



College of Health and Human Services  
School of Nursing  
Clinical Research Program

**Student Handbook**  
**for**  
**Clinical Research Students**  
**2024 - 2025**

Bachelor of Science in Clinical Research  
Post-Baccalaureate Certificate in Clinical Research Operations  
Master of Science in  
Clinical Research and Product Development

Updated May 2024

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#### WELCOME FROM THE CLINICAL RESEARCH FACULTY

Welcome to the University of North Carolina Wilmington – Home of the Seahawk!

Thank you for joining the Clinical Research Program as the place that will help you soar! The School of Nursing is one of three schools in the College of Health and Human Services. The Clinical Research Program is in the School of Nursing but is not a nursing degree.

Clinical research is the process by which new medical therapies (e.g., drugs, biological agents, or medical devices) are tested in clinical studies prior to approval for use in a market. Clinical researchers oversee the development, monitoring, and management of clinical studies. Students completing our programs earn either a Bachelor of Science in Clinical Research; Post-Baccalaureate Certificate in Clinical Research Operations; or Master of Science in Clinical Research and Product Development. Our programs are primarily offered in an online format providing our students flexibility in their education.

We invite you to explore our school, our programs, and our faculty on our website and take advantage of our many resources and opportunities.

Again, welcome to the School of Nursing and the Clinical Research Program!

## PREFACE

The purpose of this Student Handbook is to assist students in understanding the policies, procedures, and general information specific to the Clinical Research Program. The Clinical Research Program (CLR Program) is within the School of Nursing (SON), which is one of three schools in the College of Health and Human Services (CHHS) at the University of North Carolina Wilmington (UNCW). The information in this Student Handbook is a supplement to the published current issues of UNCW's [Academic Catalogues](#) and the [Code of Student Life](#).

Successful matriculation and completion or graduation from an academic program in the Clinical Research Program requires adherence to all policies, procedures, and regulations as stipulated by the CLR Program, SON, CHHS, and UNCW. Questions regarding requirements or policies should be referred to the Student Success Center, Academic Advisor, Program Coordinator, School of Nursing Director, or another appropriate person(s).

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The University of North Carolina Wilmington is committed to and will provide equality of educational and employment opportunity for all persons regardless of race, gender, gender identity, sex (such as marital status or pregnancy), age, color, national origin (including ethnicity), religion, disability, sexual orientation, genetic information, political affiliation, veteran status or relationship to other university constituents-except where a protected status represents a bona fide educational or occupational qualification or where marital status is a statutorily established eligibility criterion for state-funded employee benefit programs.

# **1. OVERVIEW**

## **1.1. ORGANIZATION AND HISTORY**

### **1.1.1. SCHOOL OF NURSING**

In the early 1960s, the New Hanover County Commissioners consolidated James Walker Memorial Hospital and Community Hospital creating the New Hanover Memorial Hospital, which has since become New Hanover Regional Medical Center (NHRMC). With the acquisition of Cape Fear Hospital, the current designation as New Hanover Health Network (NHHN) evolved. The New Hanover Memorial Hospital Board of Directors discontinued the diploma nursing programs that had existed at James Walker Memorial Hospital and Community Hospital. In response, county officials requested that Wilmington College establish a two-year associate degree program in nursing. The first Wilmington College nursing class graduated with an Associate of Arts degree in nursing in 1967.

During the 1970s, UNCW initiated plans for a Bachelor of Science program with a concentration in professional nursing. In 1980 a baccalaureate program was recommended to meet the needs of both first-time nursing students and registered nurses wishing to earn a four-year degree. In 1984, the UNC (University of North Carolina) Board of Governors approved establishing the UNCW baccalaureate program in nursing. The curriculum received initial (provisional) approval from the Board of Nursing in June 1984. Having acquired approval from the University of North Carolina System and the North Carolina Board of Nursing, UNCW established the School of Nursing (SON) on July 1, 1984.

### **1.1.2. CLINICAL RESEARCH PROGRAM**

In June 2003, the Office of the President of the University of North Carolina approved the intent to plan the Bachelor of Science in Clinical Research (non-nursing major). The UNCW School of Nursing received funding to support early development of the program from Pharmaceutical Product Development, Inc. (PPD). The following year in Fall 2004, a cohort of five students commenced the program of study. This inaugural class of five students graduated in May 2006 and the second and third cohorts graduated nine in May 2007 and nine in May 2008, respectively. Enrollment has increased steadily in the Clinical Research Program. A clinical research minor was subsequently added to the curriculum. In the spring of 2010, the General Administration of the University of North Carolina approved the proposal to begin a Master of Science (MS) degree in Clinical Research Management and Product Development. The first students in the MS degree enrolled in January 2011. In 2017, a Post-Baccalaureate Certificate in Clinical Research Operations program was added.

### **1.1.3. COLLEGE OF HEALTH AND HUMAN SERVICES**

The School of Nursing moved into a new state-of-the-art building and the building was dedicated as McNeill Hall on April 18, 2011. A task force was charged with examining the state health related programs at UNCW in 2007. The Report of the Task Force on the Future of Health-related Programs at UNCW envisioned the establishment of a College of Health and Human Services (CHHS) to foster a transdisciplinary model. Subsequently, the UNCW Board of Trustees and the UNC Board of Governors established the formation of a CHHS in 2008 and to be operationalized in 2010. An Interim Dean was appointed in 2010 and the Founding Dean, Dr. Charles Hardy, was



appointed July 1, 2011. The CHHS includes the School of Nursing, the School of Health and Applied Human Science, and the School of Social Work. In March 2016, a North Carolina Bond of \$66 million was approved for an Allied Health & Human Services Building.

## **1.2. VISION AND MISSION**

### **1.2.1. UNCW**

**Vision:** UNCW transforms lives.

**Mission:** The University of North Carolina Wilmington, the state's coastal university, integrates teaching and mentoring with research and service. UNCW's commitment to student engagement, creative inquiry, critical thinking, thoughtful expression, and civic responsibility defines the student experience. Graduates of our undergraduate, master's, and doctoral programs are prepared to serve the needs of local, state, and global communities.

### **1.2.2. COLLEGE OF HEALTH AND HUMAN SERVICES**

**Vision:** CHHS will be nationally recognized for our interprofessional and collaborative approach to enhancing the health and quality of life of individuals, families, and communities in southeastern North Carolina and beyond. Our work, based in teaching, research and engagement will advance health knowledge and apply prevention, health promotion/maintenance, and the restoration and enhancement of personal and social well-being.

**Mission:** The mission of CHHS is to enhance health and quality of life across the lifespan for individuals, families, and communities within southeastern North Carolina and beyond through innovation and excellence in workforce development, scholarship, research, professional service, and community engagement. We are committed to the development of health professionals who will practice in a sound, intellectually and ethically accountable fashion and who will commit their practice to the health and well-being of the people of our region.

To accomplish our mission, we are committed to:

- Educating students to assume leadership roles in the health and human services;
- Advancing knowledge and practice through scholarly activity;
- Educating professionals of ethical conscience and commitment;
- Partnering effectively with health service providers and professional organizations;
- Serving the Region and Communities of Southeastern North Carolina and beyond.

### **1.2.3. SCHOOL OF NURSING**

**Vision:** Together we improve health and well-being.

**Mission:** The School of Nursing educates and empowers nursing and clinical research professionals to advance the health of diverse individuals and communities, through excellence in teaching, practice, research, and scholarly activity.

## **2. GENERAL PROCEDURES AND POLICIES**

### **2.1. STANDARDS OF CONDUCT**

The Clinical Research Program (in addition to all other School of Nursing programs) subscribes to the UNCW Code of Student Life.

Key points of emphasis include:

- Students share in the responsibility for maintaining an environment in which the rights of each member of the academic community are respected. When asked to report to any university office, a student is expected to appear at the time specified or to arrange another appointment.
- All students and their guests shall be responsible for conducting themselves in a manner that helps to enhance an environment of learning in which the rights, dignity, worth and freedom of each member of the academic community are respected.
- All students and faculty are expected to be honest and honorable in all academic and professional endeavors. It is further expected that they will refrain from any activity, which might impair the image of the university, school, or the clinical research profession.

### **2.2. ACADEMIC CONDUCT**

The Clinical Research Program (in addition to all other School of Nursing programs) follows the policies and procedures as outlined in the academic catalogues (i.e., sections discussing Student Conduct, the Code of Student Life, Student Gender-Based/Sexual Misconduct Policy, Academic Honor Code, and the UNCW Honor Pledge). All students and faculty are expected to refrain from acts of academic misconduct including, but not limited to:

- Plagiarism;
- The giving or falsifying of any academic documents or related materials;
- Use of generative artificial intelligence (AI) like ChatGPT to prepare and submit work as one's own.;
- Using websites like Chegg, Course Hero, and Wyzant for exams or assignments.;
- Collaborating without faculty approval or sharing answers with other students on exams.;
- Offering compensation to use someone else's work as your own.;
- Looking up materials or answers online during an exam.;
- Sharing or using previous course materials posted online.;
- The giving or receiving of unauthorized aid in tests, examinations, or other assigned schoolwork

The University of North Carolina is a community of high academic standards where academic integrity is valued. UNCW students are committed to honesty and truthfulness in academic inquiry and in the pursuit of knowledge.

### **2.3. COPYRIGHT NOTICE**

Any dissemination of lecture slides, recordings, handouts, exam, or any other derivative work without the permission of the instructor is prohibited by UNCW policy. [UNCW Copyright Use and Ownership Policy](#) specifies that class notes and related materials are considered derivative of original intellectual property of the course instructor. Therefore, the instructor (not the student) owns the copyright and must provide specific permission to either distribute, reuse, or both those materials for anything other than personal scholarship by the student. Commercial use, display, or dissemination of such notes, copies, or recordings (including posting to websites), will generally qualify as an infringement of copyright and the Honor Code. Materials that qualify as student-owned are listed in this policy.

### **2.4. HONOR CODE PLEDGE**

The Academic Honor Code is expressed in the following pledge, taken by students upon admission to UNCW.

“As a student at The University of North Carolina Wilmington, I am committed to honesty and truthfulness in academic inquiry and in the pursuit of knowledge. I pledge to uphold and promote the UNCW Student Academic Honor Code.”

This pledge and additional information on this topic are found on the Office of the Dean of Students, Student [Academic Honor Code](#).

### **2.5. PROFESSIONAL CONDUCT**

Professional misconduct is construed as any violation of the following provisions:

- Faculty and students assume responsibility for individual and professional judgments and actions. It is expected that they will seek consultation and clarification on professional actions in which there is uncertainty.
- A student assumes responsibility and accountability for individual judgments and actions at his/her level of knowledge and expertise.
- Faculty and students exercise informed judgment and use individual competence and qualifications as criteria in seeking consultation, accepting responsibilities, and delegating activities to others.

Faculty and students are expected to respect and uphold the rights of all their coworkers and research participants, if applicable, by:

- Providing services with respect for human dignity and the uniqueness of the research participant, unrestricted by considerations of social or economic status, personal attributes, or the nature of health problems.
- Safeguarding the research participants' right to privacy by judiciously protecting information of a confidential nature.

Faculty and students are expected to protect research participants against incompetent, unethical, or illegal practice by:

- Participating in the profession's efforts to protect the public from misinformation and misrepresentation and to maintain the integrity of clinical research.
- Collaborating with members of the health profession and other citizens in promoting community and national efforts to meet the health needs of the public.
- Assuming responsibility for reporting incompetent, unethical, or illegal practice to the appropriate authority (i.e., incident reports, etc.)

Faculty are expected to respect and uphold the rights of students by:

- Maintaining confidentiality of students' records.
- Obtaining or disseminating to the appropriate persons only information strictly pertinent to student's current academic performance.
- Treating the student as a person of worth and dignity.

Students are expected to respect and uphold the rights of faculty by:

- Maintaining confidentiality of faculty records.
- Obtaining or disseminating to the appropriate persons only information strictly pertinent to faculty's current academic performance.
- Treating the faculty member as a person of worth and dignity.

### 2.5.1. CONFIDENTIALITY STATEMENT

As a student, faculty, or staff member assigned to an internship site or invited to conduct research at a clinical study site, a person may be allowed access to patient or research participant records. Patient or research participant information from any source and in any form, including paper records, oral communication, audio recording, and electronic display, is **strictly confidential**. Access to confidential patient or research participant information is permitted only on a need-to-know basis. **Students, faculty, and staff must understand the critical importance and seriousness of sharing confidential information and the consequences from both academic, and potentially, legal perspectives.**

The policy of the Clinical Research Program holds that students in the School of Nursing shall respect and preserve the privacy and confidentiality of patient and research participant information, regardless of the agency to which the student is assigned. Violations of this policy include but are not limited to, the examples provided in Table 1.

Violation of this policy by students, faculty, or staff to any agency with which the School of Nursing has a contractual agreement or memorandum of understanding, may constitute grounds for corrective action up to and including loss of agency privileges, dismissal, or termination from the school in accordance with applicable agency, school, or university procedures. Unauthorized release of confidential information may also result in civil liability criminal liability, or both in accordance with local state and federal laws.

**Table 1.** Examples of Breaches of Confidentiality

<b>Policy Violation</b>	<b>Examples</b>
Assessing information that is not within the scope of your job/role as a student, faculty, or staff member.	Unauthorized reading of patient account information. Unauthorized access of personnel file information. Unauthorized reading of a patient's chart. Accessing information that you do not need to know for the proper execution of your job/internship function.
Misusing, disclosing without proper authorization, or altering patient or personnel information.	Making unauthorized marks on a patient or research participant's chart. Making unauthorized changes to a personnel file. Sharing or reproducing information in a patient or research participant's chart or personnel file with unauthorized personnel. Discussing confidential information in a public area, including but not limited to waiting room, restroom, or elevator. Posting confidential patient information on social media such as Facebook, Instagram, Twitter, etc.
Disclosing to another person your sign-on code and password for accessing electronic or computerized records.	Telling a co-worker your password so that he/she can log in to your work. Telling an unauthorized person the access codes for personnel files or patient accounts.
Using another person's sign-on code and password for accessing electronic or computerized records.	Using a co-worker's password to sign in to and/or "Log on" to the hospital or clinic's computer system. Unauthorized use of a log-in code for access to personnel files or patient or research participant accounts.
Leaving a secured application unattended while signed into a computer.	Being away from your desk while you are logged into an application. Allowing a co-worker to use your secured application for which he or she does not have access after you have been logged in.

Attempting to access a secured application without proper authorization.	Trying passwords and log-in codes to gain access to an unauthorized area of the computer system.  Using a co-worker's application for which you do not have access after he/she is logged in.
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## 2.5.2. RESPONSIBLE USE OF DIGITAL AND SOCIAL MEDIA

Social media sites are online communities used in our professional and personal lives to communicate and distribute information. Some examples of these include Facebook, Instagram, YouTube, LinkedIn, Snapchat, and Twitter. The usage of such sites has provided new ways to network, nurture relationships, and discuss education, research, and practice. There are also new concerns for students to be aware of and an increased diligence in communicating on these sites is necessary to maintain an atmosphere of integrity and respect that is free of harassment, exploitation, and intimidation

Responsible Social Media Use by students in the Clinical Research Program: The federal rules on privacy and security are expected to be followed by all students in the Clinical Research Program as they relate to any internship experience or research conduct at a clinical study site. Students must be aware that social networking sites can be accessed by and then shared with patients, research participants, family members, colleagues, and others. Students must avoid sending or posting anything that can be used to identify the patient or research participant in any form. (HIPAA Act, 1996 and the HITECH Act, 2012, which modified HIPAA (Rules and Regulations. Federal Register. 2013;78(17)) Students may be legally liable for what is posted on a social media site by themselves or others.

## 2.5.3. CIVILITY STATEMENT

The Clinical Research Program is dedicated to creating and maintaining a civil community that supports respectful discourse and openness to opposing viewpoints. Members of the clinical research community are asked to:

- 2.5.3.1. Assume goodwill and approach situations positively
- 2.5.3.2. Communicate respectfully
- 2.5.3.3. Address issues to the person directly involved.
- 2.5.3.4. Follow the chain of command if not resolved when discussed with person involved.

## 2.6. INFORMATION SECURITY POLICY

### 2.6.1. INFORMATION SECURITY IN PROFESSIONAL SETTINGS

**Policy:** Information, as defined hereafter, in all its forms and throughout its life cycle will be protected in a manner consistent with its sensitivity and value to any agency to which a student or faculty member is assigned via a contractual agreement or memorandum of understanding between the equipment and software used to process, store, and transmit information.

This policy applies to all information, which includes clinical information generated in the context of patient or research participant care. Examples of this policy include laboratory data, x-ray results, results of other tests and procedures, and dictated and written notes detailing patient histories and physical exam findings. Such patient/participant-related data may be available electronically or in written form in standard records and patient charts; it may be available for individual research participants or for groups of participants. Such information may reside in large central computer databases, such as those maintained by large hospitals and academic health centers, where it is available via computers to clinical workstations or other clinical databases maintained by individual agency personnel. It may also reside in databases that are separate from the centrally maintained database, such as the clinical databases developed for certain research personnel members.

**Scope:** The scope of information security is protection of information that is written, spoken, recorded electronically, or printed from accidental or intentional modification, destruction, or disclosure. Information will be protected throughout its life cycle, including origination, entry, processing, distribution, storage, and disposal.

## 2.6.2. INFORMATION SECURITY IN THE ACADEMIC SETTING

Information security related to UNCW systems is described on UNCW's Information Technology Services (ITS) webpage. Some of the topics covered on this webpage are listed in **Table 2**. External resources are also available.

**Table 2.** Information Security Topics

Topics	What you should know about
Antivirus	Posting personal information
Email frauds	Protecting data & identity
File Sharing	Social Networking
Hurricane/storm preparedness	Spam filter
Mobile device security	Spyware & viruses
NC Data Retention Requirements (PDF)	UNCW's IT policies
Passwords	Windows Updates on UNCW computers

## 2.7. REASONABLE ACCOMMODATIONS

If an otherwise qualified student believes that he or she cannot meet one or more of the standards without accommodation or modifications, the following process will be used:

1. The University of North Carolina Wilmington is committed to providing reasonable

accommodations to enable qualified students with documented disabilities to accomplish their educational goals. It is the responsibility of the student who desires a reasonable accommodation to notify the Disability Resource Center and to provide appropriate documentation . . They will determine a student's eligibility for accommodations and will recommend appropriate resources, accommodations and service.

([www.uncw.edu/disability](http://www.uncw.edu/disability)). Accommodations cannot be provided retrospectively.

2. Decisions regarding recommendations from the Disability Resource Center for reasonable accommodations will be carefully reviewed by the Program Coordinator, Assistant Director of Undergraduate Programs and the SON Director. Decisions for provision of reasonable accommodations must not jeopardize patient safety nor compromise the integrity of the nursing program. Applicants and students should be aware that accommodations provided at the UNCW SON may not be provided by the National Council of State Boards of Nursing on NCLEX or in practice. Once established, responsibility for disability-related accommodations and access is shared by DRC, faculty, and the student. Disability Resource Center: DePaolo Hall, Suite 1033; 910.962.7555; [DRC@uncw.edu](mailto:DRC@uncw.edu).

## **2.8. FINANCIAL AID**

Information on financial aid options, including scholarships, for UNCW students is available on the website of the [Office of Scholarships and Financial Aid](#).

# **3. THE CLINICAL RESEARCH PROGRAM AT UNCW**

## **3.1. ACADEMIC CALENDAR**

Clinical Research Program courses follow the regular term instruction (RTI) in the UNCW Academic Calendar provided by the Office of the Registrar: <https://uncw.edu/myuncw/academics/registrar/dates-deadlines>. An academic year is 24 credits and 32 weeks of instructional time. The academic year consists of a fall semester and spring semester. A semester is one of three, usually 15-week periods of instruction that make up an academic year. Semesters are commonly referred to as summer, fall and spring.

The UNCW Calendar Committee, representative of multiple campus divisions, develops the annual academic calendar and ensures that required instructional minutes are met each term as outlined in the UNC Policy Manual 400.1.6 and the UNCW Calendar Committee Guidelines. In an effort to ensure all courses meet the academic credit hour requirements, the fall 2024 calendar will include two "swap days" on December 5th and 6th, 2023 as stated in the calendars posted in the online catalogues).

Online and Asynchronous Course Content - the Clinical Research Program courses provide content online and asynchronously (OLASY). Online technologies are used extensively in the Clinical Research Program. Web-based asynchronous means the instructional materials are available on the internet without time-dependent slots (e.g., real-time). The undergraduate degree program is predominantly online (internships might have an opportunity for in-person experiences). The graduate programs are primarily online (experiential learning



opportunities may be in-person). The School of Nursing reserves the right, at any time, to use distance-learning technologies (e.g., interactive video to and from remote sites) in the delivery of educational offerings.

### **3.2. TIME COMMITMENT FOR ONLINE COURSES**

Online courses are designed to be as rigorous and time intensive as regular face-to-face class/traditional classroom courses. While online courses give students much flexibility in scheduling, they do not take less time than conventional classes. In fact, more responsibility and effort shift to the student in the learning process and more involvement and commitment is required. The time commitment will vary according to the level of the class and a student's aptitude for the subject matter. A good rule of thumb is to plan on about three times the credit hour value of the class; e.g., around 9 hours a week for a 3-credit hour course.

### **3.3. RESOURCES FOR STUDENTS**

A library of information is available for online students on the UNCW website, [Online Education webpage](#). Of particular importance is the "Resources and Services" link.

#### **3.3.1. RANDALL LIBRARY**

Since this is a research-related program, all students should know how to log in and retrieve "paid subscription" articles (i.e., scientific articles that are not free to the public) from Randall Library. The library offers various resources (i.e., instructions, tutorials, course guides, etc.) and support options for a student not on campus. Student fees pay for databases such as ProQuest Central, Science Direct, Web of Science, and many others. Learning how to access these databases is essential to student success.

Students are encouraged to visit the [Randall Library webpage](#) on the UNCW website and familiarize themselves with this excellent resource upon entering the program.

#### **3.3.2. PROFESSIONAL DEVELOPMENT AND MENTORSHIP OPPORTUNITIES**

Professional development content is infused throughout the curriculum. Undergraduates are especially encouraged to participate as they seek internship and employment opportunities. Communications about professional development and mentoring opportunities are shared via email, social media, and course announcements. Opportunities include seminars with guest speakers, career fairs, and other activities.

The CHHS [Center for Workforce Development](#), offers various programs and opportunities for students to enhance their understanding of the clinical research industry and prepare for the workforce. A mentorship program pairs students with an industry professional in a formal, structured partnership. This program is designed to help orient students to the clinical research profession, build their professional networks, and increase their communication and leadership skills. The Center also offers career preparation assistance through resume reviews and mock interviews with industry professionals.

### **3.3.3. STUDENT SUPPLIES**

#### **3.3.3.1. COMPUTERS**

Students are responsible for having electronic equipment in good working order to participate fully in this course. Minimally, students must have a working computer with speakers and a microphone. Students without personal electronic equipment must make arrangements to use equipment at the University or another location. Lack of access to equipment will not be accepted as a reason for not meeting the course requirements. Students should develop a technology backup plan (e.g., friend's computer or Randall Library), as computers may crash when an assignment is due.

#### **3.3.3.2. SOFTWARE**

Internet browsers are used extensively for online learning and distance education. Browsers should be compatible with the current version of Canvas used by UNCW. UNCW recommends using Google Chrome, Microsoft Edge, or Mozilla Firefox for Canvas courses. [Adobe Acrobat Reader DC](#) is needed for reading PDFs and is available to students for free through Adobe Creative Cloud at UNCW.

Microsoft Word will be used extensively in Clinical Research Program courses and is a firm requirement. All students have access to Microsoft 365. The suite is available for free for both Mac and PC users for UNCW students. The Microsoft 365 suite includes the following: Word, Excel, PowerPoint, OneNote, Access, Teams, and OneDrive for Business. Contact the UNCW Technology Assistance Center (TAC) if assistance is needed.

#### **3.3.3.3. COMPUTER ACCESS AND TECHNICAL ISSUES**

Students are responsible for maintaining constant access to a computer with internet access for online Clinical Research courses. The online courses in the Clinical Research Program are designed in such a way that students must review the Clinical Research classes on Canvas MULTIPLE TIMES EVERY WEEK to keep current with assignments, updates, news, and newly updated course content. Thus, the faculty strongly recommended that students find a computer or facility with computers for access to their on-line Clinical Research courses if their computers or internet connectivity is interrupted. It is also prudent to copy completed assignments to a USB drive in case of computer crashes. Computer and internet access are critical to participating in the Clinical Research Program; each student is responsible for participating in their online Clinical Research courses in a timely manner, as well as submitting assignments on time. Students should consider the following key points:

- Document interactions with technical support staff for UNCW or Canvas issues.
- Completing assignments on the day assignments are due is not prudent in the event of a computer or server issue.
- Do not contact a Clinical Research instructor for computer support services.

In the unlikely event that there are UNCW, Canvas, or both server issues that affect a student's ability to complete a course assignment, students must contact the UNCW Technology Assistance Center (TAC) at 910-962-4357 (HELP) or use the ticketing system available from the [TAC](#) website. Technology issues related to UNCW or Canvas resulting in delays should be communicated to the instructor. Students are required to document their issue in an e-mail sent to the TAC.

Students are also required to copy, paste, and send the sent e-mail (so that the date and time is included in the e-mail) to their instructor in the course e-mail. In general, for a student to receive credit for a missed or late

assignment due to a UNCW or Canvas issue, the student must copy, paste, and e-mail in the course the response received from the TAC to their instructor. Only those computer issues deemed an issue due to the UNCW or Canvas server that is documented in an e-mail response to the student from the TAC will serve as a reason for an instructor to allow a student to miss a deadline.

### 3.4. COURSE POLICIES AND EXPECTATIONS

The clinical research profession and curriculum are challenging and complex. To foster success in the program, the faculty identifies the following course policies and course expectations:

- Apply previously learned concepts introduced in pre- and co-requisite courses to the program of study in clinical research.
- Plan at least 2-3 hours of weekly study for each 1 hour of course credit per week. This means that students in a 3 credit, online CLR course **should be spending approximately 6 to 9 hours per week on the course to master the content.**
- Access all class materials, class assignments, and announcements from the course and documents.
- Notify faculty of any special situations, disabilities, or specialized learning needs during the first week of class.
- Use UNCW email for all communication between students, staff, and faculty unless otherwise specifically outlined in the course syllabus.
- Demonstrate respect for fellow students and faculty by practicing professional behavior in all communications between class peers, staff, and faculty.
- Acquire technology skills prior to starting an online course.
- Actively participate in online and hybrid courses through submission of written assignments, completion and submission of quizzes and tests, discussion boards, blogs and any face-to-face, "real time" and remote, web-based forums, as required."
- Any concerns or questions relating to an assigned grade on a test, quiz, or written assignment must be made in writing within 10 days after the due date. The instructor will provide feedback on a timely basis after the written concerns have been received. Under no circumstances will assigned grades be discussed after the final semester grades have been posted.
- Maintain access to recommended computer hardware to access web-based course materials and documents. Plan accordingly if there are technological difficulties experienced at the student end. In other words, the student is responsible for maintaining access to the online course materials and being able to take online tests and quizzes within the allotted time.

### 3.5. NEW STUDENT ORIENTATION

New students are required to participate in a Clinical Research Program orientation session prior to beginning the core courses (i.e., at the beginning of their first semester). The orientation is designed to familiarize students with program requirements and policies and to introduce students to Clinical Research Program faculty. The undergraduate and graduate Program Coordinators will facilitate the orientation. Clinical Research Program faculty will provide an overview of courses and tips for success in both the academic programs and their clinical research career. All students must successfully complete the Indiana University Plagiarism Tutorial and test for their degree level as assigned by the Program Coordinator.

Undergraduate students are encouraged to attend in person; however, remote participation is available. Graduate students may attend either in-person or remotely. University-level orientation is separate from the clinical research orientation, as it emphasizes other aspects of academic life. Both are useful and encouraging.

### 3.6. ACKNOWLEDGEMENT OF GUIDING DOCUMENTS

Following orientation, students will be asked to **confirm and document the following statements, as directed by the Program Coordinator:**

I have been instructed to access the on-line copies of the following publications:

- UNCW Clinical Research Program Student Handbook
- UNCW Catalogue (graduate or undergraduate, as applicable)
- UNCW Code of Student Life

I have attended the Clinical Research New Student Orientation, where the importance of the following publications has been explained:

- UNCW Clinical Research Student Handbook
- UNCW Catalogue (graduate or undergraduate, as applicable)
- UNCW Code of Student Life

I understand that it is my responsibility to thoroughly read and understand all information detailed within the following publications:

- UNCW Clinical Research Student Handbook
- UNCW Catalogue (graduate or undergraduate, as applicable)
- UNCW Code of Student Life

I have read and agree with the terms of the **Confidentiality Statement** (Clinical Research Student Handbook, section 2.5.1 and will readily comply with agency and Clinical Research Program policies and standards pertaining to information security. **Formal documentation is required for undergraduates, due in part to the internship requirements.**

For graduate students, the reading and agreement with the terms of the **Confidentiality Statement** (Clinical Research Student Handbook, section 2.5.1) is implied as a condition of enrollment in the CLR Program and will readily comply with agency and Clinical Research Program policies and standards pertaining to information security.

### 3.7. GRADING POLICIES

The Clinical Research Program faculty have provided a few guiding principles about grades:

- Grades are measures – an agreed-upon system of communication about course performance between instructor and student.

- Grades reflect the work (and the quality of that work) that a student invests in class. Grades do not determine how the instructors interact with students—Instructors do not judge students, or their potential based on the grade a student receives.
- Instructors take the privacy of grades very seriously. All communication related to grades will occur via private email and through the “My Grades” function of the Canvas course. Instructors will not discuss your grade with other students or UNCW staff not involved in your educational experience. Your instructors suggest you do the same.

Instructors’ grading policies may vary across courses in the programs. Review all grading policies in the syllabus of each course at the beginning of the semester and ask for clarification promptly. The handling of late assignments is one example of this variability – for some courses, late assignments and/or online discussions are expressly not graded. Students should not try to complete assignments on the assignment due date as technical issues or questions about the assignment may arise.

Unless otherwise specified, all coursework must be submitted no later than the last day of class (i.e., before reading day and the final exam period). Course work submitted after the last day of classes will not be graded unless prior arrangements have been made with the instructor.

### **3.7.1. GRADING SCALE**

Clinical Research faculty have adopted a 10-point scale letter grade scale as shown in the below table for all undergraduate degree programs, excluding courses that are graded categorically (e.g., pass/fail). Graduate degree programs have a similar grade scale as shown in the table below excluding courses that are graded categorically (e.g., pass/fail) except a “D” letter grade is not used per UNCW Graduate School grade policies. The plus and minus letter grades are not included (e.g., A-, B+) in the grading for Clinical Research courses. Students should review course-specific grading policies in the syllabus for each course.

A = 90 - 100%
B = 80 -89%
C = 70 – 79%
D = 60 - 69%
F = < 60%

### **3.7.2. WRITING STYLE**

Part of the mission of the Clinical Research Program is to prepare students as professionals in the clinical research arena. The standard for submission of written work should be considered ready for publication as an official business document or in a newspaper or print journal. In most courses and assignments, points are deducted for any graded activities containing any text messaging language, misspelled words, or incorrect grammar.

### **3.7.3. DISCUSSION FORUMS**

Like any community, the online learning community has guidelines in place to protect participants and promote discussion and learning. Carefully consider your tone when posting messages to Canvas. Since there are no visual clues, other than the message posted, pay careful attention to the way messages are posted so that messages will not be taken out of context. These “netiquette” rules are extensive and relate to your participation in email, asynchronous and synchronous discussions, and all interaction within your courses.

### **3.7.4 GRADING APPEAL PROCEDURE**

Any student considering an appeal on a final course grade should understand that each faculty member has the academic freedom and responsibility to determine grades according to any method chosen by the faculty member that is professionally acceptable, communicated to everyone in the class, and applied to all students equally. However, discriminatory, arbitrary, or capricious academic evaluation by a faculty member is a violation of a student’s rights and is the only valid ground for a final course grade appeal.

Any student who contests a final course grade under this procedure shall first attempt to resolve the matter with the instructor involved. Failing to reach a satisfactory resolution, the student may appeal the grade in accordance with the steps outlined below. An appeal must be made in writing no later than 30 days after the grade was issued. Grades not appealed by that time become permanent.

1. The student shall present the appeal in writing to the Associate Director of Academic Programs, SON (Associate Director). The written statement shall limit itself to a factual description of evidence pertaining to the valid ground(s) for appeal and documentation of all attempts to reach resolution. By conferring with the student and the instructor, the Associate Director will seek resolution by mutual agreement. The Associate Director will provide a written statement of the results of this effort to the faculty member and student.
2. Failing such resolution, the Associate Director shall transmit the written appeal to the Director of the SON, who finding no further need for conferral with the Associate Director, the student or the instructor will then transmit the written appeal to the CHHS Associate Dean for Academic Affairs, who will convene the CHHS Grade Appeals Committee.
3. The Grade Appeals Committee shall consist of the convening Associate Dean, and five faculty members appointed by the Associate Dean. The Associate Dean will serve as Chair of this committee. If the committee affirms the instructor’s decision, the Associate Dean will notify in writing the faculty member, the student, and the Director as appropriate. If the committee affirms the student’s appeal, it shall prescribe the method by which the student will be reevaluated. The grade resulting from the re-evaluation is a final university decision and may not be appealed further.

### **3.8. COMMUNICATION WITH INSTRUCTORS**

Refer to each course syllabus for information about instructor office hours and communication plans within the course. Typically, instructors will offer online or teleconference options and often, by appointment. Students are

advised to send the instructor an e-mail requesting a meeting time for the appointment. Confirmation from the instructor should be received before attending the meeting.

Students should expect that, in most instances, instructors will respond to student inquiries within 48 hours, Monday through Friday. Students are referred to the course syllabus for specific communication plans.

### **3.8.1. STUDENT INVOLVEMENT IN RESEARCH AND IRB REVIEW**

All students and faculty conducting research projects involving human subjects must be approved by the UNCW Institutional Review Board (IRB). All IRB policies, procedures, and forms can be accessed at from UNCW's Sponsored Programs and Research Compliance ([SPARC](#)). Students are encouraged to evaluate their research projects (e.g., capstone, honors, independent study) for the need for IRB review and approval.

## **3.9. STUDENT REPRESENTATION AND ORGANIZATIONS**

### **3.9.1. CLINICAL RESEARCH COUNCIL AND COMMITTEES**

Student representation on selected committees/councils is required in accordance with the School of Nursing by-laws. Leadership opportunities include the Clinical Research Council, School of Nursing Faculty Council and Student Association of Clinical Research (SACR) officers (see section 3.7.2). A student representative will be recruited each year to serve in this role.

### **3.9.2. STUDENT ASSOCIATION OF CLINICAL RESEARCH (SACR)**

Involvement in student organizations is encouraged as a way to connect with other students and professionals and to build leadership and involvement skills and experience. A directory of student associations is available on the UNCW webpage under [Registered Student Organizations](#). SACR is the student organization for both undergraduate and graduate clinical research students. Participation in this organization is highly encouraged; however, membership is optional.

## **4. BACHELOR OF SCIENCE, CLINICAL RESEARCH**

### **4.1. STUDENT LEARNING OUTCOMES**

Upon completion of BS curriculum, the graduate will be able to:

1. Explain scientific concepts related to the design and analysis of clinical trials.
2. Explain the care of patients, aspects of human subject protection, and safety in the conduct of a clinical trial.
3. Describe how investigational products are developed and regulated.
4. Explain the study management (adverse event identification and reporting, post-market surveillance, and pharmacovigilance), and handling of investigational product.

5. Explain the operations at the site level to run a study (financial and personnel aspects).
6. Demonstrate how data are acquired and managed during a clinical trial, including source data, data entry, queries, quality control, and correction and the concept of a locked database.
7. Demonstrate the principles and practice of leadership and professionalism in clinical research.
8. Describe elements of communication within the site and between the site and sponsor, contract research organization (CRO), and regulators including the teamwork skills necessary for conducting a clinical trial.

## **4.2. ADMISSION PROCESS AND ADVISING**

Admission to UNCW is required prior to admission to the Clinical Research program. Refer to admission deadlines for the Clinical Research program.

### **4.2.1. ADMISSION REQUIREMENTS**

Admission requirements are described in the undergraduate catalogue. Students are expected to follow the program of study delineated for their “catalogue year” unless advised otherwise.

Additional details on the evaluation of the admission criteria are provided below.

#### **4.2.1.1. PRE-REQUISITE COURSES - 10 YEAR RULE**

All prerequisite courses must have been completed within 10 years of the application deadline. If any course is older than 10 years, students must retake/audit those courses.

Examples: August 1, 2023, major request deadline: any courses taken in Spring 2013 or prior are not valid.

Note: The 10-year rule can be waived under specific circumstances with Clinical Research Program Coordinator approval. The student should contact the Study Success Center for further information.

#### **4.2.1.2. GRADE POINT AVERAGE**

The grade point average (GPA) for application evaluation purposes will be calculated based on all completed pre-requisite **credit bearing courses**. Where courses have multiple options, the highest grade will be used for calculations. The following categories apply to this rule: MAT Category and STT Category. Students can repeat a course as many times as they feel necessary or desire. The highest score will be used.

#### **4.2.1.3. TRANSFER CREDITS**

Occasionally, students transfer to UNCW to major in Clinical Research after taking clinical research-related courses at another university.

- Clinical Research courses from another Clinical Research program are evaluated by the Clinical Research Program Coordinator.
- Other courses are evaluated by a Student Success Center Advisor to determine potential acceptance of transfer credits.



#### **4.2.1.4. MAJOR DECLARATION**

Admission into the Clinical Research major requires a 2.7 UNCW GPA or higher, and a C or higher in the pre-requisite courses outlined in the Undergraduate Catalog. Major declaration is open for the Clinical Research program during the spring and summer prior to the start of the fall semester/cohort. New majors begin CLR courses in the fall semester. Students are not considered a major until they have successful completion with a grade of "C" (2.00) or better of all but one prerequisite course and maintaining a cumulative GPA of at least 2.0. Program Coordinator reviews student's prerequisites and approves Major requests in the UNCW declaration portal.

If a student has more than one prerequisite course left at the start of the fall semester, the request for major declaration will not be approved.

If a student does not complete their final prerequisite prior to the start of the summer between the 1st and 2nd years of the program, they will not be allowed to start the clinical research internship that fall.

Denied: Students denied from declaring the major are eligible to re-submit a declaration request in subsequent semesters.

#### **4.2.1.5. ACADEMIC ADVISEMENT**

It is essential that each student obtain advisement throughout his/her course of study in order to progress smoothly through the sequence of courses. The assigned advisor is listed on the student's degree audit.

The following policies and procedures are designed to facilitate the student's progression throughout the Clinical Research program:

#### **4.2.1.6. ADVISOR PRIOR TO ADMISSION TO THE PROGRAM**

The student will be assigned an advisor from the Student Success Center (SSC) to assist the student in preparing their plan of study for application to the Clinical Research Program (Pre- CLR/PCLR).

#### **4.2.1.7. ADVISOR AFTER ADMISSION TO PROGRAM**

Each admitted student will be assigned an academic advisor by the SSC for the first year in the Clinical Research program. A Clinical Research faculty advisor will be assigned to the student during the student's senior year in the program.

#### **4.2.1.8. CONTACTING YOUR ADVISOR**

Contact your advisor via e-mail or telephone to schedule an appointment. If the faculty advisor is unavailable, please contact the Director of Student Success Center to provide alternative assistance with advising.

Each student must meet with their academic advisor at least once each semester prior to the pre- registration period to discuss and update the student's program of study. The meeting is to be documented. Should any issues arise in between official advising meetings, it is the student's responsibility to schedule an appointment with their SSC or Clinical Research advisor to discuss those matters.

#### **4.2.1.9. DEVELOPING A PLAN OF STUDY**

Once a student has been admitted into the Clinical Research Program and declared clinical research as their major, a meeting will be held between the SSC advisor and student prior to registration to develop an initial plan of study. While the outcome of the meeting is the development of the plan, there are several goals for this

meeting. First, the entire program should be overviewed, so that the student has a context for the plan of study. The investment of time needed for the program should be addressed, so the student can make necessary adjustments to work or personal schedules to accommodate any unanticipated demands.

To assist in planning the course of study, the advisor will explore with the student both long-term and short-term goals, as well as any aids the student perceives s/he will need to complete the program. Knowledge of the student's goals will help the advisor in the recommendations of electives or courses that will support the student's goals. The advisor can link the student with campus resources that might be of assistance to the student. The advisor will inform the student how s/he handles advisement appointments and provide the student with information about the advisor's availability and ways s/he can be contacted.

The process of academic advisement is one of information exchange, communication, teaching, and guidance. Not only does the advisor/advisee relationship supply the opportunity for the student to obtain information needed to maintain status as a student and stay abreast of the rules and regulations of the Clinical Research program, School of Nursing, and the university, but it also should provide the student with a trusted guide or academic consultant. The advisor should be the advisee's most accurate source of information about the system, at the school and university levels. The advisor makes sure that the advisee receives relevant notices, is available on a regular basis for questions or consultation, and helps the student manage problems that interfere with the student's educational progress.

As a guide or academic consultant, the advisor has the opportunity to assist the student with articulating and realizing some segment of his/her career goals. Advisors are responsible for and instrumental in guiding the student to plan and pursue a program of study that meets all requirements for graduation as well as focusing on the student's goals. The advisor is more than a source of information about registration; s/he is a coordinator of a student's entire educational experience.

#### **4.2.1.10. CHANGING ADVISORS**

To change a major academic advisor, the student must submit a written request for approval to the Clinical Research Program Coordinator. Upon approval, the Clinical Research Program Coordinator will provide information of the status change to the Student Success Center.

#### **4.2.1.11. AUDIT REVIEW**

Although the student will meet with his/her advisor throughout the course of the enrollment period, **the responsibility to ensure that all courses have been completed and all hours toward graduation have been met rests with the individual student.** The student must work closely with his/her advisor to ensure that all academic mandates for graduation have been met.

#### **4.2.1.12. ACCESS TO FILES**

In addition to the educational records kept by the University, the Student Success Center (SCC) advisor will maintain electronic files on student's admission and progression through graduation. The student may, upon completion of the appropriate form, have access to his/her official files, except for those items to which the student has waived access for review. Items from the electronic file may be duplicated upon request. Refer to the [Student Success Center](#) contact information to obtain procedure details.

#### **4.2.1.13. REGISTRATION**

Students register for courses through [Registration Information](#). Issues regarding registering for courses, such as time

conflicts, full sections, or other concerns regarding academics while in the Clinical Research Program may need escalation to the Program Coordinator, and if so, it is the student's responsibility to notify the Clinical Research Program Coordinator of the situation. Notification does not equate resolution of your specific situation; however, every effort will be made to review your particular case.

#### **4.2.1.14. ACADEMIC AND NON-ACADEMIC DIFFICULTIES**

Students experiencing academic difficulty are expected to schedule an appointment with the relevant course faculty for assistance.

Students unable to resolve academic problems in Clinical Research courses should consult individuals in the following order:

1. Clinical Research course instructor
2. Clinical Research Undergraduate Program Coordinator
3. Associate Director for Academic Programs, School of Nursing
4. Director of the School of Nursing
5. Dean of the College of Health and Human Services
6. Office of the Chancellor and Provost of Academic Affairs

The grade appeal process is summarized in section 3.7.4 in this document. For additional assistance or information, contact the Program Coordinator or the Student Success Center.

Students experiencing non-academic difficulties or concerns should consult with their academic advisor, Program Coordinator, or Assistant Dean, Student Success.

#### **4.2.1.15. TIME LIMITS FOR DEGREE COMPLETION**

Bachelor of Science programs must be completed within a consecutive six calendar year period.

### **4.3. ACADEMIC PERFORMANCE**

#### **4.3.1. RETENTION AND PROGRESSION POLICY**

In addition to the Retention, Dismissal and Re-Enrollment policies and degree requirements listed in the catalogue, students must comply with the following requirements for the BS in Clinical Research.

##### **4.3.1.1. MINIMUM PASSING GRADE FOR COURSES IN THE MAJOR**

A letter grade of 'C' or higher is required for all pre-requisite and major courses with the exception of pass/fail courses, for which "pass" is required (e.g., senior internship courses). The grade of "C-" is not considered a passing grade for pre-requisite and major courses. This may be evaluated and considered by the undergraduate Program Coordinator.

##### **4.3.1.2. REPEATING COURSES**

Students not meeting the requirements of a C or better (or "pass" for pass/fail courses) in major courses are allowed to repeat 1 course a maximum of 1 time or 2 courses a maximum of 1 time).

Permission to repeat a course is contingent upon approval by the Program Coordinator and School of Nursing Director or designer and availability of space in the course. This does not apply to pre-requisite courses which are addressed in the undergraduate academic catalogue.

#### **4.3.1.3. GRADE POINT AVERAGE (GPA)**

Maintaining a cumulative GPA of at least 2.0 is required for progression in the Program and for graduation.

#### **4.3.1.4. PRE-REQUISITES**

Students admitted to the Program with one outstanding pre-requisite must complete the course by the end of the spring semester following admission to the Program.

#### **4.3.1.5. COURSE SEQUENCING**

Excluding pre-requisite courses, students must take all courses in the major in the sequence specified in the Program of Study with two exceptions: PAR 215 (or PAR 115), and the major elective course, which may be taken as scheduling permits. However, students must complete PAR 215 (or PAR 115) before the beginning of the fall semester of the final year in the Program. Students must achieve the minimum passing grades for all courses designated in the Program of Study for the first year in the CLR Program before enrolling in the internship courses (i.e., CLR 496 & 497).

#### **4.3.1.6. FAILING A COURSE IN THE MAJOR**

Students failing a course in the major will be designated “out of sequence” from the Program of Study. The student must meet with their academic advisor to write an academic contract, which outlines the student’s plan for completing the remaining courses. The Program Coordinator and the School of Nursing Director or designee must approve the academic contract. Students failing two major courses will be dismissed from the program.

#### **4.3.1.7. FAILURE OF INTERNSHIP COURSES**

If a student is terminated from his/her internship by the internship site preceptor due to performance issues prior to the end of the semester, the student fails the internship course (i.e., CLR 496 or 497). Students may also fail if they do not meet course requirements for achieving a passing grade. In either situation, students failing the internship course must meet with the Program Coordinator and Internship Coordinator immediately. Following advisement from the Program Coordinator, the student will be responsible for identifying a suitable internship site for completing the Program requirements.

#### **4.3.1.8. HONOR CODE VIOLATIONS**

Violation of UNCW’s Academic Student Honor Code may result in failure of the associated course, as applicable. Students receiving a failing grade due to an honor code violation will not be allowed to repeat the course.

#### **4.3.1.9. VOLUNTARY WITHDRAWAL**

To initiate the request for a voluntary withdrawal from the Program for a specified amount of time, students must submit a request in writing to the Program Coordinator and School of Nursing Director. If the request is approved, then the Program Coordinator will request the Office of the Registrar designate the student as “inactive.” Permission to re-enter the Program is contingent upon approval from the Program Coordinator and School of Nursing Director and on space availability.

Students who become inactive in the Program without proper approval (i.e., withdraw or take a leave of absence without Program approval/notification) are required to re-declare their major in the Program. If the

student's inactivity results in a university requirement to re-apply to UNCW, the student will also be required to re-declare to the Program.

#### **4.3.1.10. DISMISSAL**

*Failure to meet the requirements described above and in the academic catalogue will result in dismissal from the Program. Students dismissed from the Program may not re-declare as a major.*

Only under unusual circumstances will a student who has been dismissed or voluntarily withdrew under the above circumstances be allowed to re-enter the Clinical Research program. Reentry into the Clinical Research Program after dismissal will be reviewed on a case-by-case basis with the Clinical Research Program Coordinator and Director of the School of Nursing. Any student who has been dismissed has the right to due process.

### **4.4. SENIOR INTERNSHIP**

The Senior Internship of UNCW's Clinical Research Program (CLR) involves two six-credit courses offered in the fall and spring of the student's senior year. In these courses, students obtain applied learning clinical research experience in preparation for graduation and entry into the clinical research profession. While most of the Clinical Research Program is online and asynchronous, the two internship courses require in-person attendance, in addition to the online component.

Students are required to participate in the internship for approximately 14 hours per week (September – April) on-site in a clinical research setting such as a Contract Research Organization (CRO) or Clinical Research Site. Remote internships may be permitted based on the request of the research site and Internship Coordinator approval. The internship hours are during regular, US business hours, Monday through Friday; the hosting institution determines specific schedules with students directly. Students are also enrolled in an online course requiring learning activities and graded work taught by UNCW faculty. See full Program of Study and list of required courses on UNCW Clinical Research website.

#### **4.4.1. HOST ORGANIZATIONS**

Graduates of the UNCW Clinical Research Program consistently rate the Senior Internship as the most influential and formative aspect of the Program. The generosity of the hosting organizations makes this possible. Students are expected to represent UNCW with this gratitude in mind.

The Clinical Research faculty members wish to express appreciation and sincere gratitude for the generosity of the sponsoring organizations and preceptors.

#### **4.4.2. RESPONSIBILITIES**

##### **4.4.2.1. PLACEMENT**

The Program Coordinator or the Course Coordinator arranges internships initially. Students are asked about their preferences on the type of internship site (e.g., site, CRO) or functional area (e.g., data management).

Students are typically required to complete an interview with the potential internship site prior to confirmation of their internship. Students may be required to complete drug screening and background checks prior to confirmation of the internship site.

Student interns are expected to follow their sponsoring company's policies and procedures and to become contributory team members while also learning from their preceptors. Preceptors, who are employees at the sponsoring company, are responsible for facilitating an environment where the student can learn and contribute to the work of the company. Preceptors are asked to communicate any issues related to student performance to the Clinical Research Program Coordinator.

#### **4.4.2.2. INTERNSHIP SCHEDULE AND ABSENCES**

Students are expected to be on-site approximately 14 hours per week with an additional 1 hour per week for communication with instructors and preceptors. Internship hours are Monday through Friday during business hours.

Students begin the on-site portion of the internship during the first week of September for the fall semester and begin the spring semester during the second week of January. The preceptor and student negotiate specific start/stop dates within these weeks. Please note specific begin/end dates and holiday breaks in the course syllabus or schedule.

Students are not expected to attend their internship during university breaks or holidays. *However, students are required to inform their preceptors of university breaks and holidays at the beginning of the semester and provide a reminder in advance of any planned absences.*

In the event of unplanned absences such as illness, students are expected to notify preceptors or internship site supervisor as soon as possible and *minimally, before the start of the business day*, and include specific information about anticipated days/time missed at the internship site.

Students are expected to make up time missed at the internship site due to unanticipated absences. Other arrangements may be negotiated with instructors or internship site personnel on a case-by-case basis.

#### **4.4.2.3. UNIVERSITY CLOSURE DUE TO INCLEMENT WEATHER**

University closure due to inclement weather does not automatically communicate that a student intern will not be on-site on a given day. It is the student's responsibility to communicate inclement weather concerns and university closure with his/her preceptor and develop a plan for making up the missed day.

#### **4.4.2.4. PROFESSIONALISM REQUIREMENTS AND DRESS CODE**

UNCW Clinical Research students are required to present themselves in a professional manner at all times, and especially when representing the school at internship sites. Students may be expected to comply with the dress code policies prescribed by the specific internship agency to which they are assigned. Students are expected to conduct business in a professional manner, and at all times, abide by the UNCW Seahawk Respect Compact.

#### **4.4.2.5. TRANSPORTATION FOR COURSE REQUIREMENTS**

Students are responsible for providing their own transportation to campus and for internship

experiences. Internship assignments will be made in a number of off-campus companies and research sites. Students will be expected to have transportation to attend internship activities at the prescribed time and place.

#### **4.4.2.6. LIABILITY INSURANCE**

Liability insurance is required for each semester that a student is registered for internship courses and is for coverage while working in a student capacity only.

#### **4.4.2.7. DOCUMENTATION OF LEARNING**

Students will document their activities and accomplishments on the Learning Objectives and Internship Activities Forms. Students will ask their preceptor to sign and date the form periodically following the completion of learning objectives and activities. Students will keep a log of weekly activities as part of the online course. Preceptors will be asked to evaluate the students' performance by completing an online survey. (A link to the survey will be sent to preceptors via email). The internship courses also have an online learning component.

#### **4.4.2.8. STUDENT INJURIES AT INTERNSHIP SETTINGS**

If a student obtains a or becomes ill at an internship site, he/she should immediately contact the internship instructor, Clinical Research Program Coordinator, or internship instructor to report student injuries, illnesses, etc.

- If students are working in clinical settings, the clinical facilities may provide emergency care, but students are not required to obtain care at the site and can decide for themselves whether to seek care. Students agree to hold harmless and release from liability the clinical site, University, and faculty of liability in making that determination. at the expense of the student. Health insurance coverage is required for all UNCW students. Students are advised to keep their insurance information readily available at all times. The student also has the option of seeing his/her private physician or the UNCW Student Health Center (910) 962-3280. The SON Director or designee (Associate Director for Administration) can require a student to obtain medical clearance to return to clinical on a case-by-case basis. This helps to ensure that students continue to meet the program core performance standards as outlined in the student handbook and does not result in an unsafe practice environment. The cost of any first aid or medical services provided to the student shall be their responsibility. Additionally, the cost of any follow-up, referrals, or medical testing as may be necessary shall not be borne by the School of Nursing or UNCW, but shall be the responsibility of the student, regardless of whether such services are covered by the student's health insurance.

The Program Coordinator and student are responsible for completing the appropriate incident reporting forms for the internship agency and the School of Nursing. A copy of both forms should be forwarded to the Associate Director in the Office of the Director, School of Nursing, for review, disposition as appropriate, and filing in School records.

### **4.5. GRADUATION**

An application for graduation must be submitted online by the date specified in the university calendar for the desired graduation term. A diploma fee is added to the student's account at the time of application.

Students may qualify for the bachelor's degree by completing successfully (1) the university studies requirements, (2) the residency requirement, (3) an approved course of study in an academic major, (4) a minimum of 120 semester hours of credit, and (5) a minimum grade point average of 2.00.

Graduation will be certified at the end of the term in which all academic requirements are complete. Upon completion of all requirements, the student will receive the Bachelor of Science in Clinical Research degree. In advising and registering students, the deans, the Office of the Registrar, and faculty advisors try to ensure that

every student who intends to graduate from the university registers for those courses required for a degree. **The student, however, must assume the final responsibility for meeting the graduation requirements set forth in the university catalogue.**

#### **4.5.1. PARTICIPATING IN GRADUATION BEFORE COMPLETION OF REQUIREMENTS**

Students may be allowed to participate in the graduation ceremony if they have completed requirements for graduation or if they are expected to meet the graduation requirements with the completion of **1 course of up to 4 hours during the term immediately following the graduation ceremony**. Students who are one course short must notify the Office of the Registrar by the end of the 7th week of the semester of their intent to participate in the ceremony. Their names will not be published in the Commencement Program.

## **5. GRADUATE PROGRAMS IN CLINICAL RESEARCH**

UNCW has two graduate programs in clinical research: the Post-Baccalaureate Certificate in Clinical Research Operations (18 credits) and the Master of Science (MS) in Clinical Research Management and Product Development (36 credits). Both programs are online, distance education programs.

### **5.1. ACADEMIC REGULATIONS AND PROCEDURES**

Graduate school policies are provided in detail in the academic catalogue. Note that academic program requirements may be more stringent than Graduate School policies. Refer to the program requirements for specific programs, also located in the catalogue. Refer to the [Academic Catalogue](#) for regulations, policies, and procedures provided by the Graduate School.

### **5.2. GRADUATE STUDENT SUPPORT SITE**

The [Graduate Student Support Site](#) provides additional information for graduate students.

### **5.3. ORIENTATION**

The following 2 separate orientations are available to new graduate students:

- **Graduate School Orientation:** Attendance is strongly recommended. Students should check their UNCW email for an announcement about the orientation, which may be offered in-person, online, or recorded. Contact the Graduate School ([gradschool@uncw.edu](mailto:gradschool@uncw.edu)) with questions.
- **Clinical Research Graduate Program Orientation:** Attendance is required. Students can participate in-person, online, or via a recorded session.

All students must successfully complete the Indiana University Plagiarism Tutorial and test for their degree level as assigned by the Program Coordinator. Confirm with the Program Coordinator each year's attendance about the date, time, and format options (e.g., in-person, online, web conference, recorded, etc.).



## 5.4. ACADEMIC ADVISEMENT

Each student is assigned a faculty academic advisor by the Program Coordinator. A list of advisors is available from the Program Coordinator. The faculty academic advisor for each student is listed in the Starfish (i.e., advising software tool), SeaNet (i.e., student records), and DegreeWorks (i.e., degree planning and audit software).

## 5.5. ACADEMIC PERFORMANCE

### 5.5.1. WITHDRAWALS

Graduate students who seek to withdraw from a course, semester, or the university should review the “Withdrawal Policy for Graduate Students” in the current Graduate Catalogue before completing any forms. Graduate students may seek advice from the course instructor, faculty academic advisor, Program Coordinator, or the Graduate School.

Graduate students are required to complete a withdrawal form available from the Graduate School when they plan to withdraw from any course after the add/drop period ends. Withdrawal dates are provided in the university calendar and Academic Catalogue. To withdraw from a course without a failing grade, it is necessary to withdraw before the last day to withdraw deadline. Withdrawing after the deadline results in a failure of the course.

Students who need to drop one or more courses or must withdraw from all courses during a semester should complete a Course and Semester Withdrawal form available from the Graduate School. Students who withdraw from all courses during a semester should also complete a Leave of Absence form to be eligible to continue with course work at a later semester.

Students who plan to leave the university and have no immediate intention to return should submit a Complete Withdrawal Form to the Graduate School.

### 5.5.2. LEAVE OF ABSENCE

Students who are withdrawing from a term and plan to return in a subsequent term up to 1 year from the current term should complete a Leave of Absence form. If a graduate student requests, and is granted a leave of absence, the student must return in the term specified on the Leave of Absence form. If a student fails to return in the agreed upon term, then the student must reapply for admission. During a leave of absence, students will not be able to use university resources.

**Important:** *Taking one or more semesters off without notifying the University may result in dismissal.* Graduate students *must* follow the policies for withdrawal and leave of absence as specified by the Graduate School.

### 5.5.3. RETENTION POLICY

Students are dismissed from their graduate program for any of the following scenarios. This includes all undergraduate courses taken as graduate students.

- Three grades of C+, C or C- or any combination thereof

- One grade of F or I/F
- One grade of U or I/U

If a student's GPA falls below a 3.0 at any time, the student goes on academic probation and has either three subsequent courses or nine hours to bring the GPA up to at least a 3.0. A student must have at least a 3.0 GPA to begin any program-specific exit requirements (i.e., graduate). Students must have a minimum GPA of 3.0 before starting the capstone course (i.e., CLR 597).

Students who are dismissed from the program may apply for readmission after a 3 consecutive term (i.e., 1-year) waiting period following the dismissal date.

#### **5.5.4. POLICY ON REPEATING COURSES**

According to the "Policy on Repeating Courses" in the current Graduate Catalogue a student may not repeat a course in which they received a grade of A or B. The initial grade of "C" will count in the total number of grades of "C" for retention purposes. Furthermore, the Clinical Research Program does not allow students to repeat a course to improve a grade. All courses have a "no repeat" classification.

### **5.6. GRADUATION**

#### **5.6.1. ELIGIBILITY FOR GRADUATION**

For graduate students to be eligible for graduation, a student must apply for graduation through SeaNet. Graduate students are not allowed to "walk" for graduation if degree requirements are outstanding. They must wait for the appropriate May or December graduation.

#### **5.6.2. APPLYING FOR GRADUATION**

All graduate students planning to complete a Post-Baccalaureate Certificate or graduate with a MS degree must apply for graduation through SeaNet by the dates specified by the Graduate School. Only students graduating with a degree may participate in the commencement ceremonies for graduation. Graduation commencement ceremonies occur in May and December only. The university does not hold a summer commencement. Students finishing during the summer must participate in the December commencement.

#### **5.6.3. CLEARING FOR GRADUATION**

Students are responsible for making sure that they have met graduation requirements and are "cleared for graduation" by their advisor or Program Coordinator.

The program degree audit must show that all requirements for the degree are completed before the student is cleared to graduate. Program degree audit issues or questions should be directed to the Program Coordinator.

**The student is responsible for following-up with their adviser or Program Coordinator to ensure that all paperwork necessary to clear the degree audit for graduation before the end of the term that the student intends to graduate is complete.**

The Program Coordinator will provide a final program sign-off to notify the Graduate School that a student's program degree audit is complete and that he/she is cleared for graduation.

When all courses and other requirements, as specified in the Graduate Catalogue, have been completed satisfactorily the student will receive his/her degree.

#### **5.6.4. GRADUATION EXIT SURVEY**

Students are encouraged to participate in the graduation exit surveys from the Clinical Research Program, Graduate School, and UNCW. The information collected will be analyzed to help improve and support graduate programs at UNCW. The survey is available through SeaNet (navigate to Student Services & Financial Aid Student Records I am running a few minutes late; my previous meeting is running over. Graduate Student Survey). The Clinical Research Program Faculty appreciate your feedback!

## **6. POST-BACCALAUREATE CERTIFICATE IN CLINICAL RESEARCH OPERATIONS**

The Post-Baccalaureate Certificate in Clinical Research Operations ("Certificate") is designed for individuals with a bachelor's degree who are interested in 1) entering the clinical research field or 2) obtaining additional education to facilitate a move into a different area within the clinical research field including career progression.

The Certificate program focuses on foundational knowledge and skills necessary to understand the structure, function, and operations of biopharmaceutical companies, clinical research organizations, clinical study sites, academic medical centers, and other organizations involved in biopharmaceutical clinical trials. The Certificate program is ideal for students who want to enter the clinical research industry but lack the undergraduate degree or experience to apply for the full MS program.

The Certificate program requires 18 credit hours for completion and is an online distance education program that requires 1 semester of experiential learning at a clinical research site.

Students in the Certificate program may take many of the same courses as the MS degree students. The following courses are specific to the Certificate program:

- CLR 505 Fundamentals of Clinical Research
- CLR 596 Clinical Research Experiential Learning

### **STUDENT LEARNING OUTCOMES**

Upon completing the Clinical Research Operations Certificate, participants will be able to:

1. Explain scientific concepts related to the design and analysis of clinical trials.
2. Explain the care of patients, aspects of human subject protection, and safety in the conduct of a clinical trial.
3. Describe how investigational products are developed and regulated.
4. Describe the study management (adverse event identification and reporting, post-market surveillance, and pharmacovigilance), and handling of investigational product.
5. Describe the operations at the site level to run a study (financial and personnel aspects).
6. Describe how data is acquired and managed during a clinical trial, including source data, data entry, queries, quality control, and correction and the concept of a locked database.
7. Demonstrate the principles and practice of leadership and professionalism in clinical research.

8. Describe elements of communication within the site and between the site and sponsor, CRO, and regulators including the teamwork skills necessary for conducting a clinical trial.

## 6.1. ADMISSION REQUIREMENTS

The minimum admission standards for candidates for the Clinical Research Operations Certificate program:

- A bachelor's degree preferably in a life science, health care discipline, or mathematics/statistics from a regionally accredited university or college in the U.S. (or its equivalent from a foreign institution based on a four-year program) with a minimum GPA of 2.5.

To apply for admission to the Post-Baccalaureate Certificate in Clinical Research Operations program, the candidate must submit the following:

1. An application for graduate admission.
2. Official transcripts of all prior university or college coursework (undergraduate and graduate).
3. Three letters of recommendations describing the individual's potential to complete the program (at least one from a current or former employer).
4. Current professional resume or curriculum vitae.
5. Application and supplemental documents must be submitted by the published deadline.

Students interested in combining the certificate program with a master's degree will have to meet all admission criteria for that degree. A separate and subsequent application for admission is required. Students in the Certificate program is not automatically admitted into the MS program, nor are they automatically accepted into the MS program.

Experience is not weighed as heavily in the Certificate admissions criteria as the MS program. Since experience is preferred for the MS program, Certificate students are encouraged to gain experience in clinical research or related fields prior to applying for the MS program.

The program requires a minimum of 18 credit hours. A Certificate graduate student may enroll in Graduate School on either a part-time or a full-time basis. Students should plan to take 2 to 3 courses per semester. A student may take 1 course per semester if they meet the Graduate School degree time limit.

Application decisions are communicated as full admission, provisional admission, or denied admission. Provisional admission refers to admission contingent on specific criteria, analogous to a trial period; e.g., students applying to the program with an undergraduate GPA less than 2.5 may be admitted, based on committee decision, provisional on completing the first 9 credits attempted with a grade of B or better; or, students admitted with another UNCW degree or certificate that is in progress might be admitted provisional on successful completion of that program of study before the first semester in the clinical research program.

A set of [Frequently Asked Questions \(FAQs\): Master of Science & Certificate Programs](#) on the Clinical Research Program webpages and updated regularly. Prospective students are encouraged to check the online list of FAQs for updates.

## **6.2. ACADEMIC PERFORMANCE**

Successful completion of the Certificate program requires an overall cumulative GPA of 3.0 for all courses. Completed Certificate courses may be applied to the Master of Science in Clinical Research and Product Development, in accordance with the GPA guidelines (3.0 or greater) and other admission requirements of the Graduate School, and contingent upon acceptance into the master's degree program. However, the 2 courses (CLR 505 & 596) are specific for the Certificate program and transferrable only as general electives to the MS degree. The remaining credits are courses in the MS curriculum.

### **6.2.1. TRANSFER CREDIT**

No transfer credit from another institution will be counted toward the completion of the Certificate program. The 2 courses (CLR 505 & 596) specific for the Certificate program are transferrable as general electives to the MS degree. The remaining credits are courses in the MS curriculum.

## **6.3. CERTIFICATE COURSE SEQUENCE**

The program requires a minimum of 18 credit hours to be successfully completed. Successful completion of the Certificate program requires an overall cumulative GPA of 3.0 for all courses. Completed Certificate courses may be applied to the Master of Science in Clinical Research and Product Development, in accordance with the GPA guidelines (3.0 or greater) and other admission requirements of the Graduate School, and contingent upon acceptance into the Master's degree program.

As of fall 2023, students admitted to the program must take the following course in their 1<sup>st</sup> semester:

- CLR 505 - Fundamentals of Clinical Research (3 credit hours)

After successful completion of CLR 505, students are required to take 4 required courses and 1 of the additional elective courses listed below.

Required Courses:

- CLR 501 - Clinical Research Monitoring and Ethics (3 credit hours)
- CLR 520 - Regulatory Affairs & Quality Management (3 credit hours)
- CLR 550 - Clinical Research Trial Design & Data Management (3 credit hours)
- CLR 596 - Clinical Research Experiential Learning (3 credit hours)

Elective Courses:

- CLR 512 - Pharmacotherapeutics for Clinical Research and Product Development (3 credit hours)
- CLR 515 - Epidemiology and Safety (3 credit hours)
- CLR 525 - Current Issues in Global Regulatory Development and Management (3 credit hours)
- CLR 520 - Project Management in Clinical Research (3 credit hours)
- CLR 540 - Post-Marketing Studies (3 credit hours)
- CLR 545 - Biopharmaceutical Technology Management (3 credit hours)
- CLR 555 - Innovative Drug Product Development (3 credit hours)

Prior to spring 2023, students admitted to the program were placed into 1 of 2 tracks based on their level of clinical research experience. The track and course options selected are subject to approval by the Program Coordinator. The curriculum is available from the Graduate Catalogue version prior to the 2023-2024 academic year.

## **7. MASTER OF SCIENCE DEGREE IN CLINICAL RESEARCH AND PRODUCT DEVELOPMENT**

The UNCW Clinical Research Program offers a Master of Science degree in Clinical Research and Product Development. This is not a laboratory-based degree. The Program provides a didactic and rigorous curriculum that prepares graduates for mid-to upper-level roles in the biopharmaceutical clinical research industry.

Graduates work in biopharmaceutical companies, contract research organizations, clinical research investigator sites, academic medical centers, government agencies, niche service providers, and other associated organizations in research teams. Clinical researchers conduct clinical trials necessary to move new drugs, biologics, and biomedical devices through the regulatory process to reach regulatory approval and post-marketing studies required for drug safety and used for label/market expansion.

An understanding of the 4 phases of clinical research involving human subjects is fundamental to all coursework. The importance of laws, regulations, guidance, and Good Clinical Practice is emphasized throughout the curriculum. Business aspects of the industry, particularly project management and market competition, are also covered.

### **7.1. STUDENT LEARNING OUTCOMES**

Upon completion of MS curriculum, the graduate will be able to:

1. Apply scientific concepts related to the design and analysis of clinical trials.
2. Apply the care of patients, aspects of human subject protection, and safety in a clinical trial.
3. Explain how investigational products are developed and regulated.
4. Apply study management (adverse event identification and reporting, post-market surveillance, and pharmacovigilance) and handling of investigational product.
5. Evaluate the operations at the site level to run a study (financial and personnel aspects).
6. Evaluate how data are acquired and managed during a clinical trial, including source data, data entry, queries, quality control, and correction and the concept of a locked database.
7. Demonstrate the principles and practice of leadership and professionalism in clinical research.
8. Demonstrate elements of communication within the site and between the site and sponsor, CRO, and regulators including the teamwork skills necessary for conducting a clinical trial.

### **7.2. ADMISSION TO THE PROGRAM**

Students who are taking or have taken graduate work elsewhere must be in good standing at the last institution to be eligible to take graduate work at UNCW.

Admission requirements include:

- A minimum of a bachelor's degree, preferably in a life science, health care discipline or mathematics/statistics, from a regionally accredited college or university completed before graduate study begins.
- Strong academic record with an undergraduate GPA of 3.0 or better.
  - Students may apply to the program with an undergraduate GPA of less than 3.0.
  - If accepted, admission will be provisional on completing the first 9 credits attempted with a grade of B or better.
- Experience working in the biopharmaceutical or a related industry of at least 2 years is preferred.
- Applicants must have access to a computer capable of supporting electronic mail, a web browser, a word processing program and multi-media presentations. In addition, applicants must be proficient in the use of these computer applications.
- Application and supplemental documents must be submitted by the published deadline.

Supplemental documents required for admission:

- An application for graduate admission;
- Official transcripts of all college work (graduate and undergraduate);
- Current resume or curriculum vitae;
- Brief essay (not to exceed 2 pages, double spaced); and,
- Three recommendations (at least one from a current or former employer).

Application decisions are communicated as full admission, provisional admission, or denied admission. Provisional admission refers to admission contingent on specific criteria, analogous to a trial period; e.g., students applying to the program with an undergraduate GPA less than 3.0 may be admitted, based on committee decision, provisional on completing the first 9 credits attempted with a grade of a B or better; or, students admitted with another UNCW degree or certificate that is in progress might be admitted provisional on successful completion of that program of study before the first semester in the clinical research program.

### **7.2.1. MS COURSE SEQUENCE**

Information on the course sequence for the MS curriculum is outlined in the [Degree Requirements](#) section of degree program in the current Graduate Catalogue. As stated Graduate Catalogue 2024-2025 version, a total of 36 credit hours is required, this includes: 15 credit hours of required courses, 15 credit hours of elective courses, and 6 credit hours for the required capstone project. Prior to fall 2024, the credit for required and elective courses was different as reflected in the curriculum available from the Graduate Catalogue versions prior to the 2024-2025 academic year.

### **7.2.2. TRANSFER CREDIT**

Six semester hours of graduate level transferred credit from a regionally accredited institution may be accepted upon approval.

### **7.2.3. FAQ'S ADMISSION TO MS PROGRAM**

A set of [Frequently Asked Questions \(FAQs\): Master of Science & Certificate Programs](#) on the Clinical Research Program webpages and updated regularly. Prospective students are encouraged to check the online list of FAQs

for updates.

### **7.3. ACADEMIC PERFORMANCE**

Students must maintain a 3.0 GPA while enrolled in the M.S. in Clinical Research and Product Development degree. All coursework must be submitted no later than the last day of class for the semester according to the UNCW calendar (i.e., before reading day and final exam period) to be accepted unless otherwise specified by the course instructor.

### **7.4. CAPSTONE**

All students enrolled in the MS degree program must complete a culminating capstone project, which is completed during the Clinical Research Master's Project course (CLR 597). The project is a faculty-guided, student-led scholarly experience that provides evidence of a student's critical thinking, ability to integrate information, and understanding of research. Students must complete the course over 2 semesters to ensure they have enough time to identify and complete their project with adequate support and to incorporate feedback from the Clinical Research faculty.

Students may enroll in the capstone course after completing the 5 core courses (e.g., CLR 501, 510, 520, 550, and 560) and with instructor approval. The Capstone Course Coordinator will distribute a registration notice to students during the spring semester (e.g., February) preceding their expected enrollment in Part 1 of the capstone course in fall or spring of the next academic year. Students must inform the Capstone Course Coordinator of their intent to enroll in the capstone course by the stated deadline (e.g., March 1<sup>st</sup>) via a survey distributed through Qualtrics XM.

Faculty will do their best to accommodate students who fill out the survey to start capstone. However, the number of seats is limited by the number of faculty that can teach the class. Spots will be filled first come, first served. Occasionally, students need to withdraw from capstone before completing the course for a valid personal and professional reason. Students who enroll and then must drop the part 1 capstone class to take it again the next semester (or later) will go to the bottom of the list/waitlist in an event of a limit in the number of faculty or classes. This program policy makes sure we have enough seats and instructors for everyone who needs it to stay on track.

A capstone project requires research, involves an applied project that relates to the student's M.S. degree in Clinical Research and Product Development, and results in addressing a specific business or scientific problem. A capstone project may involve hypothesis testing, data collection, or address practical questions, such as how best to solve a real-world business problem. Projects require significant background research using literature from scientific, peer-reviewed or reputable trade journals, data analysis, or formulation of a usable product.

A cumulative analysis of findings is required of each project. The analysis must demonstrate an understanding of data preparation, basic statistics, and data visualization techniques. Each project must be accompanied by a technical report (e.g., scientific paper) that documents the background research performed including methodologies, references, and lessons learned. A literature review alone is NOT an sufficiently rigorous to be acceptable for a capstone project in this MS program.

The student learning outcomes are as follows:



After taking this course, the student will gain the knowledge and skills needed to:

1. Use scientific knowledge and methods gained in master's courses to investigate current issues or problems relevant to the field of clinical research.
2. Develop a systematic literature review that supports the investigation of a problem amenable to investigation.
3. Formulate and conduct an independent research plan that is rigorous yet feasible.
4. Analyze and synthesize evidence as it is related to an identified issue or problem.
5. Disseminate the findings to colleagues and the community.

#### **7.4.1. CAPSTONE COURSE STRUCTURE**

The capstone project is divided into two semesters (Part 1 and Part 2). Part 1 is the development of a project proposal consisting of formalizing a project idea, a rigorous literature review, and methodology design. Part 2 is project execution consisting of generating or collecting data, analyzing and distilling data, and drawing conclusions as to broader impacts and meaning of the results.

##### **7.4.1.1. CAPSTONE PROJECT OVERVIEW**

Capstone topics should seek to address a specific business or scientific problem faced by the clinical research industry. A capstone project requires research. Projects must be relevant to clinical research and approved by the course instructor in Part 1.

Projects developed at your place of employment may be appropriate if they allow you to help your organization and improve practices. However, changes in reporting structure, lay-offs, career opportunities, and demands of daily business may interfere with Capstone timelines and success. Therefore, careful evaluation should be undertaken before deciding upon this type of project.

The capstone project should reflect an innovation or evolution of a current process (e.g., measurement of change before and after a process change; note that a basic team training module is not sufficient). However, students are not required to conduct capstone research at their place of employment.

If you are conducting your project at your workplace, be sure to verify company approval for your project idea before committing significant time and resources to a proposal. Working with your company to identify a problem they face can encourage buy-in.

Regardless of location, the local Institutional Review Board (IRB) should approve the project as necessary (i.e., if conducting human subjects research). Please refer to the UNCW IRB policies to ensure compliance.

Students are expected to conduct an extensive literature review to determine what is currently known and what needs to be known about the topic. A literature review is considered essential background reading and will be part of the project proposal and introduction of the final paper. Most importantly, a topic should require critical analysis by the student and consist of appropriate rigor and uniqueness to be publishable in the literature though it is not required that students publish their capstone projects.

**The Capstone is described below; however, refer to the CLR 597 syllabus for the most up-to- date requirements.**

##### **7.4.1.2. Proposal Generation (Part 1)**

Part 1 of the Capstone project involves the development of a formal research proposal document. Details are

provided in the course; but in general, the steps include:

- 1) Proposal development
  - a. Identify a topic that addresses a problem in or related to the clinical research and product development industry.
  - b. Conduct a comprehensive literature review to define the current state of knowledge and gap in knowledge to be addressed by the project.
  - c. Develop a project proposal with
    - i. Clearly specified, measurable objective(s)
    - ii. Detailed proposed methods and data collection instruments (if appropriate)
    - iii. Supporting details as described in the syllabus
- 2) Formal oral presentation
  - a. Present the project proposal to the Clinical Research Program faculty
  - b. The proposal is accepted as presented; accepted with recommended changes; or denied due to lack of rigor, adherence to instructions; or other factors. The faculty can make their approval conditional on the changes, whether minor or substantial, and require a follow-up proposal review.
  - c. Revise the proposal to achieve approval to proceed to Part 2.

When considering a potential topic idea, students should think about the study's purpose and be prepared to articulate responses to the following questions:

- What question do you want to answer?
- What data will you collect? How will you access such data?
- What is your dependent variable (what are you measuring)?
- What are your independent variables (what groups are you comparing)?
- At the end of your project, what will you produce (what are your deliverables)?
- What is the impact of your project (i.e., who cares)?

Students may propose an atypical project (e.g., a business case study), which does not have dependent or independent variables. Not all projects will check these boxes, but all studies will benefit from clearly stating study objectives, impact, and deliverables.

Another reliable source for topic ideas is to collaborate with research active faculty in the Clinical Research Program. Information about faculty research is found in the faculty directory or webpages.

#### **7.4.1.3. Project Execution (Part 2)**

Part 2 of the Capstone project involves executing the approved project proposal. Details are provided in the course; but in general, the steps include:

- 1) Conduct the research:
  - a. Collect data;
  - b. Conduct a quantitative or qualitative analysis; and,
  - c. Interpret the results.
- 2) Summarize the project in a final Capstone project paper
- 3) *Oral Comprehensive Exam* – Final Presentation (exit requirement): Present the outcome of the research to the project committee and wider community.

- 4) *Capstone Project* – Final Report (exit requirement)
- 5) Finalize project report after receiving feedback and final assessments from faculty members.
- 6) Obtain final approval of Capstone project report.

#### **7.4.1.4. Oral Comprehensive Exam – Final Presentation**

A formal presentation of the project is required and must be scheduled in coordination with the student's capstone instructor. Successful completion of this presentation is required for graduation (exit requirement) and is listed on the degree audit as the Oral Comprehensive Exam.

The presentation should span no more than 20 minutes with 10 minutes for discussion. Following the presentation, faculty members provide comments.

At the conclusion of the presentation, the faculty will decide one of the following:

- Accept the project as is.
- Request minor revisions to be done but approve the project, pending these changes, without additional review.
- Request specific and substantial changes. The committee will review these changes before the project is officially approved. If substantial changes are necessary, the committee will determine whether these changes are extensive enough to require another presentation meeting.
- The course syllabus provides key details about revision processes.

## **8. QUESTIONS AND ACKNOWLEDGING YOUR REVIEW**

Please contact your Program Coordinator or advisor for questions. Your enrollment in the program implies that you have read and acknowledge the relevant contents of this Handbook, with emphasis on the Honor Code, Code of Student Life, Confidentiality, and your program, as delineated below:

### **8.1. ACKNOWLEDGEMENT OF GUIDING DOCUMENTS**

I have been instructed to access the on-line copies of the following publications:

- UNCW Clinical Research Program Student Handbook
- UNCW Catalogue (graduate or undergraduate, as applicable)
- UNCW Code of Student Life

I have attended the Clinical Research New Student Orientation, where the importance of the following publications has been explained:

- UNCW Clinical Research Student Handbook
- UNCW Catalogue (graduate or undergraduate, as applicable)
- UNCW Code of Student Life

I understand that it is my responsibility to thoroughly read and understand all information detailed within the following publications:

- UNCW Clinical Research Student Handbook

- UNCW Catalogue (graduate or undergraduate, as applicable)
- UNCW Code of Student Life

I have read and agree with the terms of the Confidentiality Statement (Clinical Research Student Handbook, section 2.5.1) and will readily comply with agency and Clinical Research Program policies and standards relative to information security.

## **9. CONCLUSION**

This Handbook is updated regularly and is often duplicative of catalogue information. The catalogue and Handbook contain the answers for most questions that arise from students.

And finally, Clinical Research Program faculty wish you an enjoyable and successful experience in our programs!