

**2022-23**

## **REGULATORY SCIENCE FOR FACILITATING ETHICAL RESEARCH**

Degree Offered: Certificate



### **Program Description**

This certificate is designed to explore advanced topics in human subjects' protections relevant to IRB work in the area of ethics, regulations, current topics, and IRB member skills and professionalism. Graduates of this certificate program will be able to specialize in IRB work and research, akin to recent developments in quality improvement, in which faculty and staff have undertaken specialization in their field. Upon completion of this program, graduates will be ready to conduct their own research to advance the field of regulatory science in addition to being better equipped to serve as senior IRB members, perhaps eventually moving into leadership roles. The certificate will enroll a cohort of new students every other year, as the bioethics-based courses will only be offered every other year.

### **Admission Requirements**

In addition to the general [Graduate School admission requirements](#), this program has additional specific requirements.

Criteria for admission include a minimum of 2 years professional experience as a member of an IRB; college and, if applicable, graduate, or professional school grades; commitment to the field of research ethics; and promise in the program's academic areas.

### **Credits Required to Graduate**

12 credits

### **Program Credit Requirements**

The certificate will enroll a cohort of new students every other year, as the bioethics-based courses will only be offered every other year. Therefore, students will take one course per semester to complete the program.

All the courses of the certificate program are offered online. The technical requirements are minimal, i.e., ability to use a web-browser and email. Class discussions and case analyses are conducted primarily in non-real time, so students can participate at their convenience during each week. However, students are paced on a week-to-week basis just as in a campus course. Moreover, the pedagogical capabilities of the online environment enhance the class discussions and allow for individualized instructor feedback, which empowers the learners and makes the courses truly student-centered.

Participants receive a Certificate of Regulatory Science for Facilitating Ethical Research from the Medical College of Wisconsin's Graduate School of Biomedical Sciences upon completion of the four courses. Each course is also worth graduate credit which may be applicable to the Bioethics MA degree.

## Required Courses

### **10207 Introduction to Research Ethics.** *3 credits.*

This course provides students with a comprehensive introduction to the ethical issues involved in scientific, animal and human subject's research. After a brief look back at the history of research ethics, students will spend time considering issues that impact research in both the laboratory setting and in the clinical setting. This course provides the necessary research ethics instruction required to satisfy the United States Public Health Service Policy on Instruction in the Responsible Conduct of Research for institutions receiving research funds from the Department of Health and Human Services. (Issued December 1, 2000.)

### **10226 Regulatory Issues in Human Subject Research Protections.** *3 credits.*

There is no question that the fruits of research have fueled medical progress. Yet, the history of research involving human subjects is not unblemished. Federal regulations, based on ethical principles set forth in the Belmont Report, now govern much of the research undertaken in the United States. In this course, we will explore the history and substance of research regulations in the United States, the application of the regulations to specific research issues, and situations where the regulations do not provide clear guidance.

### **10228 Current Topics in Research Ethics.** *3 credits.*

Rapidly evolving scientific and technologic capabilities in medicine combined with an ever-increasing demand to translate these scientific developments to the bedside presents new challenges to regulating human subject's research. This course seeks to keep pace with many of these new and emerging challenges, providing students an opportunity to critically examine the ethical and legal implications of these topics. Specific topics for analysis will be drawn from the current medical literature, popular press, and evolving policy guidance.

### **20262 Mastering Human Subjects Protections: Meetings, Members, and Processes.** *3 credits.*

This course is an advanced examination of the concepts, theories, and principles of IRB decision-making designed for experienced (3 years or more) IRB members. The course will consider ways to satisfy regulatory requirements and ethical review for biomedical research with focus, efficiency, and depth. The course will pay particular attention to distinguishing between major regulatory or ethical questions, on one hand, and non-critical questions or change requests, on the other. The course will also review ways that IRB Chairs and IRB members can more quickly illuminate differences of opinion in a way that allows thoughtful committee resolution of controversial impasses.

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