The Secondary Field of Study (SFS) is intended to provide current GW undergraduates knowledge within the field of Clinical Research Administration (CRA), including an understanding of the different phases of drug and device development, basic terminology in the field, the key stakeholder roles and their responsibilities, good clinical practice, and principle components of clinical research trials for drugs, devices, and combination products.

This SFS offers GW students an opportunity for an additional concentration related to their area of study. Previous experience in health care is not required. While the program can offer a unique insight into health care for all majors, the SFS is particularly useful for those students interested in public policy, business, and biomedical engineering. Students in the public policy realm will explore healthcare policies that shape current healthcare practice and delivery. Business students can apply basic project management principles and business practices to facilitate quality clinical research activity. Biomedical engineering students will develop a general foundation in clinical trial conduct practices for developing new drugs and devices.

Curriculum

Foundation Courses
(12 credit hours)

- CRA 2101 Basics of Clinical Research
- CRA 2102 Processes of Clinical Research
- CRA 2103 Good Clinical Practices
- HSCI 2105 Current Issues in Bioethics

Electives
(3 credit hours; chosen with academic advisor)

- CRA 2104 The Business of Clinical Research
- HSCI 2103 Health Policy and the Health Care System

Recommended for GW Business Students

Connect

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Clinical Research Administration

THROUGHOUT THE PROGRAM, ALL STUDENTS WILL

• Demonstrate a working knowledge of drug and device development.

• Explore commonly used terminology, the phases of clinical development, the major stakeholders in clinical trial conduct and their roles and responsibilities.

• Examine and apply Good Clinical Practice (GCP) guidelines and bioethical considerations from the sponsor, investigator and regulatory (HHS, FDA & IRB) oversight perspectives.

• Develop a general foundation in clinical trial conduct practices for developing new drugs and devices.

BUSINESS STUDENTS WILL

• Explore healthcare policies that shape current healthcare industry delivery and business considerations related to new drugs and treatments.

• Apply basic project management principles and business practices to facilitate quality clinical research activity.

PUBLIC POLICY STUDENTS WILL

• Explore healthcare policies that shape current healthcare practice and delivery.

BIOMEDICAL ENGINEERING STUDENTS WILL

• Analyze healthcare policies that shape healthcare practice and delivery related to new drugs and devices.

HEALTH SCIENCES COURSES

HSCI 2103 Health Policy and the Health Care System
Incorporates economic theory and policy analysis methodology to analyze the impact of changes in the health care system on the practice of health sciences professionals and the quality and process of health care. Development of critical thinking skills through review of current medical literature.

HSCI 2105 Ethics for Health Professionals
Basic issues, approaches, and requirements of ethically acceptable decision-making with patients, including patient confidentiality, conflicts of interest, allocation of scarce resources, occupational risks in health care, and professional responsibility for overall quality of care.

Course Descriptions

CLINICAL RESEARCH ADMINISTRATION COURSES

CRA 2101 Basics of Clinical Research
Fundamental concepts, trends, regulations, and practices in clinical research. An overview of industry and government practices and policies in the development of patient care products (drug, devices, biologicals, and diagnostics) and treatment protocols.

CRA 2102 Processes of Clinical Research
Introduction to the processes, procedures, and treatment protocols in the development of patient care products, including RO1 applications, clinical trials protocols, institutional review board standards, adverse event monitoring, and the supporting documentation and practices to obtain Food and Drug Administration approval. Prerequisite: CRA 2103.

CRA 2103 Good Clinical Practices
The organization and management of data, documents, materials and findings resulting from clinical research as prescribed by governmental institutions, regulatory agencies, industry sponsors, and research organizations. Audit standards and mechanisms are introduced, and practice audits are conducted. Prerequisite: CRA 2101.

CRA 2104 The Business of Clinical Research
Fiscal and managerial components of clinical research, including the budgeting processes, fiscal management, software applications, legal and contractual issues, and recruitment of personnel and subjects. Examination of all entities involved in clinical research, including drug, device, biological, and diagnostics sponsors; academic medical centers; and contract research organizations, site management companies, physician-run organizations, and health delivery organizations. Prerequisite: CRA 2103.

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