

**SOUTH DAKOTA BOARD OF REGENTS**

**Academic and Student Affairs**  
**Consent**

**AGENDA ITEM: 6 – E**  
**DATE: December 7-8, 2022**

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**SUBJECT**

**New Undergraduate Certificate Request – USD – Clinical Research Coordinator**

**CONTROLLING STATUTE, RULE, OR POLICY**

[BOR Policy 2:23](#) – New Programs, Program Modifications, Curricular Requests, and Inactivation/Termination

**BACKGROUND / DISCUSSION**

The University of South Dakota (USD) requests authorization to offer a Clinical Research Coordinator undergraduate certificate. Clinical Research Coordinators support medical clinical trials through maintaining daily processes and monitoring for compliance with all institution, state, and federal regulations. Clinical Research Coordinators must hold a degree in a health-related field that includes specific instruction in content related to clinical research trials (i.e., biostatistics, healthcare management, epidemiology, and human anatomy). USD’s clinical partner has expressed a need for trained workforce in this area due to increased demand.

**IMPACT AND RECOMMENDATION**

USD plans to offer the certificate in Clinical Research Coordinator on campus and online. USD does not request new state resources. Two new courses will be required.

Board office staff recommends approval.

**ATTACHMENTS**

Attachment I – New Certificate Request Form: USD – Clinical Research Coordinator

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**DRAFT MOTION 20221207\_6-E:**

I move to authorize USD to offer a Clinical Research Coordinator undergraduate certificate, as presented.



**SOUTH DAKOTA BOARD OF REGENTS  
ACADEMIC AFFAIRS FORMS**

**New Certificate**

Use this form to propose a certificate program at either the undergraduate or graduate level. A certificate program is a sequence, pattern, or group of academic credit courses that focus upon an area of specialized knowledge or information and develop a specific skill set. Certificate programs typically are a subset of the curriculum offered in degree programs, include previously approved courses, and involve 9-12 credit hours including prerequisites. In some cases, standards for licensure will state explicit requirements leading to certificate programs requiring more than 12 credit hours (in such cases, exceptions to course or credit requirements must be justified and approved). The Board of Regents, Executive Director, and/or their designees may request additional information about the proposal. After the university President approves the proposal, submit a signed copy to the Executive Director through the system Chief Academic Officer. Only post the New Certificate Form to the university website for review by other universities after approval by the Executive Director and Chief Academic Officer.

<b>UNIVERSITY:</b>	<b>University of South Dakota</b>
<b>TITLE OF PROPOSED CERTIFICATE:</b>	<b>Clinical Research Coordinator</b>
<b>INTENDED DATE OF IMPLEMENTATION:</b>	<b>January 2023</b>
<b>PROPOSED CIP CODE:</b>	<b>51.0719</b>
<b>UNIVERSITY DEPARTMENT:</b>	<b>Public Health &amp; Health Sciences</b>
<b>BANNER DEPARTMENT CODE:</b>	<b>UHSC</b>
<b>UNIVERSITY DIVISION:</b>	<b>School of Health Sciences</b>
<b>BANNER DIVISION CODE:</b>	<b>2H</b>

<b>x</b>	<p><b><u>Please check this box to confirm that</u> (place an “X” in the left box):</b></p> <ul style="list-style-type: none"> <li>The individual preparing this request has read <a href="#">AAC Guideline 2.7</a>, which pertains to new certificate requests, and that this request meets the requirements outlined in the guidelines.</li> <li>This request will not be posted to the university website for review of the Academic Affairs Committee until it is approved by the Executive Director and Chief Academic Officer.</li> </ul>
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**University Approval**

*To the Board of Regents and the Executive Director: I certify that I have read this proposal, that I believe it to be accurate, and that it has been evaluated and approved as provided by university policy.*

<i>Elizabeth M. Freeburg</i>	<i>9/12/2022</i>
Institutional Approval Signature	Date
<i>President or Chief Academic Officer of the University</i>	

Note: In the responses below, references to external sources, including data sources, should be documented with a footnote (including web addresses where applicable).

**1. Is this a graduate-level certificate or undergraduate-level certificate? (place an “X” before the graduate type)**

<input checked="" type="checkbox"/> Undergraduate Certificate	<input type="checkbox"/> Graduate Certificate
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**2. What is the nature/ purpose of the proposed certificate? Please include a brief (1-2 sentence) description of the academic field in this certificate.**

A Clinical Research Coordinator supports the PI of medical clinical trials through maintaining daily processes and monitoring for compliance with all institutional, state, and federal regulations. A Clinical Research Coordinator must hold a degree in a health-related field that includes specific instruction in content related to clinical research trials (i.e. biostatistics, healthcare management, epidemiology, and human anatomy).

**3. If you do not have a major in this field, explain how the proposed certificate relates to your university mission and strategic plan, and to the current Board of Regents Strategic Plan 2014-2020.**

*Links to the applicable State statute, Board Policy, and the Board of Regents Strategic Plan are listed below for each campus.*

BHSU:	<a href="#">SDCL § 13-59</a>	<a href="#">BOR Policy 1:10:4</a>
DSU:	<a href="#">SDCL § 13-59</a>	<a href="#">BOR Policy 1:10:5</a>
NSU:	<a href="#">SDCL § 13-59</a>	<a href="#">BOR Policy 1:10:6</a>
SDSMT:	<a href="#">SDCL § 13-60</a>	<a href="#">BOR Policy 1:10:3</a>
SDSU:	<a href="#">SDCL § 13-58</a>	<a href="#">BOR Policy 1:10:2</a>
USD:	<a href="#">SDCL § 13-57</a>	<a href="#">BOR Policy 1:10:1</a>

[Board of Regents Strategic Plan 2014-2020](#)

This certificate will serve the strategic plans of the SHS and BOR by meeting goals for student success and workforce development. A review of the 4-state region (SD, IA, MN, NE) identified only one institution that offers a Clinical Research certificate program. That program is on campus and requires 14 credits. The proposed certificate at USD would be 100% online and 12 credits. The certificate will prepare learners for in-demand positions and for positions that will be needed to meet the 3,000 hours of professional experience for the Certified Clinical Research Coordinator (CCRC) and Certified Clinical Research Associate (CCRA) exams through the Academy of Clinical Research Professionals (ACRP). Students with this educational training will graduate with a skillset that is in demand and provides a salary in the middle-income bracket. As they gain experience, they will be well positioned for job placement in higher level positions and income potential.

**4. Provide a justification for the certificate program, including the potential benefits to students and potential workforce demand for those who graduate with the credential. For workforce related information, please provide data and examples. Data may include, but are not limited to the South Dakota Department of Labor, the US Bureau of Labor Statistics, Regental system dashboards, etc. Please cite any sources in a footnote.**

The Research Coordinator Certificate will be a 12-credit undergraduate certificate that would meet all six of the knowledge criteria to prepare the learner to work as a Clinical Research Coordinator (CRC) or Clinical Research Associate (CRA). After completing 3,000 hours of professional experience, the learner would be eligible to sit for the CCRC or CCRA exam through the Association of Clinical Research Professionals (ACRP; <https://acrpnet.org/>). The proposed start date for the certificate is Spring 2023.

ACRP definitions:

*A CRC (clinical research coordinator) works at a clinical research site, with study subjects, under the immediate direction of a principal investigator, whose research activities are conducted under Good Clinical Practice guidelines.*

*A CRA (clinical research associate; also commonly known as a monitor) supervises, monitors, and supports the administration and progress of a clinical trial on behalf of a sponsor. The sponsor, whose intent is the research of pharmaceuticals, biologics, or devices, may employ these individuals either directly or indirectly via contract research organizations (CROs), or as independent consultants or contractors.*

This certificate will be delivered in collaboration with a clinical partner. USD, in collaboration with the clinical partner, will seek federal funding to support the program. There is a proposed funding agreement through the clinical partner if the grant funding is not received.

Our clinical partner employs over 50 research coordinators per year systemwide. The clinical research partner currently has clinical trials underway in South Dakota in the following research areas: cancer, children's health, women's health, diabetes/thyroid, gastrointestinal, genitourinary, heart, infectious disease, neonatology, neurology, orthopedics and trauma. The current regional workforce demand in this and related fields is expected to grow 14.4% in the next 10 years with ~5,000 annual openings (Lightcast, 2022).

A search on 7.19.2022 of the South Dakota Department of Labor & Regulation job search website yielded 14 open positions (using variation of clinical research coordinator and clinical research associate). These positions had been posted from 3 to 57 weeks ago. The same search on a national recruiting site yielded 9,094 open positions (not 100% were specific to a clinical research coordinator/associate, but a review of the listing identified a significant majority were applicable). The estimated average salary for a clinical research coordinator is \$66,437 (salary.com). A regional entry-level salary range provided by USD's clinical partner was \$50,960 - \$57,200 depending upon qualifications.

- Indeed (2022). *Clinical research associate*. <https://www.indeed.com/jobs?q=clinical%20research%20associate&l&vjk=675f549b85fbf310>
- Lightcast (2022). *Program overview: Clinical research coordinator*. [www.economicmodeling.com](http://www.economicmodeling.com)
- Salary.com (2022). *Clinical research coordinator salary in the United States*. <https://www.salary.com/research/salary/benchmark/clinical-research-coordinator-salary>
- South Dakota Department of Labor & Regulation (2022). *SDWORKS*. <https://www.southdakotaworks.org/vosnet/Default.aspx>

**5. Who is the intended audience for the certificate program (including but not limited to the majors/degree programs from which students are expected)?**

Students in all programs in the School of Health Sciences could benefit from this certificate program. Our clinical partner has expressed a need to train a workforce for their increasing demand, which would include their own current employees and employees of their international partners. It will be delivered 100% online to provide access to current USD students, healthcare practitioners in the workforce, students at the SD Technical Colleges, and international partners.

## 6. Certificate Design

- A. Is the certificate designed as a stand-alone education credential option for students not seeking additional credentials (i.e., a bachelor's or master's degree)? If so, what areas of high workforce demand or specialized body of knowledge will be addressed through this certificate?**

This certificate could benefit individuals currently in the workforce who want to increase their job skills and marketability in their healthcare field. Offering the certificate 100% online will allow working individuals to receive the training while maintaining their current employment. The certificate is designed to meet the 6 criteria of knowledge needed to be successful on the Certified Clinical Research Coordinator or Certified Clinical Research Associate exams:

1. Scientific concepts and research design
2. Ethical and participant safety considerations
3. Product development and regulation
4. Clinical trial operations (GCPs)
5. Study and site management
6. Data management and informatics

- B. Is the certificate a value-added credential that supplements a student's major field of study? If so, list the majors/programs from which students would most benefit from adding the certificate.**

This certificate will add value to any existing student at USD or the South Dakota Technical Colleges by providing an additional skillset that is in demand in the healthcare industry.

- C. Is the certificate a stackable credential with credits that apply to a higher-level credential (i.e., associate, bachelor's, or master's degree)? If so, indicate the program(s) to which the certificate stacks and the number of credits from the certificate that can be applied to the program.**

N/A – this certificate is not designed for stackable credentialing

- 7. List the courses required for completion of the certificate in the table below (if any new courses are proposed for the certificate, please attach the new course requests to this form).**

Prefix	Number	Course Title	Prerequisites for Course	Credit Hours	New (yes, no)
HSC	111	Introduction to Research	None	3	No
HSC	450	Patient Safety & Quality Improvement	None	3	No
HSC	498	Undergraduate Research Part I	None	3	Yes
HSC	498	Undergraduate Research Part II	None	3	Yes
Subtotal				12	

As part of the certificate, we are requesting to activate the HSC 498 course. This course will serve as a 2-part course offering to meet the objectives of the certificate. There are no other courses that meet the specific objectives for the CCRC/CCRA exam domains III – VI.

**8. Student Outcome and Demonstration of Individual Achievement.**

*Board Policy 2:23 requires certificate programs to “have specifically defined student learning outcomes.*

**A. What specific knowledge and competencies, including technology competencies, will all students demonstrate before graduation? *The knowledge and competencies should be specific to the program and not routinely expected of all university graduates.***

The certificate is designed to meet the 6 content areas of knowledge required to become a Certified Clinical Research Associate. The courses will provide the student with knowledge in:

1. Scientific concepts and research design
2. Ethical and participant safety considerations
3. Product development and regulation
4. Clinical trial operations (GCPs)
5. Study and site management
6. Data management and informatics

See pages 8 – 10 for complete knowledge statements.

**B. Complete the table below to list specific learning outcomes – knowledge and competencies – for courses in the proposed program in each row. Label each column heading with a course prefix and number. Indicate required courses with an asterisk (\*). Indicate with an X in the corresponding table cell for any student outcomes that will be met by the courses included. All students should acquire the program knowledge and competencies regardless of the electives selected. Modify the table as necessary to provide the requested information for the proposed program.**

Individual Student Outcome	Program Courses that Address the Outcomes			
	HSC 111*	HSC 450*	HSC 498 (I)*	HSC 498 (II)*
Scientific concepts and research design	x			
Ethical and participant safety considerations		x		
Produce development and regulation			x	
Clinical trial operations (GCPs)			x	
Study and site management				x
Data management and informatics				x

*Modify the table as necessary to include all student outcomes. Outcomes in this table are to be the same ones identified in the text.*

**9. Delivery Location.**

*Note: The accreditation requirements of the Higher Learning Commission (HLC) require Board approval for a university to offer programs off-campus and through distance delivery.*

**A. Complete the following charts to indicate if the university seeks authorization to deliver the entire program on campus, at any off campus location (e.g., USD Community College for Sioux Falls, Black Hills State University-Rapid City, Capital City Campus, etc.) or deliver the entire program through distance technology (e.g., as an on-line program)?**

	Yes/No	Intended Start Date
<b>On campus</b>	No	

	Yes/No	If Yes, list location(s)	Intended Start Date
<b>Off campus</b>	No		

	Yes/No	If Yes, identify delivery methods <i>Delivery methods are defined in <a href="#">AAC Guideline 5.5</a>.</i>	Intended Start Date
<b>Distance Delivery (online/other distance delivery methods)</b>	Yes	015 – Internet Asynchronous – Term based instruction 018 – Internet Synchronous	<b>Spring 2023</b>
<b>Does another BOR institution already have authorization to offer the program online?</b>	No	<b>If yes, identify institutions:</b>	

**B. Complete the following chart to indicate if the university seeks authorization to deliver more than 50% but less than 100% of the certificate through distance learning (e.g., as an on-line program)? This question responds to HLC definitions for distance delivery.**

	Yes/No	If Yes, identify delivery methods	Intended Start Date
<b>Distance Delivery (online/other distance delivery methods)</b>	No		

## 10. Additional Information: