This multi-level dual degree program offers academically qualified individuals a seamless and accelerated pathway for completing both the Bachelor of Science in Health Sciences (BSHS) in Clinical Research Administration (CRA), a degree completion program, and the Master of Science in Health Sciences (MSHS) in Regulatory Affairs (RAFF). Undergraduate and graduate degrees will be conferred sequentially, with the BSHS awarded upon completion of 120 credits (9 of which are taken for graduate credit). The MSHS is awarded following completion of an additional 27 credits of graduate coursework.

**BSHS IN CLINICAL RESEARCH ADMINISTRATION**

The BSHS with a major in Clinical Research Administration requires successful completion of 120 credit hours, including at least 60 credit hours of GW coursework:

<table>
<thead>
<tr>
<th>Transferable Coursework</th>
<th>General Education</th>
<th>Advanced Standing and Electives</th>
</tr>
</thead>
<tbody>
<tr>
<td>60 credit hours</td>
<td>21 credit hours</td>
<td>39 credit hours</td>
</tr>
</tbody>
</table>

For an assessment on the transferability of your previous coursework, please contact the program office. Coursework will be evaluated for transfer using the following criteria:

- College-level
- Academic in nature
- Completed at a regionally accredited institution
- Earned with a 'C' or better

**Curricula**

**BSHS**

- General Education (16 credit hours)
- English Composition (3 credits)*
- Science with lab (4 credits)
- Humanities (3 credits)*
- Social Sciences (6 credits)*

*Applicants may complete outstanding coursework through additional Health Sciences Distance Education courses.

Advanced Standing and Electives (44 credit hours)

Academic credit may be awarded for ACE-recognized military courses. Additionally, up to 39 credits of advanced standing may be awarded to graduates of non-college based health programs who present appropriate documentation (e.g. EMT or RN license).

**Coursework at GW**

(60 credit hours; 3 credits each)

- Health Sciences Distance Education
- CRA 2101 Basics of Clinical Research
- CRA 2102 Processes of Clinical Research
- CRA 2103 Good Clinical Practices
- CRA 2104 Business of Clinical Research
- CRA 2105 Selected Topics in Clinical Research
- CRA 2107 Introduction to Monitoring Clinical Trials
- HSCI 2102 Pathophysiology
- HSCI 2103 Health Policy and the Health Care System
- HSCI 2105 Current Issues in Bioethics
- HSCI 2107 Health Care in Literature
- HSCI 2112W Writing in the Health Sciences
- HSCI 2113 Informatics in the Health Sciences
- HSCI 2115 Introduction to Biostatistics
- HSCI 4103 Health Care Law & Regulation
- HSCI 4105 Case Studies in Health Care
- HSCI 4106 Introduction to Epidemiology
- HSCI 4112W Research and Writing for Health Professionals

**MSHS IN REGULATORY AFFAIRS**

Requires successful completion of an additional 36 credit hours of graduate coursework, including 6 credit hours in research.

**MSHS**

- Regulatory Affairs Courses
  - RAFF 6201 Analysis of Regulatory Affairs
  - RAFF 6202 Regulatory Strategy: Drugs & Biologics
  - RAFF 6203 Regulatory Strategy: Devices & Diagnostics
  - RAFF 6204 Integration of Regulatory Science
  - RAFF 6205 Regulatory Compliance
  - RAFF 6275 Leadership and Change in Regulatory Affairs

- Professional Core
  - HSCI 6241 The Health Care Enterprise

- Research Core
  - HSCI 6263 Biostatistics for Clinical & Translational Research
  - HSCI 6264 Epidemiology for Clinical & Translational Research

- Elective Course (choose one)
  - CML 6274 Health Economics and Finance
  - CRA 6203 Partnership with Human Subjects
  - CRA 6208 International Clinical Research
  - CRA 6209 Monitoring Clinical Research
  - CRA 6210 Medical Writing in Clinical Research
  - HCQ 6201 Building a Quality Culture

- Regulatory Affairs Field
  - RAFF 6201 Introduction to Global Regulatory Affairs
THROUGHOUT THE PROGRAM STUDENTS WILL

• Develop critical thinking, analytical, communication skills in order to respond to emerging trends in the field of regulatory science.

• Examine and apply Good Clinical Practice (GCP) regulations and guidance that govern the conduct of clinical trials from the vantage point of the sponsor, the investigator and the regulatory health authorities and to coalesce these perspectives into an integrated strategy for insuring GCP compliance.

• Develop and defend a proposal for a key strategic change initiative within the field of regulatory affairs.

• Analyze and evaluate the principle components of global regulatory strategy for drugs, biologics medical devices and diagnostics.

• Acquire the necessary tools and skills to assume roles and responsibilities of a multidisciplinary team and be able to identify sponsor and study site needs and perspectives necessary for the conduct of clinical trial operations.

• Develop strategies for integrating business needs into regulatory strategic planning.

• Analyze the process and requirements of clinical monitoring to assure human subjects protection and clinical research data integrity adequate.

• Demonstrate a working knowledge of the four stage of clinical development Phases I–IV.

• Develop quality improvement skills to improve systems across the broader health care context.

• Analyze and evaluate regulatory compliance issues across product categories.

• Define relevant clinical research terminology, and apply the terminology in the review of key essential documents.

Apply for Admission

ADMISSIONS REQUIREMENTS
All applicants are required to complete an online application as well as submit the following supporting documents:

• Official transcripts from all previous academic institutions
• One letter of recommendation
• Current resume
• A statement of purpose

Admitted students may begin their course of study during the Spring, Summer, or Fall semester.

COSTS AND FUNDING
Current information concerning tuition, fees, and other estimated expenses can be found at colonialcentral.gwu.edu.

Students who are on active-duty are eligible for a special military discount tuition rate. Please contact the program office for further information.

REQUIRED TESTS
The program does not require the submission of an entrance exam. Applicants whose native language is not English or who are not citizens of countries where English is the official language are required to submit scores from either TOEFL or IELTS. Please visit the Admissions website for more detailed information.

Connect

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