

Clinical Research Coordinator

Associate in Applied Science (AAS)

Overview

The Clinical Research Coordinator 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.

Students are required to purchase a subscription to the American Health Information Association's Virtual Lab when registering for the following 530 courses: Medical Records and Electronic Medical Records for CRCs. The subscription provides the student with access to software and data needed for lab activities. Lab subscription cost is \$75 for the academic year or \$50 per semester. The subscription packets are obtained directly from AHIMA. <https://secure.ahima.org/VLab/Login.aspx>

The Clinical Research Coordinator program is offered at MSTC's Marshfield campus. However, most classes are offered online so they are largely 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 data base, correct and clean the data, assist with data accuracy verification and conduct preliminary analysis of data
- Interact with other regulatory agencies (i.e. Federal 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
Research Study Coordinator

Potential for Advancement

Clinical Research Associate (requires additional experience)
Clinical Research Coordinator Senior
Clinical Research Studies Manager
Potential advancement generally requires further education.

Admissions Procedures

To apply to the Clinical Research Coordinator program, please submit the following to MSTC Student Affairs Admissions Office:

1. WTCS application form and \$30 non-refundable application fee
2. Completed Accuplacer test. (Other test scores may be acceptable alternatives.) Entrance exam requirements for the Clinical Research Coordinator program are:

Reading–Accuplacer score of 89 or equivalent

Language–Accuplacer score of 103 or equivalent

Math–Accuplacer score of 79 or equivalent

If a student does not meet the required scores in these academic areas, they may remediate and retest or complete an identified structured remediation course(s) in the Academic Support Center. To progress in the program, students must achieve an 80% or greater in all preceding courses.

3. High school transcript or GED/HSED scores
4. Completed Background Information Disclosure (BID) Form. Placement in Clinical Experience may require a Caregiver Background Check.

Mid-State Technical College
Admissions
500 32nd Street North
Wisconsin Rapids, WI 54494
mstc.edu
888.575.MSTC

Program Course Descriptions

10103106 Microsoft Office-Beginning 3 credits

Develops introductory skills in the Microsoft Office Suite (Word, Excel, Access, PowerPoint), Windows Explorer, Internet and computer concepts through demonstrations and lab exercises.

10152105 Database Management 3 credits

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-Beginning 10103106

10196180 Applied Data Analysis 3 credits

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 Managing for Quality 3 credits

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 Medical Terminology 3 credits

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.

10501122 Pharmacology for Allied Health 2 credits

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.

10530111 Medical Records 3 credits

Focuses on the purpose, format, content, use, confidentiality and administrative issues of a patient's medical history and care. Students will study the use of the patient's medical record as a basis for planning patient care, documenting communication between the healthcare provider and any other health professional contributing to the patient's care, assisting in protecting the legal interest of the patient and the healthcare providers responsible for the patient's care, and documenting the care and services provided to the patient. Emphasis is placed on accuracy, organization and confidentiality. Students will be introduced to EMR concepts. Corequisite: Medical Terminology 10501101

10558101 Intro to Clinical Research 3 credits

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

10558102 Electronic Medical Records for CRC's 2 credits

Course introduces students to the electronic medical record (EMR) as a technology-based representation of healthcare data integration from a participating collection of varied systems for a single patient. Course covers emerging use of the electronic medical record, an overview of EMR, applications, benefits and barriers to its use, ontologies, vocabularies, principles of implementation, health information exchange, standards, privacy, security, information retrieval, digital libraries and image management. Prerequisites: Medical Terminology 10501101; General A & P 10806177; Medical Records 10530111

Curriculum

First Semester (16 Credits)

10103106	Microsoft Office-Beginning	3
10501101	Medical Terminology	3
10530111	Medical Records	3
10558101	Intro to Clinical Research	3
10806177	General Anatomy & Physiology	4

Second Semester (17 Credits)

10196192	Managing for Quality	3
10558102	Electronic Medical Records for CRC's	2
10558103	Epidemiology	3
10558104	Legal & Regulatory Research Compliance	3
10801195	Written Communication	3
10804189	Introductory Statistics	3

Third Semester (15 Credits)

10152105	Database Management	3
10196180	Applied Data Analysis	3
10501122	Pharmacology for Allied Health	2
10801197	Technical Reporting	3
10806197	Microbiology	4

Fourth Semester (18 Credits)

10558105	Clinical Research Management	3
10558106	Genetics	3
10558107	Patient Assessment	3
10558108	Healthcare Leadership, Ethics & Application	3
10809166	Intro to Ethics: Theory & Application	3
10809196	Intro to Sociology	3
10809198	Intro to Psychology	3

Total Credits 66

Please Note:

- The Clinical Research Coordinator program has August and January starting dates. However, we advise you to meet with a counselor to successfully plan your academic schedule.
- Degree completion time may vary based on student scheduling needs and course availability.
- For General Education course descriptions (800 level courses), see section marked under Course Descriptions.

Clinical Research Coordinator (Continued)

10558103

Epidemiology

3 credits

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 casual 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

Legal & Regulatory Research Compliance

3 credits

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: Intro to Clinical Research 10558101, Medical Terminology 10501101

10558105

Clinical Research Management

3 credits

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: Intro to Clinical Research 10558101, Medical Terminology 10501101, Technical Reporting 10801197

10558106

Genetics

3 credits

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

Patient Assessment

3 credits

This course is designed to prepare the student to do baseline assessments including taking basic vital signs such as blood pressure, pulse and respiration. Students will recognize normal range values and appropriate action to be taken when assessments are outside of acceptable ranges. The course will address drug accountability, vital signs, EKG's, CPR, Universal Precautions, lab preparation and shipping, human subject protection training and other related assessments. The course includes a multi-faceted practicum.

10558108

Healthcare Leadership, Ethics & Application

3 credits

Course introduces students to leadership concepts and ethical foundations applicable to a healthcare environment. Leadership concepts include communication, collaboration, delegation, conflict management, problem-solving and professional behavior. Ethical foundations include integrity, honesty, the nature of moral judgments and respect. Application of leadership concepts and ethical responsibilities involves working with the entire healthcare community including underserved and vulnerable populations. Other topics addressed include ensuring informed consent, human rights, violence toward others, resource allocation, impaired professionals, reporting errors and role delineation. May substitute Intro to Ethics: Theory and Application 10809166