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SEP 15 2020
WCHHS
Office of the Dean

COLLEGE OF GRADUATE STUDIES AND RESEARCH
REVISION OF EXISTING DEGREE OR CERTIFICATE PROGRAM

Name of program	Master of Science in Health Sciences (MSHS)
Department or School or College	Public Health and Healthcare Leadership Department (Waldron College)

Contact Person:

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Indicate type(s) of revision:
____Change in catalog description ____Change in course requirements ____Add/modify/delete subarea ____Change in total credit hours ____ Delete program __X__Other(s) describe Addition of a concentration

Consult with SCHEV liaison regarding SCHEV reporting or review	_X_ not needed ___ report as simple modification ___ submit proposal for approval as a substantial modification
Consult with SACS liaison regarding SACS reporting or review	_X_ not needed ___ submit letter of notifications ___ submit substantive change prospectus

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Proposal Description with Rationale: Include the current language and use track changes to indicate proposed changes. Explain why the change is desired.

Excerpts from the attached concept document

Clinical research provides vital information for medical advancement in disease prevention, detection, and treatment. In the past 10 years, there has been a 286% increase in registered studies on ClinicalTrials.gov with studies currently listed in all 50 states and 209 countries (ClinicalTrials.gov, 2019). The global clinical trials market size is projected to be worth $68.9 billion by 2026 (Grand View Research, 2019) and the contract research organization industry is expected to grow by at least 50% in the next five years with its market value soaring to $553 million in 2024 (Reuters, 2019).

In addition to healthcare professionals and research scientists, clinical research associates (CRAs) have become an integral member of the research team. Research team members and CRAs work in partnership to coordinate, implement, manage, and evaluate a clinical study. Based on workforce need and minimal competition from other public four-year institutions in Virginia, an opportunity exists for Radford University Carilion (RUC) to create a Clinical Research Administration concentration in the Master of Science in Health Sciences program that will help to fill the regional and national shortage of CRAs and other clinical research administration professionals.

RUC offers an online, 36 credit, Master of Science in Health Sciences (MSHS) program that provides students with a broad-based education in the health sciences. Students who follow the plan of study can complete the MSHS degree in as little as four semesters and then pursue a variety of careers in the health sciences or opt to further their education. There is a clear and essential need for clinical research professionals in the workforce; therefore, a MSHS with a concentration in Clinical Research Administration (MSHS-CRA) can provide graduates to fulfill industry needs for clinical research professionals. A student earning a MSHS-CRA degree will have both the knowledge and culminating experiences to make him/her competitive for CRA positions and be proficient in the core competencies needed for certification in clinical research.

The CRA core competency areas for both the Association of Clinical Research Professionals (ACRP) certification exam and Commission on Accreditation of Allied Health Education Programs (CAAHEP) accreditation can be met by modifying the current MSHS plan of study and incorporating courses in clinical research administration.

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Signatures

Signature	Title	Date
	Department Curriculum Committee Chair	8/28/2020
	Department Chair (on behalf of faculty)	8/28/20
	College Curriculum Committee Chair	9/11/20
	College Dean	9/16/2020
	Graduate College Dean (on behalf of the Graduate Affairs Council)	
	Provost	

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Approval/recommendation pathway:

Department Curriculum Committee (if for one discipline)
College Curriculum Committee
College Dean
Academic Course and Program Review
Graduate Affairs Council
Faculty Senate (recommendation)
Provost
SCHEV if required
SACS if required

Instructions:

- Indicate the type of change in the current degree program that is requested. The proposal can include more than one change in a program.
- Consult with the SCHEV liaison to determine if the proposed program revision would require notifying SCHEV of the change or SCHEV approval. The current SCHEV liaison is George Santopietro, Assistant Provost for Academic Operations, gsantopi@radford.edu x5460.
- Consult with the SACS liaison to determine if the proposed program revision would require notifying SACS of the change or SACS approval. The current SACS liaison is Sandra Baker, Director of the Office of Institutional Effectiveness and Quality Improvement, sbaker10@radford.edu x5792.
- Attach graduate proposal signature page.

MSHS-CRA Concentration: Plan of Study

MSHS vs. MSHS-CRA Summary

MSHS Required Courses (36 credits)	MSHS-CRA Required Courses (36 credits)
HADM 507: Ethical & Legal Practice in Healthcare	HADM 520: Advanced Health Information Systems
HADM 520: Advanced Health Information Systems	HADM 530: Organizational Theories & Leadership
HADM 530: Organizational Theories & Leadership	HADM 620: Strategic Healthcare Economics & Policy
HADM 550: Research Methods & Analysis	HSCI 501: Professional Communication in Healthcare
HADM 620: Strategic Healthcare Economics & Policy	HSCI 620: Epidemiology for Health Sciences
HSCI 501: Professional Communication in Healthcare	HSCI 650: Health Analytics
HSCI 620: Epidemiology for Health Sciences	PBHL 600: Population Health
HSCI 650: Health Analytics	
HSCI 690: Culminating Experience	**CRA Track Courses (15 credits)**
PBHL 600: Population Health	HSCR 555: Clinical Research Methods
PBHL 710: Occupational & Environmental Health	HSCR 565: Clinical Research Administration I
Elective (500-600 level)	HSCR 575: Clinical Research Administration II
	HSCR 635: Medical Product Development & Regulation
	HSCR 695: Clinical Research Administration Internship

Both MSHS and MSHS-CRA courses

MS Health Sciences: Clinical Research Administration Concentration (Plan of Study)

PREFIX	COURSE TITLE	CREDITS
	Semester 1: Fall	
HSCI 501	Communication in Healthcare Administration	3
PBHL 600	Population Health	3
HADM 520	Advanced Health Information Systems	3
HSCR 555	Clinical Research Methods	3
	Total Credits	**12**
	Semester 2: Spring	
HADM 620	Strategic Healthcare Economics and Policy	3
HADM 530	Organizational Theories and Leadership	3
HSCR 565	Clinical Research Administration I	3
	Total Credits	**9**
	Semester 3: Summer	
HSCI 650	Health Analytics	3
HSCR 575	Clinical Research Administration II	3
HSCR 635	Medical Product Development and Regulation	3
	Total Credits	**9**
	Semester 4: Fall	
HSCI 620	Epidemiology for Health Sciences	3
HSCI 695	Clinical Research Administration Internship	3
	Total Credits	**6**
	Total Credits	**36**

RUC MSHS-CRA Courses with Associated CRA Core Competencies

HSCR 555: Clinical Research Methods

1. Identify clinically important questions that are potentially testable clinical research hypothesis, through review of the professional literature
2. Explain the elements (statistical, epidemiological and operational) of a clinical or translational study design
3. Describe the component parts of a traditional scientific publication
4. Compare the requirements for human subject protection and privacy under different national and international regulations and ensures their implementation throughout all phases of a clinical study
5. Explain the evolution of the requirement for informed consent from research participants and the principles and content of the key documents which ensure the protection of human participants in clinical research.
6. Describe the ethical issues involved when dealing with vulnerable populations and the need for additional safeguards
7. Explain how inclusion and exclusion criteria are included in a clinical protocol to assure human subject protection

HSCR 565: Clinical Research Administration I (Clinical Trial Operations)

1. Summarize the principles and methods of distributing and balancing risk and benefit through selection and management of the clinical trial subject
2. Compare and contrast clinical care and clinical management of research participants
3. Evaluate the conduct and management of clinical trials within the context of a Clinical Development Plan
4. Describe the roles and responsibilities of the clinical investigation team as defined by Good Clinical Practice Guidelines
5. Evaluate the design conduct and documentation of clinical trials as required for compliance with Good Clinical Practice Guidelines
6. Compare and contrast the regulations and guidelines of global regulatory bodies relating to the conduct of clinical trials
7. Differentiate the types of adverse events which occur during clinical trials, understand the identification process for adverse events and describe the reporting requirements to institutional review boards/institutional ethics committees, sponsors and regulatory authorities
8. Describe how global regulations and guidelines assure human subjects protection and privacy during the conduct of clinical trials
9. Describe the reporting requirements of global regulatory bodies relating to clinical trial conduct
10. Describe the role and process for monitoring of the study
11. Describe the roles and purpose of clinical trial audits
12. Describe the various methods by which safety issues are identified and managed during the development and post-marketing phases of clinical research
13. Define the concepts of "clinical equipoise" and "therapeutic misconception" as they relate to the conduct of a clinical trial

HSCR 575: Clinical Research Administration II (Study and Site Management)

1. Design a clinical trial
2. Describe the methods utilized to determine whether or not to sponsor, supervise or participate in a clinical trial
3. Develop and manage the financial, timeline and cross-disciplinary personnel resources necessary to conduct a clinical or translational research study
4. Apply management concepts and effective training methods to manage risk and improve quality in the conduct of a clinical research study
5. Utilize elements of project management related to organization of the study site to manage patient recruitment, complete procedures and track progress
6. Identify the legal responsibilities, issues, liabilities and accountability that is involved in the conduct of a clinical trial
7. Identify and explain the specific procedural, documentation and oversight requirements of principal investigators, sponsors, contract research organizations (CRO) and regulatory authorities which relate to the conduct of a clinical trial
8. Identify and implement procedures for the prevention or management of the ethical and professional conflicts that are associated with the conduct of clinical research
9. Identify and apply the professional guidelines and codes of ethics which apply to the conduct of clinical research
10. Describe the impact of cultural diversity and the need for cultural competency in the design and conduct of clinical research

HSCR 635: Medical Product Development and Regulation

1. Demonstrate knowledge of pathophysiology, pharmacology and toxicology as they relate to medicines discovery and development
2. Critically analyze study results with an understanding of therapeutic and comparative effectiveness
3. Evaluate and apply an understanding of the past and current ethical issues, cultural variation and commercial aspects on the medicines development process
4. Discuss the historical events which precipitated the development of governmental regulatory processes for drugs, devices and biologicals
5. Describe the roles and responsibilities of the various institutions participating in the medicines development process
6. Explain the medicines development process and the activities which integrate commercial realities into the life cycle management of medical products
7. Summarize the legislative and regulatory framework which supports the development and registration of medicines, devices and biological and ensures their safety, efficacy and quality
8. Describe the specific processes and phases which must be followed in order for the regulatory authority to approve the marketing authorization for a medical product
9. Describe the safety reporting requirements of regulatory agencies both pre and post approval
10. Appraise the issues generated and the effects of global expansion on the approval and regulation of medical products
11. Describe appropriate control, storage and dispensing of investigational product

HSCR 695: Clinical Research Administration Internship (120 or 240 hours)

1. Discuss the relationship and appropriate communication between Sponsor, CRO and clinical research site
2. Effectively communicate the content and relevance of clinical research findings to colleagues, advocacy groups and the non-scientist community
3. Describe methods necessary to work effectively with multidisciplinary and inter-professional research teams

HSCI 650: Health Analytics ***(Note: May need to revise syllabus)***

1. Describe the role that biostatistics and informatics serve in biomedical and public health research
2. Describe the typical flow of data throughout a clinical trial
3. Summarize the process of electronic data capture (EDC) and the importance of information technology in data collection, capture and management
4. Describe the International Conference on Harmonisation (ICH) Good Clinical Practice Guideline (GCP) requirements for data correction and queries
5. Describe the significance of data quality assurance systems and how standard operating procedures (SOPs) are used to guide these processes

HADM 530: Organizational Theories and Leadership

1. Describe the principles and practices of leadership, management and mentorship, and apply them within the working environment

HADM 520: Advanced Health Information Systems

1. Summarize the process of electronic data capture (EDC) and the importance of information technology in data collection, capture and management

MSHS-CRA Concentration: Course-Core Competencies Mapping

1. Scientific Concepts and Principles of Research Design

Learning Outcomes	*MSHS-CRA Course*	*Outcome #*
a. Demonstrate knowledge of pathophysiology, pharmacology and toxicology as they relate to medicines discovery and development	HSCR 635	1
b. Identify clinically important questions that are potentially testable clinical research hypothesis, through review of the professional literature	HSCR 555	1
c. Explain the elements (statistical, epidemiological and operational) of a clinical or translational study design	HSCR 555	2
d. Design a clinical trial	HSCR 575	1
e. Critically analyze study results with an understanding of therapeutic and comparative effectiveness	HSCR 635	2

2. Ethical and Participant Safety Considerations

Learning Outcomes	*MSHS-CRA Course*	*Outcome #*
a. Compare and contrast clinical care and clinical management of research participants	HSCR 565	2
b. Define the concepts of "clinical equipoise" and "therapeutic misconception" as they relate to the conduct of a clinical trial	HSCR 565	13
c. Compare the requirements for human subject protection and privacy under different national and international regulations and ensures their implementation throughout all phases of a clinical study	HSCR 555	4
d. Explain the evolution of the requirement for informed consent from research participants and the principles and content of the key documents which ensure the protection of human participants in clinical research	HSCR 555	5
e. Describe the ethical issues involved when dealing with vulnerable populations and the need for additional safeguards	HSCR 555	6
f. Evaluate and apply an understanding of the past and current ethical issues, cultural variation and commercial aspects on the medicines development process	HSCR 635	3
g. Explain how inclusion and exclusion criteria are included in a clinical protocol to assure human subject protection	HSCR 555	7
h. Summarize the principles and methods of distributing and balancing risk and benefit through selection and management of the clinical trial subject	HSCR 565	1

3. Medicines Development and Regulation

Learning Outcomes	*MSHS Course*	*Outcome #*
a. Discuss the historical events which precipitated the development of governmental regulatory processes for drugs, devices and biologicals	HSCR 635	4
b. Describe the roles and responsibilities of the various institutions participating in the medicines development process	HSCR 635	5
c. Explain the medicines development process and the activities which integrate commercial realities into the life cycle management of medical products	HSCR 635	6
d. Summarize the legislative and regulatory framework which supports the development and registration of medicines, devices and biological and ensures their safety, efficacy and quality	HSCR 635	7
e. Describe the specific processes and phases which must be followed in order for the regulatory authority to approve the marketing authorization for a medical product	HSCR 635	8
f. Describe the safety reporting requirements of regulatory agencies both pre and post approval	HSCR 635	9
g. Appraise the issues generated and the effects of global expansion on the approval and regulation of medical products	HSCR 635	10

4. Clinical Trial Operations

Learning Outcomes	*MSHS Course*	*Outcome #*
a. Evaluate the conduct and management of clinical trials within the context of a Clinical Development Plan	HSCR 565	3
b. Describe the roles and responsibilities of the clinical investigation team as defined by Good Clinical Practice Guidelines	HSCR 565	4
c. Evaluate the design conduct and documentation of clinical trials as required for compliance with Good Clinical Practice Guidelines	HSCR 565	5
d. Compare and contrast the regulations and guidelines of global regulatory bodies relating to the conduct of clinical trials	HSCR 565	6
e. Describe appropriate control, storage and dispensing of investigational product	HSCR 635	11
f. Differentiate the types of adverse events which occur during clinical trials, understand the identification process for adverse events and describe the reporting requirements to institutional review boards/institutional ethics committees, sponsors and regulatory authorities	HSCR 565	7
g. Describe how global regulations and guidelines assure human subjects protection and privacy during the conduct of clinical trials	HSCR 565	8
h. Describe the reporting requirements of global regulatory bodies relating to clinical trial conduct	HSCR 565	9
i. Describe the role and process for monitoring of the study	HSCR 565	10
j. Describe the roles and purpose of clinical trial audits	HSCR 565	11
k. Describe the various methods by which safety issues are identified and managed during the development and post-marketing phases of clinical research	HSCR 565	12

5. Study and Site Management

Learning Outcomes	*MSHS Course*	*Outcome #*
a. Describe the methods utilized to determine whether or not to sponsor, supervise or participate in a clinical trial	HSCR 575	2
b. Develop and manage the financial, timeline and cross-disciplinary personnel resources necessary to conduct a clinical or translational research study	HSCR 575	3
c. Apply management concepts and effective training methods to manage risk and improve quality in the conduct of a clinical research study	HSCR 575	4
d. Utilize elements of project management related to organization of the study site to manage patient recruitment, complete procedures and track progress	HSCR 575	5
e. Identify the legal responsibilities, issues, liabilities and accountability that is involved in the conduct of a clinical trial	HSCR 575	6
f. Identify and explain the specific procedural, documentation and oversight requirements of principal investigators, sponsors, contract research organizations (CRO) and regulatory authorities which relate to the conduct of a clinical trial	HSCR 575	7

6. Data Management and Informatics

Learning Outcomes	*MSHS Course*	*Outcome #*
a. Describe the role that biostatistics and informatics serve in biomedical and public health research	HSCI 650	1
b. Describe the typical flow of data throughout a clinical trial	HSCI 650	2
c. Summarize the process of electronic data capture (EDC) and the importance of information technology in data collection, capture and management	HSCI 650 *(and HADM 520)*	3
d. Describe the International Conference on Harmonisation (ICH) Good Clinical Practice Guideline (GCP) requirements for data correction and queries	HSCI 650	4
e. Describe the significance of data quality assurance systems and how standard operating procedures (SOPs) are used to guide these processes	HSCI 650	5

7. Leadership and Professionalism

Learning Outcomes	*MSHS Course*	*Outcome #*
a. Describe the principles and practices of leadership, management and mentorship, and apply them within the working environment	HADM 530	1
b. Identify and implement procedures for the prevention or management of the ethical and professional conflicts that are associated with the conduct of clinical research	HSCR 575	8
c. Identify and apply the professional guidelines and codes of ethics which apply to the conduct of clinical research	HSCR 575	9
d. Describe the impact of cultural diversity and the need for cultural competency in the design and conduct of clinical research	HSCR 575	10

8. Communication and Teamwork

Learning Outcomes	*MSHS Course*	*Outcome #*
a. Discuss the relationship and appropriate communication between Sponsor, CRO and clinical research site	HSCR 695	1
b. Describe the component parts of a traditional scientific publication	HSCR 555	3
c. Effectively communicate the content and relevance of clinical research findings to colleagues, advocacy groups and the non-scientist community	HSCR 695	2
d. Describe methods necessary to work effectively with multidisciplinary and inter-professional research teams	HSCR 695	3

Moving from Compliance to Competency: A Harmonized Core Competency Framework for the Clinical Research Professional

PEER REVIEWED | Stephen A. Sonstein, PhD | Jonathan Seltzer, MD, MBA, MA, FACC | Rebecca Li, PhD | Honorio Silva, MD | Carolynn Thomas Jones, DNP, MSPH, RN | Esther Daemen, BSN, PG, PMP, MBA

[DOI: 10.14524/CR-14-00002R1.1]; Clinical Researcher, June 2014

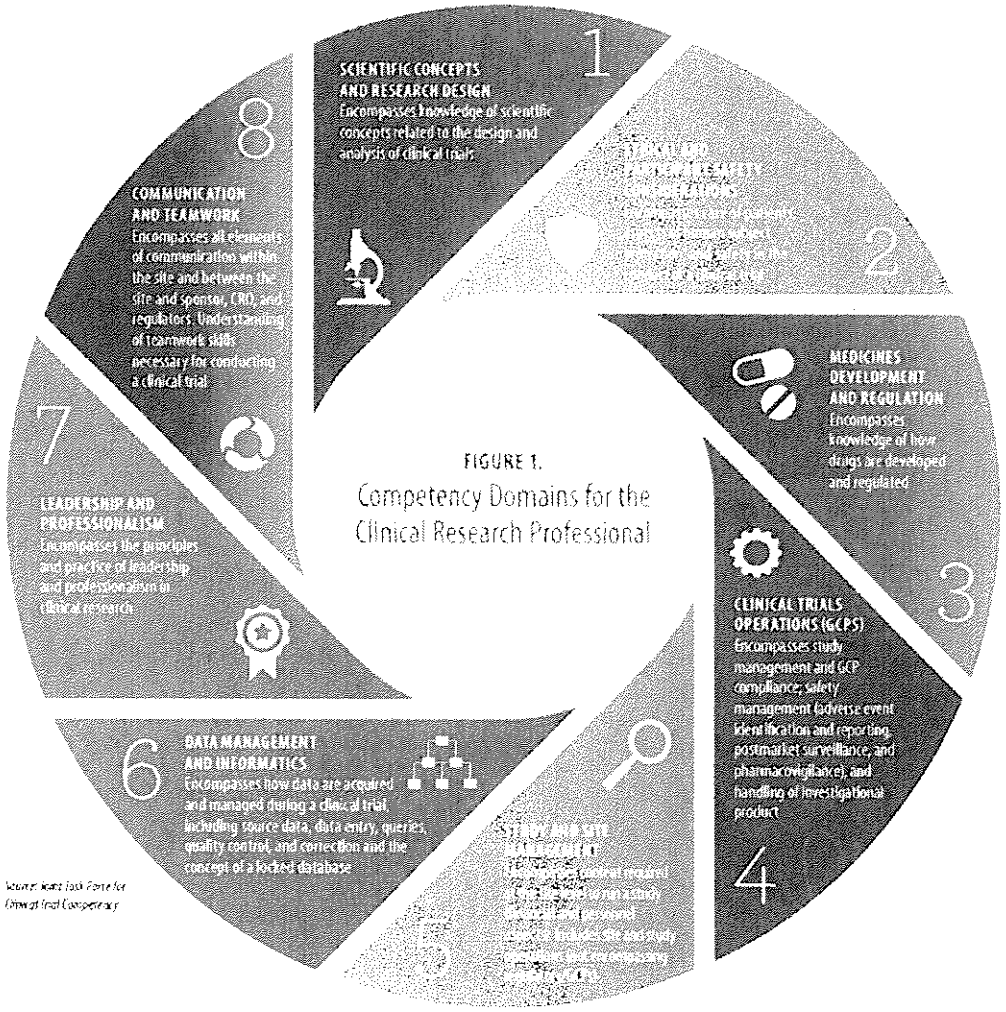

FIGURE 1.
Competency Domains for the Clinical Research Professional

Source: Joint Task Force for Clinical Trial Competency

Master of Science in Health Sciences
Clinical Research Administration Concentration

Introduction

Clinical research provides vital information for medical advancement in disease prevention, detection, and treatment. In the past 10 years, there has been a 286% increase in registered studies on ClinicalTrials.gov with studies currently listed in all 50 states and 209 countries (ClinicalTrials.gov, 2019). The global clinical trials market size is projected to be worth $68.9 billion by 2026 (Grand View Research, 2019) and the contract research organization industry is expected to grow by at least 50% in the next five years with its market value soaring to $553 million in 2024 (Reuters, 2019). In Roanoke and the surrounding southwest Virginia region, the outlook for clinical research growth is noteworthy. For example, the Fralin Biomedical Institute at Virginia Tech Carilion had 28 research teams with over 300 faculty, staff, and students in 2017 (Virginia Polytechnic Institute and State University, 2019) and is expected to add an additional 25 research teams in the upcoming years (Roanoke Times, 2017). As the field of clinical research continues to grow, it can be surmised that the number of supporting jobs will increase in a similar manner; therefore, the Commonwealth of Virginia's higher education institutions must be prepared to meet those clinical research workforce needs through its educational programs.

In addition to healthcare professionals and research scientists, clinical research associates (CRAs) have become an integral member of the research team. Research team members and CRAs work in partnership to coordinate, implement, manage, and evaluate a clinical study. The duties of a CRA can include, but are not limited to, database management, study protocol monitoring, reviewing study site records, ensuring the ethical treatment and protection of study participants, quality assurance, preparing study reports, budget oversight, and staff management (ACRP, 2019). CRAs work in a variety of settings such as pharmaceutical, medical device, and biotechnology companies, academic research centers, hospitals, and consulting firms (DePaulo, P., 2015).

Between 2018 and 2028, healthcare jobs are expected to grow by 14%, creating about 1.9 million new jobs in the field (Bureau of Labor Statistics (BLS), 2019). Medical and health services manager jobs are projected to increase by 18% from 2018 to 2028 and jobs for natural sciences manager are expected to grow by 6% during the same time period. The BLS does not have an occupational listing for clinical research associates or coordinators in its Occupational Outlook Handbook. A recent search (2019, October 25) on Indeed found full-time job postings as follows: "clinical research associate" (648 jobs), "clinical research coordinator" (1,454 jobs) and "clinical research manager" (216 jobs). However, a broader search found greater than 4,300 full-time job postings for a clinical research associate or similar, with over 1,700 being designated for entry-level experience. Within the past 15 days (2019, October 12-27), there were 28 clinical research associate-related job postings in Virginia on Indeed.

Depending on experience, certification, location, and funding, salaries for CRAs can range from around $45,000 to over $100,000 (Indeed; Glassdoor; PayScale; 2019, October 14). In the 2015 Society of Clinical Research Associates (SOCRA) Salary Survey, CRAs had a median salary of $79,569 (DePaulo, P., 2015). A sampling of job postings on Indeed and Glassdoor found that the minimal educational requirement was typically a bachelor's degree in the health

sciences or a related field and having a Clinical Research Associate (CCRA®) or Clinical Research Professional (CCRP®) certification (or eligibility) was desired.

Clinical Research Associate Certification

The Association of Clinical Research Professionals (ACRP) is an industry leader in clinical research workforce development with a mission to "promote excellence in clinical research." ACRP offers six clinical research certifications, including the Certified Clinical Research Associate (CCRA®). Eligibility to sit for the ACRP CRA Certification exam requires documentation of job experience and cumulative performance of CRA essential duties. CRAs with a bachelor's degree or higher need a minimum of 3,000 hours performing essential CRA duties. However, ACRP will substitute 1,500 hours of CRA work experience if the individual has graduated from a Council for Higher Education accredited program in clinical research. The ACRP CRA certification exam requires demonstrated proficiency in six core knowledge areas: 1) Scientific Concepts and Research Design; 2) Ethical and Participant Safety Considerations; 3) Product Development and Regulation; 4) Clinical Trial Operations; 5) Study and Site Management; and 6) Data Management and Informatics.

After passing the ACRP CRA Certification exam, the CRA will be credentialed as a Certified Clinical Research Associate (CCRA®). Some of the benefits of being a CCRA® include career advancement opportunities, higher salary, increased job responsibility, and recognition in clinical research. There are benefits to employing staff with a certification in clinical research. From a business perspective, ACRP certification results in higher enrollment rates, improved regulatory compliance, decreased warnings, and fewer protocol deviations (ACRP, 2019).

Educational Programs in Clinical Research

With recommendation from the Committee on Accreditation of Academic Programs in Clinical Research (CAAPCR), educational programs in clinical research are accredited by the Commission on Accreditation of Allied Health Education Programs (CAAHEP). CAAHEP is recognized by the Council for Higher Education Accreditation (CHEA) and accredits over 2200 programs in 32 health sciences professions (CAAHEP, 2019). The Consortium of Academic Programs in Clinical Research has established eight competency domains and quality standards for clinical research educational programs. For a clinical research educational program to be accredited by CAAHEP, the program must demonstrate learning outcomes in all six ACRP core knowledge areas, plus in the areas of Leadership and Professionalism and Communication and Teamwork (CAAHEP, 2017).

In November 2019, there were six universities who were in the application/self-study process for CAAPCR accreditation (S. Sonstein, personal communication, November 5, 2019). At present, Arizona State University has an accredited Master of Science in Clinical Research Management and graduate certificate in Clinical Research Management and Durham Technical Community College has an accredited associate degree in Clinical Trials Research (CAAHEP, 2020, February 25). A review of undergraduate and graduate degree programs in the Commonwealth of Virginia's four-year public institutions was conducted to determine the

number and type of health/clinical research degrees offered by these institutions. Health or clinical research-related degrees are offered by the following:

University of Virginia	M.S. Clinical Research (31 credits)
George Mason University	Ph.D. Health Services Research (72 credits)
Old Dominion University	Ph.D. Health Services Research (60 credits after masters)
Virginia Commonwealth University	M.S. Clinical and Translational Sciences *(only open to VCU scholar-researchers)*
Virginia Tech	M.S. & Ph.D. Translational Biology, Medicine, and Health (M.S., 38 credits; Ph.D., 100 credits)

While the degrees listed above are related to health or clinical research, none of the programs appeared to have a curriculum that addresses all the core competencies required for CAAHEP accreditation and the ACRP CRA certification exam. Based on workforce need and minimal competition from other public four-year institutions in Virginia, an opportunity exists for Radford University Carilion (RUC) to create a Clinical Research Administration concentration in the Master of Science in Health Sciences program that will help to fill the regional and national shortage of CRAs and other clinical research administration professionals.

M.S. Health Sciences, Clinical Research Administration Concentration

RUC offers an online, 36 credit, Master of Science in Health Sciences (MSHS) program that provides students with a broad-based education in the health sciences. Students who follow the plan of study can complete the MSHS degree in as little as four semesters and then pursue a variety of careers in the health sciences or opt to further their education. There is a clear and essential need for clinical research professionals in the workforce; therefore, a MSHS with a concentration in Clinical Research Administration (MSHS-CRA) can provide graduates to fulfill industry needs for clinical research professionals. A student earning a MSHS-CRA degree will have both the knowledge and culminating experiences to make him/her competitive for CRA positions and be proficient in the core competencies needed for certification in clinical research.

The CRA core competency areas for both the ACRP certification exam and CAAHEP accreditation can be met by modifying the current MSHS plan of study and incorporating courses in clinical research administration. The MSHS-CRA draft plan of study (36 credits, 4-semesters) includes the following courses (15 credits total): Clinical Research I & II, Clinical Research Administration I & II, and Medical Product Development and Regulation. (See Appendices A-C) The curriculum will be evaluated annually for adherence to core competencies, student recruitment and retention, graduation rates, job placement, and attainment of CCRA® or other certification in clinical research, such as SOCRA's CCRP®. Further exploration into the MSHS-CRA concentration is needed before it can be determined if this will constitute a substantive change, what additional resources maybe needed to apply for CAAHEP accreditation, the impact on faculty workloads, and whether or not a graduate certificate in clinical research administration and/or 4+1 program should also be offered.

The MSHS-CRA program will be housed in the Department of Public Health and Healthcare Leadership (PHHL) within the Waldron College of Health and Human Services. PHHL offers three undergraduate and three graduate programs at RUC: B.S. Health Sciences, B.S. Public Health, B.S. Healthcare Administration, M.S. Health Sciences, Doctor of Health Sciences, and Master of Healthcare Administration. The PHHL department has eight doctorally prepared faculty, one faculty who is a doctoral candidate, and at least eight adjunct faculty with doctoral degrees. One PHHL faculty is a Certified Clinical Research Professional (CCRP®) and has experience as a clinical projects manager; however, no PHHL faculty are a CCRA®.

All MSHS courses will be taught by doctorally prepared faculty with expertise in the field of study. Currently, the PHHL department has faculty credentialed to teach all of the courses in the MSHS plan of study. Faculty outside of the PHHL department may be needed, though, to teach the core competency courses in the MSHS-CRA, such Clinical Research I & II and Clinical Research Administration I & II. It is recommended that a review be conducted to determine which Radford University and Radford University Carilion faculty have the credentials and experience to teach courses in clinical research administration. The results of this review can then be used to better estimate if any additional funding is needed to cover faculty overload or adjunct faculty pay to teach the specific courses in clinical research administration. Other than the possible need for additional funding for faculty pay, it is not anticipated that there will be any other costs above and beyond what is typically needed to deliver an online course in the MSHS plan of study.

Due to the anticipated and substantial growth in clinical research in the United States and globally, there is a justifiable concern that the shortage of clinical research professionals will be compounded even further. By offering a Master of Science in Health Sciences with a concentration in Clinical Research Administration, Radford University has the opportunity to become a regional and national leader in clinical research education, to potentially be one of the few CAAHEP accredited programs in clinical research in the nation, and to help fill the workforce needs for clinical research associates and professionals in the years to come.

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Appendix A

Comparison of M.S. in Health Sciences (MSHS) and M.S. in Health Sciences-Clinical Research Administration Concentration (MSHS-CRA)

Option 1

MSHS Required Courses (36 credits)	MSHS-CRA Required Courses (36 credits)
HADM 520: Advanced Health Information Systems	HADM 520: Advanced Health Information Systems
HADM 530: Organizational Theories & Leadership	HADM 620: Strategic Healthcare Economics & Policy
HADM 550: Research Methods & Analysis	HSCI 501: Professional Communication in Healthcare
HADM 620: Strategic Healthcare Economics & Policy	HSCI 620: Epidemiology for Health Sciences
HSCI 501: Professional Communication in Healthcare	HSCI 650: Health Analytics
HSCI 620: Epidemiology for Health Sciences	HSCI 690: Culminating Experience
HSCI 650: Health Analytics	PBHL 600: Population Health
HSCI 690: Culminating Experience	**CRA Track Courses (15 credits)**
IPEH 607: Ethical & Legal Practice in Healthcare	HSCR 5XX: Clinical Research Methods I
PBHL 600: Population Health	HSCR 5XX: Clinical Research Methods II
PBHL 710: Occupational & Environmental Health	HSCR 5XX: Clinical Research Administration I
Elective (500-level or higher)	HSCR 5XX: Clinical Research Administration II
	HSCR 6XX: Medical Product Development & Regulation

Option 2

MSHS Required Courses (36 credits)	MSHS-CRA Required Courses (36 credits)
HADM 520: Advanced Health Information Systems	HADM 520: Advanced Health Information Systems
HADM 530: Organizational Theories & Leadership	HADM 620: Strategic Healthcare Economics & Policy
HADM 550: Research Methods & Analysis	HSCI 501: Professional Communication in Healthcare
HADM 620: Strategic Healthcare Economics & Policy	HSCI 620: Epidemiology for Health Sciences
HSCI 501: Professional Communication in Healthcare	HSCI 650: Health Analytics
HSCI 620: Epidemiology for Health Sciences	HSCI 690: Culminating Experience
HSCI 650: Health Analytics	PBHL 600: Population Health
HSCI 690: Culminating Experience	Elective (500-level or higher)
IPEH 607: Ethical & Legal Practice in Healthcare	**CRA Track Courses (12 credits)**
PBHL 600: Population Health	HSCR 5XX: Clinical Research Methods
PBHL 710: Occupational & Environmental Health	HSCR 5XX: Clinical Research Administration I
Elective (500-level or higher)	HSCR 5XX: Clinical Research Administration II
	HSCR 6XX: Medical Product Development & Regulation

Option 3

MSHS Required Courses (36 credits)	MSHS-CRA Required Courses (36 credits)
HADM 520: Advanced Health Information Systems	HADM 520: Advanced Health Information Systems
HADM 530: Organizational Theories & Leadership	HADM 530: Organizational Theories & Leadership
HADM 550: Research Methods & Analysis	HADM 620: Strategic Healthcare Economics & Policy
HADM 620: Strategic Healthcare Economics & Policy	HSCI 501: Professional Communication in Healthcare
HSCI 501: Professional Communication in Healthcare	HSCI 620: Epidemiology for Health Sciences
HSCI 620: Epidemiology for Health Sciences	HSCI 650: Health Analytics
HSCI 650: Health Analytics	HSCI 690: Culminating Experience
HSCI 690: Culminating Experience	PBHL 600: Population Health
IPEH 607: Ethical & Legal Practice in Healthcare	Elective (500-level or higher)
PBHL 600: Population Health	**CRA Track Courses (9 credits)**
PBHL 710: Occupational & Environmental Health	HSCR 5XX: Clinical Research Methods
Elective (500-level or higher)	HSCR 5XX: Clinical Research Administration I
	HSCR 5XX: Clinical Research Administration II

Appendix B

Master of Science in Health Sciences
Clinical Research Administration Concentration
Plan of Study

Option 1 Example

PREFIX	COURSE TITLE		CREDITS
	Semester 1: Fall		
HSCI 501	Professional Communication in Healthcare		3
PBHL 600	Population Health		3
HSCR 5XX	Clinical Research Methods I		3
HSCR 5XX	Clinical Research Administration I		3
		Total Credits	**12**
	Semester 2: Spring		
HADM 620	Strategic Healthcare Economics and Policy		3
HSCR 5XX	Clinical Research Methods II		3
HSCR 5XX	Clinical Research Administration II		3
		Total Credits	**9**
	Semester 3: Summer		
HSCI 650	Health Analytics		3
HADM 520	Advanced Health Information Systems		3
		Total Credits	**6**
	Semester 4: Fall		
HSCR 6XX	Medical Product Development & Regulation		3
HSCI 620	Epidemiology for Health Sciences		3
HSCI 690	Culminating Experience in Health Sciences		3
		Total Credits	**9**
		Total Credits	**36**

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Signatures

Signature	Title	Date
	Department Curriculum Committee Chair	8/28/2020
	Department Chair (on behalf of faculty)	8/28/20
	College Curriculum Committee Chair	9/11/20
	College Dean	9/16/2020
	Graduate College Dean (on behalf of the Graduate Affairs Council)	12/8/2020
	Provost	

Approval/Recommendation Signature Sheet for Graduate Curriculum Proposals

Signature	Title	Date
	Department Curriculum Committee Chair	
	Department Chair (on behalf of faculty)	
	College Curriculum Committee Chair	
	College Dean	
	Graduate College Dean (on behalf of the Graduate Affairs Council)	
For new majors and certificates:		
	Library Liaison	
For new or discontinued majors, minors, certificates, concentrations, options or significant changes in program requirements:		
	Faculty Senate President following review by the Faculty Senate	
	Provost and VP for Academic Affairs	
For proposals going to BOV, SCHEV and/or SACSCOC:		
	President	
	Board of Visitors approval date	
	SCHEV approval date	
	SACSCOC approval date	
	Entered into catalog by Graduate College	