

CURRICULUM STANDARD

Effective Term
Fall 2009
[2009*03]

Curriculum Program Title

Clinical Trials Research Associate

Code

A45190

Concentration

(not applicable)

Curriculum Description

The Clinical Trials Research Associate curriculum prepares individuals to assist physicians and clinical researchers in the initiation, administration, coordination, and management of clinical research studies for the development of new drugs, clinical products, and treatment regimens.

Course work includes in-depth study of drug development, Federal regulations, and clinical research processes. Supervised fieldwork provides skill application in subject recruitment, regulatory compliance, accountability for drugs/devices, and documentation of subject involvement in clinical research studies.

Graduates may be eligible to sit for national certification examinations. Research employment opportunities may include medical centers, hospitals, pharmaceutical industries, clinics, research facilities, biotechnology or device companies, and physicians' offices.

*Curriculum Requirements**

[for associate degree, diploma, and certificate programs in accordance with 23 NCAC 02E.0204 (3)]

- I. General Education.** Degree programs must contain a minimum of 15 semester hours including at least one course from each of the following areas: humanities/fine arts, social/behavioral sciences, and natural sciences/mathematics. Degree programs must contain a minimum of 6 semester hours of communications. Diploma programs must contain a minimum of 6 semester hours of general education; 3 semester hours must be in communications. General education is optional in certificate programs.
- II. Major Hours.** AAS, diploma, and certificate programs must include courses which offer specific job knowledge and skills. Work experience, including cooperative education, practicums, and internships, may be included in associate in applied science degrees up to a maximum of 8 semester hours of credit; in diploma programs up to a maximum of 4 semester hours of credit; and in certificate programs up to a maximum of 2 semester hours of credit. *(See second page for additional information.)*
- III. Other Required Hours.** A college may include courses to meet graduation or local employer requirements in a certificate, diploma, or associate in applied science program. These curriculum courses shall be selected from the Combined Course Library and must be approved by the System Office prior to implementation. Restricted, unique, or free elective courses may not be included as other required hours.

	AAS	Diploma	Certificate
Minimum General Education Hours	15	6	0
Minimum Major Hours	49	30	12
Other Required Hours	0-7	0-4	0-1
Total Semester Hours Credit (SHC)	64-76	36-48	12-18

**Within the degree program, the institution shall include opportunities for the achievement of competence in reading, writing, oral communication, fundamental mathematical skills, and basic use of computers.*

Major Hours

[ref. 23 NCAC 02E.0204 (3)]

- A. Core.** The subject/course core is comprised of subject areas and/or specific courses which are required for each curriculum program. A diploma program offered under an approved AAS program standard or a certificate which is the highest credential level awarded under an approved AAS program standard must include a minimum of 12 semester hours credit derived from the subject/course core of the AAS program.
- B. Concentration** (*if applicable*). A concentration of study must include a minimum of 12 semester hours credit from required subjects and/or courses. The majority of the course credit hours are unique to the concentration. The required subjects and/or courses that make up the concentration of study are in addition to the required subject/course core.
- C. Other Major Hours.** Other major hours must be selected from prefixes listed on the curriculum standard. A maximum of 9 semester hours of credit may be selected from any prefix listed, with the exception of prefixes listed in the core or concentration. Work experience, including cooperative education, practicums, and internships, may be included in associate in applied science degrees up to a maximum of 8 semester hours of credit; in diploma programs up to a maximum of 4 semester hours of credit; and in certificate programs up to a maximum of 2 semester hours of credit.

Clinical Trials Research Associate (A45190)

	AAS	Diploma	Certificate
Minimum Major Hours Required	49 SHC	30 SHC	12 SHC
A. CORE	38 SHC		
Required Courses: CTR 110 Intro to Clinical Research 3 SHC CTR 112 Clinical Research Terminology 3 SHC CTR 115 Clinical Research Regulations 3 SHC CTR 120 Research Protocol Design 3 SHC CTR 130 Clinical Research Management 4 SHC CTR 150 Research Fieldwork I 5 SHC CTR 210 Introduction to Clinical Data 3 SHC CTR 220 Research Site Management 3 SHC CTR 250 Research Fieldwork II 8 SHC CTR 281 Professional Practice 3 SHC			
B. CONCENTRATION (<i>Not applicable</i>)			
C. OTHER MAJOR HOURS <i>To be selected from the following prefixes:</i> BIO, CIS, COE, CSC, CTR, HUM, MAT, PHM, PSY, and SOC <i>Foreign language courses (including ASL) that are not designated as approved other major hours may be included in all programs up to a maximum of 3 semester hours of credit.</i>			