MASTER OF SCIENCE IN HEALTH SCIENCES IN LEADERSHIP AND STRATEGY IN REGULATORY AFFAIRS AND CLINICAL RESEARCH ADMINISTRATION

The regulation of clinical research is in itself a dynamic and emergent field. It brings together the science in which products—drugs, devices, biologics and vaccines—and treatment protocols are developed for improved global health care. Both the master’s degree and graduate certificate programs prepare scientists and regulatory professionals to manage the key elements of the clinical research regulatory process. The rigorous curriculum focuses on regulatory strategy, regulatory guidance, legal and ethical issues, processes for product development and the business and political components of regulation in clinical research, all while reinforcing the science behind the methods. Program graduates develop knowledge and skills in regulatory strategy and clinical conduct to guide the development of new therapeutics.

The distance education format provides a contemporary option for self-directed professionals who work in the field with industry or who may be just entering the field with one of the health and human services agencies charged with providing oversight and guidance to industry. Our course work has been developed in partnership with colleagues in industry and public regulatory agencies. The core courses will provide our students with the foundation to support new product development based on the conduct and regulation of clinical trials including registration by health authorities and strategies to manage product updates and post-approval commitments. The curriculum is taught by faculty members who bring both the perspectives of the sponsor and those of public health agencies.

As a result, the program provides each graduate with a robust academic education, while giving the student access to key leaders and practitioners in regulatory affairs and clinical research. This program has been strategically designed to generate leaders who will meet the needs of the emerging trends in regulatory affairs.

Visit the program website for additional program information.

ADMISSIONS

The following requirements must be fulfilled: 36 credits, including 21 credits in required core courses and 15 credits in required and elective courses in either the regulatory affairs concentration or the clinical research administration concentration.

<table>
<thead>
<tr>
<th>Code</th>
<th>Title</th>
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<tbody>
<tr>
<td>HSCI 6264</td>
<td>Epidemiology Translational Research</td>
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<td>COHM 6235</td>
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<tr>
<td>or CRA 6275</td>
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Concentration requirements

Students must complete all requirements for either the regulatory affairs concentration or the clinical research administration concentration, as follows:

Regulatory affairs concentration

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<tr>
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<tr>
<td>RAFF 6203</td>
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### Course Selections

**Clinical research administration concentration**

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<tr>
<td>CRA 6211</td>
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And one course selected from the following:

- HCQ 6201 Building a Quality Culture
- HSCI 6263 Biostatistics Translational Research
- RAFF 6204 Clinical Research for Regulatory Affairs
- RAFF 6205 Regulatory Affairs Compliance
- RAFF 6207 Advertising and Promotion of Regulated Medical Products

**Concentration requirements**

Students must complete all requirements for either the regulatory affairs concentration or the clinical research administration concentration, as follows:

#### Regulatory affairs concentration

- RAFF 6203 Regulatory Strategy in the Development of Devices and Diagnostics
- RAFF 6204 Clinical Research for Regulatory Affairs
- RAFF 6205 Regulatory Affairs Compliance
- RAFF 6207 Advertising and Promotion of Regulated Medical Products

And one course selected from the following:

- CRA 6203 Partnerships with Human Subjects

### REQUIREMENTS

The following requirements must be fulfilled: 36 credits, including 21 credits in required core courses and 15 credits in required and elective courses in either the regulatory affairs concentration or the clinical research administration concentration.

**Code** | **Title**                                                                 | **Credits** |
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**Required core courses**

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Master of Science in Health Sciences in Leadership and Strategy in Regulatory Affairs and Clinical Research Administration

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