

CLINICAL RESEARCH COORDINATOR



Program Code 10-558-1

Estimated Program Costs: \$10,700

Median Annual Salary: \$26,000

OVERVIEW

The Clinical Research Coordinator (CRC) program prepares individuals who have responsibility for first-level integrity of a research project, including organization, collaboration and coordination, data collection, recruiting, screening and enrolling participants, scheduling, ensuring accuracy of documentation, preliminary technical report writing, and initial protocol development which ensures good clinical practice.

Clinical research coordinators work under the direct supervision of principal and co-investigators. Education and training emphasis is placed on providing assistance in the research process related to regulatory compliance and other research projects.

Graduates of the CRC program may be eligible for professional certification after a year of work experience. Six Sigma Green Belt certification can be achieved by completing the following courses (three of which are required in the CRC program): Managing for Quality, Introductory Statistics, Applied Data Analysis, Project Management, and the Green Belt certification course.

The Clinical Research Coordinator program is offered at the Marshfield campus. However, most classes are offered online and are not location dependent.

PROGRAM OUTCOMES

Employers will expect you, as a Clinical Research Coordinator graduate, to be able to:

- Assist in the design of a research study including protocol development which insures good clinical practice and consistently utilizes highest standards of accuracy, honesty, and confidentiality
- Follow all prescribed ethical principles, operationalize and comply with identified regulations on all levels in the coordination of the research study
- Conduct feasibility studies for research studies
- Screen, recruit, schedule, enroll, retain, and otherwise coordinate research study subjects
- Obtain data, enter it into a database, correct and clean the data, assist with data accuracy verification, and conduct preliminary analysis of data
- Interact with other regulatory agencies (i.e. Food and Drug Administration), ensuring that all trials are conducted according to stated specifications
- Work on related study documents and trial applications
- Assist in the development and management of a budget for the research study

- Be able to detect “gaps” in information and recommend early stages of resolution
- Gather and prepare documents for quality assurance and other audits; participate in other quality assurance activities
- Gather and prepare preliminary research information for writing teams (i.e. regulatory reports, study reports, safety narratives, etc.); provide some preliminary technical report writing
- Work effectively with other members of the research team

CAREER OPTIONS

Clinical Research Coordinator
Clinical Trial Coordinator
Data Coordinator
Medical Research Coordinator
Research Study Coordinator
Research Trial Coordinator

POTENTIAL FOR ADVANCEMENT

Clinical Research Associate
Clinical Research Studies Manager
Senior Clinical Research Coordinator

Potential advancement generally requires further education.

ADMISSIONS PROCEDURES

To apply to the Clinical Research Coordinator (CRC) program, please complete the following steps and submit documents to the MSTC Admissions Office:

Step 1:

1. Complete an MSTC application form and return it with the \$30 non-refundable application fee.
2. Complete the Accuplacer or ACT test. Minimum scores required:
 - Reading-Accuplacer score of 55
 - Sentence Skills-Accuplacer score of 60
 - Math-Accuplacer score of 34
 - ACT equivalents for above scores are acceptable.

You may take the Accuplacer again if you did not meet the required scores. Additional options, including coursework and tutoring, are also available to assist you. Contact the Student Affairs Office on your local campus to learn about your options. To schedule an Accuplacer test, contact your local Campus Office.

Written Communication, courses in mathematics, and some science courses have placement requirements. Please refer to the course description section in the back of the catalog, listed under General Education, for course specific information.

3. Submit an official copy of all academic transcripts, including high school, college or university, and HSED/GED.
4. Complete a Background Information Disclosure (BID) form and submit \$15 for Caregiver Background check. The Wisconsin Caregiver law requires a background check. This form is available at <http://www.mstc.edu/pdf/BIDform.pdf>.
5. Complete the online program information session found at mstc.edu to learn about the profession, academic requirements, and impact on one's personal life.

When the requirements for Step 1 are completed, the student will be conditionally admitted to the program and may be eligible for financial aid.

Step 2:

To be eligible to enroll in second semester CRC core courses, complete the following requirements:

1. Complete Intro to Reading and Study Skills with a grade of "C" or better, an Accuplacer Reading score of 89 or higher, or ACT equivalent.
2. Complete Written Communication with a grade of "C" or better, an Accuplacer Sentence Skills score of 103 or higher, or ACT equivalent.
3. Complete Pre-Algebra with a grade of "C" or better, an Accuplacer Math score of 79 or higher, or ACT equivalent.
4. Complete one year of high school chemistry or biology with a grade of "C" or better both semesters or one semester of college chemistry or biology with a grade of "C" or better.
5. Complete the Intent to Enroll form and submit proof of completion of all requirements to MSTC Admissions Office.

**Mid-State Technical College
Admissions
500 32nd Street North
Wisconsin Rapids, WI 54494**

FUNCTIONAL ABILITIES

A list of specific physical, emotional, and mental tasks needed to function as a Clinical Research Coordinator is available in the online program information session available at mstc.edu. It is the student's responsibility to notify the disability services coordinator in the Student Affairs Office to receive assistance.

CLINICAL RELATED REQUIREMENTS

Clinical sites have the right to refuse a student's admission based on pending charges and conviction records. If you have a criminal history, you may not be able to complete clinical courses. MSTC will make two attempts to place a student in a clinical experience.

Prior to beginning a clinical experience in a healthcare facility, students must:

- a. Submit evidence of required health work.
- b. Accept responsibility for clinical assignment(s) regardless of time and location, including transportation and other personal arrangements.

PROGRAM PROGRESSION AND COMPLETION

In order to progress in and successfully complete the program, students must:

- Repeat courses not completed with a "C" or better prior to progressing in core courses or other courses with co- or prerequisites
- Receive a grade of "C" or better in all courses required for graduation.

Please note that the ability to repeat courses is dependent upon availability in courses. Students may be required to apply for program re-entry in order to repeat courses within the program's instructional area.

CURRICULUM

Term (15 credits)

10103106	Microsoft Office-Introduction	3
10501101	Medical Terminology	3
10530184	Intro to Health Information Technology	2
10558101	Intro to Clinical Research	3
10806177	General Anatomy & Physiology	4

Term (15 credits)

10196192	Managing for Quality	3
10558103	Epidemiology	3
10558104	Legal & Regulatory Research Compliance	3
10801195	Written Communication	3
10804189	Introductory Statistics	3

Term (18 credits)

10152105	Database Management	3
10196180	Applied Data Analysis	3
10501108	Pharmacology for Allied Health	2
10558109	CRC Lab & Clinical Procedures	3
10801197	Technical Reporting	3
10806197	Microbiology	4

Term (16-17 credits)

10501109	Medical Law, Ethics, and Professionalism	2
-or-		
10809166	Intro to Ethics: Theory & Application	3
10558105	Clinical Research Management	3
10558106	Genetics	3
10558107	Clinical Research Coordinator Practicum	2
10809196	Intro to Sociology	3
10809198	Intro to Psychology	3

Total Credits 64-65

Please Note:

- The Clinical Research Coordinator program has August and January start dates. We advise you to meet with an academic advisor or counselor to successfully plan your academic schedule.
- This curriculum sequence is only for student planning. Actual student schedules will vary depending on course availability and term of program entry.
- Degree completion time may vary based on student scheduling and course availability.
- For General Education course descriptions (800 level), see section marked under Course Descriptions.

CLINICAL RESEARCH COORDINATOR

PROGRAM COURSE DESCRIPTIONS

10103106 // 3 credits

Microsoft Office-Introduction

Develops introductory skills in the Microsoft Office Suite (Word, Excel, Access, and PowerPoint) while reinforcing the students' knowledge of computer concepts, file management, Internet, and MSTC student email usage through demonstrations and lab exercises. Students must possess basic keyboarding, mouse, and Windows skills. Students may develop these skills in Academic Success Center computer training prior to enrolling or while concurrently enrolled in the Microsoft Office-Introduction course.

10152105 // 3 credits

Database Management

This course uses hands-on exercises and projects to give students experience with using databases for data storage and retrieval. To encourage students to become more sophisticated database users, background information, general relational database design concepts, and a database security overview are included. *Prerequisite: Microsoft Office-Introduction 10103106 or Applied Microsoft Office for Health 10103107*

10196180 // 3 credits

Applied Data Analysis

This course provides the student with the tools and skills to collect and analyze data allowing them to solve problems and improve processes. An emphasis will be placed on the use of statistical techniques to create and implement a data collection plan. Statistical techniques emphasized will be process mapping, failure mode and effects analysis, probability, confidence intervals, measurement systems analysis, and hypothesis testing.

Prerequisite: Introductory Statistics 10804189

10196192 // 3 credits

Managing for Quality

The learner applies the skills and tools necessary to implement and maintain a continuous improvement environment. Each learner will demonstrate the application of a personal philosophy of quality, identify stakeholder relationships, identify ways to meet/exceed customer expectations, apply a systems-focused approach, use quality models and tools, manage a quality improvement project, and measure effectiveness of continuous improvement activities.

10501101 // 3 credits

Medical Terminology

Students focus on the component parts of medical terms: prefixes, suffixes, and word roots. Students will practice formation, analysis, and reconstruction of terms. Emphasis on spelling, definition, and pronunciation. Introduction to operative, diagnostic, therapeutic, and symptomatic terminology of all body systems, as well as systemic and surgical terminology.

10501108 // 2 credits

Pharmacology for Allied Health

Introduces students to classifying medications into correct drug categories and applying basic pharmacology principles. Students apply basic pharmacodynamics to identifying common medications, medication preparation, and administration of medications used by the major body systems.

10501109 // 2 credits

Medical Law, Ethics, and Professionalism

Prepares students to display professionalism and perform within ethical boundaries in the healthcare setting. Students maintain confidentiality, examine legal aspects of the medical record, perform risk management procedures, and examine legal and bioethical issues.

10530150 // 2 credits

Introduction to Health Information Technology

Prepares learners to illustrate the flow of health information in various healthcare delivery systems and within the health information department and to retrieve data from health records. Professional ethics, confidentiality, and security of information are emphasized. This course also examines the content and structure of an EHR (inpatient and ambulatory patient records), documentation practice guidelines, and the types of user devices utilized in an EHR system. Basic concepts of clinical decision support, standards relating to content of health records, data integrity, and EHR system security are included. Students will have access to an electronic health record to apply concepts learned.

10558101 // 3 credits

Intro to Clinical Research

This course provides a comprehensive introduction to the clinical research process and its history and evolution. Topics include phases of clinical trials, protection of human subjects, roles of the clinical research teams, and responsibilities of clinical research organizations. Upon completion, students should be able to prepare an organizational chart depicting a typical research team, defining the roles or responsibilities of each member. Students should be able to describe the product approval process and discuss the general conduct of a typical clinical trial.

Corequisite: Medical Terminology 10501101

10558103 // 3 credits**Epidemiology**

Course will introduce students to the basic concepts and principles of the study of the distribution and determinants of health-related states or events in specified populations and the application of this study to the control of health problems. Topics include history of epidemiology, classification of disease, epidemiological measurement, outbreak investigation, study design, bias, and causality. Various epidemiologic study designs for investigating associations between risk factors and disease outcomes are also introduced, culminating with criteria for causal inferences. The application of these disciplines in the areas of health services, screening, genetics, and environmental policy are presented. The influence of epidemiology and biostatistics on legal and ethical issues is also covered.

Prerequisite: Medical Terminology 10501101

Corequisite: Introductory Statistics 10804189

10558104 // 3 credits**Legal & Regulatory Research Compliance**

Course covers the range of national and international regulations and guidelines governing the development of drugs, diagnostics, medical devices, and biologics. Topics include a review of regulatory agencies, guidelines for regulatory application, required documentation, and protection of human subjects. Specific topics include ICH Guidelines, FDA, IND, and IDE regulations, IRB and IEC activities, HIPAA, Human Subject Protection/Informed consent, and other rules and regulations. Upon completion, students should be able to demonstrate a basic understanding of regulations, guidelines, and legal issues associated with clinical research, and describe effective means of compliance.

Prerequisites: Admission to Clinical Research Coordinator 105581 program, Intro to Clinical Research 10558101, and Medical Terminology 10501101

10558105 // 3 credits**Clinical Research Management**

This course introduces the student to the elements involved in implementing, monitoring, and managing a clinical study from the perspective of the sponsor or contract research organization (CRO). Topics include overall project planning, development of study goals, preparation of budget and contracts, implementation of monitoring visits, and effective management of research sites. Upon completion, student should be able to design and prepare a plan for implementation and management of a sample clinical research project.

Prerequisites: Admission to Clinical Research Coordinator 105581 program, Intro to Clinical Research 10558101, Medical Terminology 10501101, and Technical Reporting 10801197

10558106 // 3 credits**Genetics**

This course will introduce students to the progression of genetic discovery including evolving legal and ethical implications. Topics covered will include Mendelian genetics, post-Mendelian genetics, population genetics, molecular genetics, DNA structure, replication, transcription and translation, and current DNA technologies.

10558107 // 2 credits**Clinical Research Coordinator Practicum**

The student will have supervised work experience in a clinical setting at various research sites agreed upon by the instructor and student. Emphasis is on the observation, performance, and enhancement of professional and management skills; interactive team communication; and the application of research principles, procedures, and regulations in the workplace.

Prerequisite: Admission to Clinical Research Coordinator 105581 program

10558109 // 3 credits**CRC Lab & Clinical Procedures**

This course prepares the student to perform comprehensive research participant baseline assessments, drug accountability, blood draws, lab preparation, and shipping.

Prerequisites: Admission to Clinical Research Coordinator 105581 program, Intro to Clinical Research 10558101, Epidemiology 10558103, Legal & Regulatory Research Compliance 10558104, and General Anatomy & Physiology 10806177

Corequisite: Microbiology 10806197