission
All qualified persons wishing to take courses, even on a non-degree basis, must be formally admitted into the program. Requirements include:

- An advanced degree in a clinical health science (or two years of medical school) from an accredited institution.
- A complete application form and the following supporting documents: 1) a current CV; 2) one letter of evaluation written by a person qualified to testify to the applicant’s capacity for graduate work; and 3) an official transcript from the graduate and or medical school attended (degree candidates only).
- The CRTP application must be completed and submitted online.

Costs & Financing
Tuition for the 2016-2017 academic year is $795 per credit.

Some faculty members are eligible for Duke University's Educational Assistance Program. Other sources of support exist in some clinical departments; prospective participants should consult with program directors and division chiefs regarding potential funding sources.

“...The program really fills a niche and provides tailored training to physicians who have unique needs relative to other professional and graduate programs."

– Michael Mugavero, MD, MHS
Associate Professor of Medicine, University of Alabama at Birmingham