



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

**Student Handbook**  
**for**  
**Clinical Research Students**

**2020-2021**

Bachelor of Science  
Clinical Research

Post-baccalaureate Certificate  
Clinical Research Operations

Master of Science,  
Clinical Research and Product Development

Updated February 2020

## Table of Contents

<b>Welcome from the Clinical Research Faculty Members!</b> .....	<b>1</b>
<b>Preface</b> .....	<b>2</b>
<b>1 Overview</b> .....	<b>3</b>
1.1 Organization and History.....	3
1.1.1 School of Nursing .....	3
1.1.2 Clinical Research Program .....	3
1.1.3 College of Health and Human Services .....	3
1.2 Mission and Vision.....	4
1.2.1.1 School of Nursing.....	4
1.2.1.2 UNCW.....	4
<b>2 UNCW Resources, Procedures, and Policies</b> .....	<b>4</b>
2.1 Academic Catalogues .....	5
2.2 University Principles and Policies.....	5
2.2.1 UNCW Code of Student Life .....	5
2.2.1.1 Table of Contents.....	6
2.2.1.1.1 Sections .....	6
2.2.1.1.2 University Policy .....	6
2.2.1.1.3 State Law .....	6
2.2.1.1.4 Federal Law .....	6
2.2.1.2 Substance Abuse Handbook .....	6
2.2.1.2.1 Policies.....	6
2.2.1.2.2 Penalties .....	6
2.2.1.2.3 Resources .....	6
2.2.2 Diversity in the University Community.....	6
2.2.3 Substance Abuse Policy .....	7
2.2.4 Seahawk Respect Compact.....	7
2.2.5 Zero Tolerance Policy Towards Violence and Harassment.....	8
2.2.6 Inclement Weather.....	8
2.3 Student Standards of Conduct .....	8
2.3.1 Academic Conduct.....	8
2.3.1.1 Student Academic Honor Code .....	9
2.3.1.2 Honor Code Pledge.....	9
2.3.2 Professional Conduct.....	9
2.3.3 Confidentiality Statement.....	10
2.3.4 Responsible Use of Digital and Social Media.....	12
2.3.5 Civility Statement.....	12
2.4 Information Security Policy.....	12
2.4.1 Information Security in Professional Settings.....	12
2.4.2 Information Security in the Academic Setting.....	13
2.5 Disability Resource Center.....	13

2.6	Financial Aid .....	14
<b>3</b>	<b>Clinical Research Programs at UNCW .....</b>	<b>14</b>
3.1	Online Learning.....	14
3.1.1	Time Commitment for Online Courses .....	14
3.1.2	Resources for Students .....	14
3.1.3	Randall Library .....	14
3.1.4	Professional Development and Mentorship Opportunities.....	15
3.1.5	Student Supplies .....	15
3.1.5.1	Computers .....	15
3.1.5.2	Software.....	15
3.1.5.3	Computer Access and Technical Issues.....	15
3.2	Course Policies and Expectations.....	16
3.3	Clinical Research Orientation.....	17
3.3.1	Acknowledgement of Guiding Documents .....	17
3.4	Grading Policies.....	18
3.4.1	Grading Scale.....	18
3.4.2	Grade Appeal Procedure .....	19
3.4.3	Writing Style .....	19
3.4.4	Discussion Forums .....	20
3.5	Communication with Instructor .....	20
3.6	Student Involvement in Research and IRB Review .....	20
3.7	Student Representation and Organizations.....	20
3.7.1	Clinical Research Council and Committees .....	20
3.7.2	Student Association of Clinical Research (SACR).....	20
<b>4</b>	<b>Bachelor of Science, Clinical Research.....</b>	<b>21</b>
4.1	Student Learning Outcomes.....	21
4.2	Application/Admission Process .....	21
4.2.1	Admission Requirements.....	21
4.2.1.1.1	Pre-requisite Courses - 10 year Rule.....	21
4.2.1.1.2	Grade Point Average.....	22
4.2.1.1.3	Transfer credits .....	22
4.2.1.2	Admission Decisions .....	22
4.2.1.2.1	Admission Deferral .....	22
4.3	Academic Advisement.....	23
4.3.1.1	Advisor Prior to Admission to the Program .....	23
4.3.1.2	Advisor After Admission to Program.....	23
4.3.1.3	Contacting Your Advisor.....	23
4.3.1.4	Developing a Plan of Study .....	23
4.3.1.5	Changing Advisors .....	24
4.3.1.6	Audit Review .....	24

4.3.1.7	Access to Files .....	24
4.3.1.8	Registration .....	24
4.3.1.9	Academic Difficulties .....	25
4.3.1.10	Time Limits for Degree Completion.....	25
4.4	Academic Performance .....	25
4.4.1	Retention and Progression Policy .....	25
4.4.1.1	Minimum Passing Grad for Courses in the Major .....	25
4.4.1.2	Repeating Courses.....	25
4.4.1.3	Grade Point Average (GPA).....	25
4.4.1.4	Pre-requisites .....	26
4.4.1.5	Course Sequencing.....	26
4.4.1.6	Failing a Course in the Major.....	26
4.4.1.7	Failure of Internship Courses .....	26
4.4.1.8	Honor Code Violations .....	26
4.4.1.9	Voluntary Withdrawal .....	26
4.4.1.10	Dismissal .....	27
4.5	Senior Internship.....	27
4.5.1	Host Organizations .....	27
4.5.2	Responsibilities.....	27
4.5.2.1	Placement .....	27
4.5.2.2	Internship Schedule and Absences .....	28
4.5.2.2.1	University Closure due to Inclement Weather .....	28
4.5.2.3	Professionalism Requirements and Dress Code .....	28
4.5.2.4	Transportation for Course Requirements.....	28
4.5.2.5	Liability Insurance .....	29
4.5.2.6	Documentation of Learning .....	29
4.5.2.7	Student Injuries at internship Settings .....	29
4.6	Graduation .....	29
4.6.1	Participating in Graduation Before Completion of Requirements.....	30
<b>5</b>	<b>Graduate Programs in Clinical Research.....</b>	<b>31</b>
5.1	Academic Regulations and Procedures .....	31
5.1.1	Graduate student resource booklet.....	32
5.2	Orientation .....	32
5.3	Academic Advisement.....	32
5.4	Academic Performance.....	32
5.4.1	Withdrawals.....	32
5.4.2	Leave of Absence .....	32

5.5	Retention Policy .....	33
5.6	Graduation .....	33
5.6.1	Applying for Graduation .....	33
5.6.2	Attending Graduation before Completing Requirements .....	33
5.6.3	Clearing for Graduation .....	33
5.6.4	Graduation Exit Survey .....	34
<b>6</b>	<b>Master of Science, Clinical Research and Product Development.....</b>	<b>34</b>
6.1.1	Student Learning Outcomes .....	34
6.1.2	Application / Admission to the Program .....	35
6.1.3	FAQ's Admission to MS program.....	36
6.2	Academic Performance.....	36
6.3	Capstone .....	36
6.3.1	Capstone Course Structure .....	37
<b>7</b>	<b>Post-baccalaureate Certificate in Clinical Research Operations .....</b>	<b>41</b>
7.1	Student Learning Outcomes.....	41
7.2	Admission Requirements .....	42
7.3	Academic Performance.....	43
7.3.1	Transfer Credit.....	43
7.4	Certificate Course Sequence .....	43
<b>8</b>	<b>Questions and Acknowledging your Review.....</b>	<b>44</b>
	ACKNOWLEDGEMENT OF GUIDING DOCUMENTS .....	44
<b>9</b>	<b>Conclusion.....</b>	<b>44</b>



**Clinical Research Program**  
**School of Nursing**

**WELCOME FROM THE CLINICAL RESEARCH FACULTY MEMBERS!**

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

Thank you for considering the Clinical Research Programs 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, and the Clinical Research Program (fondly referred to as “CLR”) is a program that sits in the School of Nursing, but it is not a nursing degree.

Clinical researchers oversee the development, monitoring, and management of clinical trials exploring the science of new medications, drugs, therapies, and devices. Students completing our programs earn either a Bachelor of Science in Clinical Research; Master of Science in Clinical Research and Product Development; or Post-baccalaureate Certificate in Clinical Research Operations. Our programs are offered in completely- or predominantly-online formats, providing our students versatility in their education.

UNCW has several programs that have achieved national recognition in academic program rankings (see: <https://uncw.edu/rankings/list.html>). The Clinical Research Programs are prominently positioned on these prestigious lists.

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 Clinical Research Student Handbook is to assist in understanding the policies, procedures, and general information specific to the Clinical Research (CLR) program of the University of North Carolina Wilmington (UNCW) School of Nursing. The information in this guide is a supplement to the published current issues of UNCW's *Undergraduate and Graduate Catalogues* and the *Student Code of Student Life*.

Successful matriculation and graduation from the Clinical Research Program require adherence to all policies, procedures, and regulations as stipulated by UNCW, the UNCW School of Nursing, and the UNCW Clinical Research Program. Questions regarding requirements or policies should be referred to the Director of Student Success Center, Academic Advisor, Program Coordinator, School of Nursing Director, or other appropriate person(s).

### *Student Success Center*

McNeill Hall, Room 1009

Email: [chhs@uncw.edu](mailto:chhs@uncw.edu)

Phone: 910.962.3208

Fax: 910.962.4921

URL: <https://uncw.edu/oss/>

The University of North Carolina Wilmington is committed to and will provide equality of educational and employment opportunity for all persons regardless of race, sex (such as gender, marital status, and pregnancy), age, color, national origin (including ethnicity), creed, religion, disability, sexual orientation, political affiliation, veteran status or relationship to other university constituents—except where sex, age or ability represent bona fide educational or occupational qualifications 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 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 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 and is projected to continue to increase for the foreseeable future. The UNCW School of Nursing received funding to support early development of the program from Pharmaceutical Product Development, Inc.(PPD). 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 Degree in Clinical Research Management and Product Development and enrolled the first students in January 2011. In 2017, a post-graduate certificate program was added.

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

The School of Nursing moved into the 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.

Additional information is available here in these fact sheets and brochures on the College of Health and Human Services website and also the School of Nursing website.

## **1.2 Mission and Vision**

The School of Nursing is an integral part of UNCW and a vital contributor to the healthcare community in New Hanover County and the surrounding southeastern region. The faculty is committed to preparing nursing and clinical research graduates at the baccalaureate and graduate level to become vital members of the workforce contributing to the health of the community. The faculty is also committed to inter-professional collaboration in teaching, scholarship, and service to promote, support, and maintain the health of the citizens.

### **1.2.1.1 SCHOOL OF NURSING**

**Vision:** The UNCW School of Nursing will be recognized as a center of excellence in education, practice, and research that prepares professionals to shape a dynamic healthcare environment and to serve a diverse community.

**Mission:** The mission of the UNCW School of Nursing is to educate nursing and clinical research professionals through excellence in teaching, scholarship, service, and community engagement. Emphasis is placed on educating individuals to improve health outcomes and quality of life in diverse populations.

### **1.2.1.2 UNCW**

**Vision:** UNCW will be recognized for excellence in everything it does, for its global mindset and for its community engagement.

**Mission:** The University of North Carolina Wilmington, the state's coastal university, is dedicated to the integration of teaching and mentoring with research and service. Our commitment to student engagement, creative inquiry, critical thinking, thoughtful expression and responsible citizenship is expressed in our baccalaureate and master's programs, as well as doctoral programs in areas of expertise that serve state needs. Our culture reflects our values of diversity and globalization, ethics and integrity, and excellence and innovation.

## **2 UNCW RESOURCES, PROCEDURES, AND POLICIES**

It is the student's responsibility to know and understand all applicable UNCW, Clinical Research, and School of Nursing policies, or know where to locate the information. Policy documents are available on the UNCW website and in the Clinical Research Student Handbook. It is also the student's responsibility to keep apprised of any new changes in the curriculum, mandates, and Clinical Research requirements.

## 2.1 Academic Catalogues

Undergraduate and graduate academic catalogues are updated and posted online annually on the UNCW website.

Students are encouraged to carefully review, and use as a reference, the undergraduate or graduate catalogue assigned at the time of admission to UNCW. This “catalogue year” is used to map progress to degree completion based on requirements delineated in the catalogue.

The academic catalogues include detailed information on a variety of important topics, including:

- University regulations
- Degree requirements
- Course descriptions
- Retention, dismissal and re-enrollment
- Student conduct
- Withdrawal policies
- Requirements for graduation
- North Carolina residency requirements

All students who are classified as out-of-state residents are strongly encouraged to review the North Carolina residency requirements.

## 2.2 University Principles and Policies

University-level principles and policies are provided elsewhere. This section identifies some of the key areas relevant to Clinical Research students and refers to the original source for further reading.

### 2.2.1 UNCW CODE OF STUDENT LIFE

The UNCW Code of Student Life outlines the rights and responsibilities and expected levels of conduct of students on and off campus. Its purpose is to prevent abuse of the rights of others and to maintain an atmosphere in the university community appropriate for an institution of higher learning.

Rather than duplicating information found in the UNCW Code of Student Life (URL: <http://www.uncw.edu/odos/documents/cosl-current.pdf> ). The Code’s *table of contents* is provided below. Students are encouraged to review this handbook and use it as a resource.

### **2.2.1.1 TABLE OF CONTENTS**

- Statement of Academic Expectations for Students
  - Statement on Diversity
  - Equal Educational and Employment Opportunity
- 2.2.1.1.1 SECTIONS
- I. Academic Honor Code (Policy 04.100)
  - II. Student Conduct and Appeals
  - III. Student Records
  - IV. University Owned Residences
  - V. Policy on Illegal Drugs (04.110)
  - VI. Student Organizations
  - VII. Use of University Facilities
  - VIII. Campus Life Facilities
- 2.2.1.1.2 UNIVERSITY POLICY
- 02.200 Harassment Prevention
  - 02.210 Harassment Resolution Procedures
  - 02.220 Improper Relationships Between Students and Employees
  - 02.330 Tobacco Policy
  - 04.110 Illegal Drugs
  - 04.130 Sexual Assault
  - 04.190 Disability Accommodations
  - 05.303 Alcohol Policy
  - 05.304 Alcohol Marketing
  - 07.100 Communicable Disease Policy Statement
  - 07.100 Responsible Use of Electronic Resources
  - Freedom of Expression
  - Grievance Procedure
  - Hurricane Policy
  - Skateboarding and Rollerblading
  - Photo Use Policy
- 2.2.1.1.3 STATE LAW
- I. Drug Law
  - II. State Policy on Firearms/Other Weapons on University Property
  - III. Policies Regarding Fire Laws
  - IV. Hazing Law
  - V. Policy Regarding Disorderly Conduct

- VI. State Policy on Possession/Manufacture of Fraudulent ID
- VII. Stalking
- VIII. Financial Transaction Card Crime Act
- IX. Financial Transaction Card Theft
- X. Assault Inflicting Serious Bodily Injury; Strangulation; Penalties

2.2.1.1.4 FEDERAL LAW  
Supplement I: Title IX of the Education Amendments of 1972

### **2.2.1.2 SUBSTANCE ABUSE HANDBOOK** Philosophy

2.2.1.2.1 POLICIES  
UNCW Alcohol Policy  
UNCW Alcohol Marketing Policy  
UNCW Illegal Drugs Policy

2.2.1.2.2 PENALTIES  
State Law and UNCW Policy  
Referral Process

2.2.1.2.3 RESOURCES  
University Resources  
Community Resources  
NC General Statutes on Alcoholic Beverages  
Other Provisions  
NC General Statutes on Controlled Substances  
Federal Regulatory Requirements: Controlled Substances  
Federal Trafficking Penalties (Schedule I-V Drugs)  
Federal Trafficking Penalties (Schedule VI Drugs/Marijuana)  
Controlled Substances: Uses and Effects  
Federal Drug-Free Workplace Act of 1988

The UNCW Policy Web site ([www.uncw.edu/policies](http://www.uncw.edu/policies)) serves as a policy index and repository for official UNCW policies. In addition to the Web site, policies are also found in various handbooks, brochures and other university publications.

## **2.2.2 DIVERSITY IN THE UNIVERSITY COMMUNITY**

As an institution of higher learning, the UNCW represents a rich diversity of human beings among its faculty, staff, and students and is committed to maintaining a campus environment that values

that diversity. Accordingly, the university supports policies, curricula, and co-curricular activities that encourage understanding of and appreciation for all members of its community and will not tolerate any harassment or disrespect for persons because of race, gender, age, color, national origin, ethnicity, creed, religion, disability, sexual orientation, political affiliation, marital status, or relationship to other university constituents. Further, no student or employee shall be subject to retaliation for bringing a good faith complaint pertaining to unlawful harassment or discrimination or for protesting such behavior directed against another member of the university community.

For more information concerning ways in which our multicultural learning community may be nurtured and protected or complaint resolution procedures, contact the Office of Institutional Diversity and Inclusion, the Office of the Dean of Students, the Office of Academic Affairs, or the Office of Human Resources.

### **2.2.3 SUBSTANCE ABUSE POLICY**

Students, faculty members, administrators, and other employees of UNCW are responsible, as citizens, for knowing about and complying with the provisions of North Carolina Law that make it a crime to possess, sell, deliver, or manufacture those drugs designated collectively as “controlled substances” in Article 5 of Chapter 90 of the North Carolina General Statutes.

Any member of the university community who violates that law is subject both to prosecution and punishment by the civil authorities and to disciplinary proceedings by UNCW. It is not “double jeopardy” for both the civil authorities and the university to proceed against and punish a person for the same specified conduct. The university will initiate its own disciplinary proceedings against the student, faculty member, administrator, or other employee when the alleged conduct is deemed to affect the interest of the university.

For a complete account, reference the current issue of *The UNCW Code of Student Life*. The Code of Student Life (See section 2.2.1 in this document).

### **2.2.4 SEAHAWK RESPECT COMPACT**

The Clinical Research Program embraces the UNCW Respect Compact.

In the pursuit of excellence, UNC Wilmington actively fosters, encourages, and promotes inclusiveness, mutual respect, acceptance, and open-mindedness among students, faculty, staff and the broader community.

- We affirm the dignity of all persons.
- We promote the right of every person to participate in the free exchange of thoughts and opinions within a climate of civility and mutual respect.
- We strive for openness and mutual understanding to learn from differences in people, ideas and opinions
- We foster an environment of respect for each individual, even where differences exist, by eliminating prejudice and discrimination through education and interaction with others.

Therefore, we expect members of the campus community to honor these principles as fundamental to our ongoing efforts to increase access to and inclusion in a community that nurtures learning and growth for all.

### **2.2.5 ZERO TOLERANCE POLICY TOWARDS VIOLENCE AND HARASSMENT**

UNCW practices a zero-tolerance policy for violence and harassment of any kind. For emergencies contact UNCW CARE at 962-2273; Campus Police at 962-3184; or Wilmington Police at 911. For University or community resources visit UNCW campus resources website.

### **2.2.6 INCLEMENT WEATHER**

In the case of inclement weather (such as hurricanes, ice storms, etc.) the School of Nursing will follow the UNCW Emergency Management Plan

Students are reminded that they are to utilize sound, personal judgment when deciding whether to commute for a learning experience.

## **2.3 Student Standards of Conduct**

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

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.

### **2.3.1 ACADEMIC CONDUCT**

The Clinical Research Program (in addition to all other School of Nursing programs) follow the policies and procedures as outlined in the academic catalogues. In particular, refer to catalogue 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
- Cheating
- The giving or receiving of unauthorized aid in tests, examinations, or other assigned school work

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.

### **2.3.1.1 STUDENT ACADEMIC HONOR CODE**

Any member of the university community who has reasonable grounds to believe that an infraction of the Student Academic Honor Code has occurred has an obligation to report the alleged violation. This obligation is a core value of the Honor Code and must be fulfilled by each and every member of the university.

Academic dishonesty takes many forms, from blatant acts of cheating, bribery, or similar misdeeds to the more subtle forms of plagiarism, all of which are totally unacceptable in an institution of higher learning. Reporting and adjudication procedures have been developed to enforce the policy of academic integrity, to ensure justice, and to protect individual rights. Complete details may be found in the current Code of Student Life and the Faculty Handbook.

Resources for adhering, enforcing, reporting violations of the honor code are found on the Student Honor Code

### **2.3.1.2 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 is found on the Office of the Dean of Students, Student Academic Honor Code web page.

## **2.3.2 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.
- The Clinical Research student assumes responsibility and accountability for individual judgments and actions at his/her level of knowledge and expertise.
- Clinical Research faculty and students exercise informed judgment and use individual competence and qualifications as criteria in seeking consultation, accepting responsibilities, and delegating activities to others.

It is expected that faculty and students will 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.
- By safeguarding the research participants' right to privacy by judiciously protecting information of a confidential nature.

It is expected that faculty and students will 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.
- By collaborating with members of the health profession and other citizens in promoting community and national efforts to meet the health needs of the public.
- By assuming responsibility for reporting incompetent, unethical, or illegal practice to the appropriate authority (i.e., incident reports, etc.)

It is expected that faculty will respect and uphold the rights of students.

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

It is expected that students will respect and uphold the rights of faculty.

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

### **2.3.3 CONFIDENTIALITY STATEMENT**

As a student, faculty, or staff member assigned to an internship site, or invited to research at the site, you may be allowed access to patient or research participant records. Patient/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/participant information is permitted only on a need-to-know basis. **It is critically important that students understand the seriousness of sharing confidential information and the consequences from both academic, and potentially, legal perspectives.**

It is the policy of the Clinical Research Program that students of the School shall respect and preserve 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:

It is the policy of the UNCW School of Nursing that Clinical Research students, faculty, and staff of the school shall respect and preserve privacy and confidentiality of information, regardless of the agency to which the student is assigned. Violations of this policy include, but are not limited to:

- Accessing information that is not within the scope of one's assignment;
- Misusing, disclosing without proper authorization, or altering research participant or personnel information;
- Disclosing to another person's sign-on code and password for accessing electronic or computerized records;
- Using another person's sign-on code and password for accessing electronic or computerized records;

- Photographing any patient or study subject’s related information, personal identifiers, fluids, blood or body parts, regardless of whether or not the patient/subject’s identity was compromised.
- Leaving a secured application unattended while signed on; and
- Attempting to access a secured application without proper authorization.

Examples of breaches of confidentiality are available in Table 1.

Violation of this policy by students, faculty or staff to any agency with which the UNCW 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 personal, civil, and/or criminal liability and legal penalties.

**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:	<ul style="list-style-type: none"> <li>• Unauthorized reading of patient account information</li> <li>• Unauthorized access of personnel file information</li> <li>• Unauthorized reading of a patient’s chart</li> <li>• Accessing information that you do not need to know for the proper execution of your job/internship function</li> </ul>
Misusing, disclosing without proper authorization, or altering patient or personnel information:	<ul style="list-style-type: none"> <li>• Making unauthorized marks on a patient/ research participant’s chart</li> <li>• Making unauthorized changes to a personnel file</li> <li>• Sharing or reproducing information in a patient/research participant’s chart or personnel file with unauthorized personnel</li> <li>• Discussing confidential information in a public area, including but not limited to waiting room, restroom or elevator.</li> <li>• Posting confidential patient information on social media such as Facebook, Instagram, Twitter, etc.</li> </ul>
Disclosing to another person your sign-on code and password for accessing electronic or computerized records	<ul style="list-style-type: none"> <li>• Telling a co-worker your password so that he/she can log in to your work</li> <li>• Telling an unauthorized person the access codes for personnel files or patient accounts</li> </ul>
Using another person’s sign-on code and password for accessing electronic or computerized records	<ul style="list-style-type: none"> <li>• Using a co-worker’s password to sign in to and/or “Log on” to the hospital or clinic’s computer system</li> <li>• Unauthorized use of a log-in code for access to personnel files or patient/research participant accounts</li> </ul>
Leaving a secured application unattended while signed on	<ul style="list-style-type: none"> <li>• Being away from your desk while you are logged into an application</li> <li>• Allowing a co-worker to use your secured application for which he or she does not have access after you have been logged in</li> </ul>



Policy Violation	Examples
Attempting to access a secured application without proper authorization	<ul style="list-style-type: none"> <li>• Trying passwords and log-in codes to gain access to an unauthorized area of the computer system</li> <li>• Using a co-worker's application for which you do not have access after he/she is logged in</li> </ul>

### 2.3.4 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 nursing as it relates to 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. UNCW has 'Social Media Use' guidelines which all employees and students are expected to be aware of and follow. The purpose is 'to help guide us' in the professional use of online communications (Refer to the following link: <https://uncw.edu/ur/documents/UNCWSocialMediaGuidelines.pdf>).

Responsible Social Media Use by CLR students: The federal rules (HIPAA Privacy Act and the HITECH Act, 2012, which modifies HIPAA [Federal Register, Volume 78. Number 17 Rules and Regulations]) are expected to be followed by all CLR students as they relate to your onsite internship experience. Students must be aware that social networking sites can be accessed by and then shared with patients and family members, colleagues and others. Students must avoid sending or posting anything that can reasonably be used to identify the patient or research participant in any form (HIPAA Privacy Act and the HITECH Act, 2012). You may be legally liable for what you post on your site and your posts on the site of others.

### 2.3.5 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:

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

## 2.4 Information Security Policy

### 2.4.1 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 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 through its life cycle, including origination, entry, processing, distribution, storage and disposal.

#### **2.4.2 INFORMATION SECURITY IN THE ACADEMIC SETTING**

Information security related to UNCW systems is described on UNCW's ITSD webpage. Some of the topics covered on this webpage are listed below. External resources are also available.

Section: *What you should know about:*

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Antivirus	Posting personal information
Email scams	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

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### **2.5 Disability Resource Center**

Current and prospective students with disabilities who need accommodations or who have questions about accessibility may contact the Disability Resource Center.

Students needing accommodations must be registered with UNCW Disability Services. Students should present their Accommodations Letter to their instructor within the first week of class or as soon as possible. Students should then meet their instructor to make mutually agreed upon arrangements based upon the recommendations in the Accommodations Letter.

## 2.6 Financial Aid

Information on financial aid options, including scholarships, for UNCW students if available on the UNCW Financial Aid website.

## 3 CLINICAL RESEARCH PROGRAMS AT UNCW

### 3.1 Online Learning

Online (also referred to as “distance-learning”) technologies are used extensively in the Clinical Research programs. The undergraduate Clinical Research Program is predominantly online (after admission into the program). The graduate Clinical Research programs are completely online program. However, in the master’s degree program, students are encouraged to attend in-person for their final capstone presentations. 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.

#### 3.1.1 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. This will vary according to the level of the class and your aptitude for the subject matter, but a good rule of thumb is to plan on about **three times the credit hour value of the class: that is, around nine hours a week for a three-hour class.** While online courses give students much flexibility in scheduling, they do not take less time than conventional classes. In fact, more responsibility and effort shifts to the student in the learning process and more involvement and commitment is required.

#### 3.1.2 RESOURCES FOR STUDENTS

A library of information is available for online students on the UNCW website, Online Education page. Of particular importance is the “Resources and Services” link.

#### 3.1.3 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 a variety of resources (i.e., instructions, tutorials) and support options for the student who is not on campus. Student fees pay for databases such as ProQuest Central, Science Direct, and 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.

### **3.1.4 PROFESSIONAL DEVELOPMENT AND MENTORSHIP OPPORTUNITIES**

Professional development content is infused throughout the curriculum, with greater emphasis in the undergraduate program. Email communication is used to announce guest speakers (for which, remote attendance is usually available) and other activities.

**FuseCR** offers various programs and opportunities for students to enhance their understanding of the clinical research industry and prepare for the workforce. Specifically, FuseCR offers a mentorship program in which students are paired 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. Mentors and students meet 2-3 times per month from November to April and are encouraged to continue their relationship after the program has ended. FuseCR also offers career preparation assistance through resume reviews and mock interviews with industry professionals. Please reference the [FuseCR website](#) to keep track of opportunities

### **3.1.5 STUDENT SUPPLIES**

#### **3.1.5.1 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 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.

Develop a technology back up plan, as computers seem to crash when an assignment is due (e.g., friend's computer, Randall Library).

#### **3.1.5.2 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 Mozilla Firefox for Canvas Courses.

Microsoft Word will be used extensively in clinical research courses and is a firm requirement. All students have access to Microsoft Office 365. The suite is available for free for both Mac and PC users for UNCW students. The Office 365 suite includes the following: Word, Excel, PowerPoint, OneNote, Access, Publisher, Skype for Business, and OneDrive for Business. Contact the TAC if assistance is needed.

#### **3.1.5.3 COMPUTER ACCESS AND TECHNICAL ISSUES**

It is the student's responsibility to maintain constant access to a computer with internet access for on-line Clinical Research (CLR) courses. The on-line 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, it is 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 on-line Clinical Research courses in a timely manner, as well as submitting assignments on time.

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 on the TAC (Technology Assistance Center) 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. Key messages include:

- Document interactions with technical support staff for UNCW or Canvas issues.
- It is not prudent to try to complete assignments on the day assignments are due in the event a server issue (or personal computer issue) is encountered.
- Do not contact a Clinical Research instructor for computer support services.

## **3.2 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 a minimum of 2-3 hours of weekly study for each 1 hour of course credit per week. This means that student in a 3 credit, online Clinical Research course should be spending approximately 6 to 9 hours per week on the course to master the content.
- Actively participate in an online course, and access all class materials, assignments, and announcements in the course.
- 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 “netiquette” in all communications between class peers, staff, and faculty according to the Netiquette Guidelines.
- Acquire technology skills prior to starting an online course.
- Any concerns/questions relating to an assigned grade on a test, quiz or written assignment must be made in writing within 10 days after the test/quiz date or assignment 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.

- Make-up work or bonus (extra credit) work is not incorporated into most courses. Evaluate the syllabus and course expectations carefully.
- 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, it is the student's responsibility to maintain access to the online course materials and be able to take online tests and quizzes within the time allotted.
- Be self-directed and self-motivated in an independent and active learning role when taking an online course. This includes contacting the TAC for technical difficulties and not the instructor.

### **3.3 Clinical Research Orientation**

New students in any of the 3 Clinical Research programs are required to participate in an 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 faculty. The undergraduate and graduate Program Coordinators will facilitate the orientation. Clinical Research faculty provide an overview of courses and tips for success in both the academic programs and their clinical research career.

Participation in the Clinical Research orientation is mandatory. Undergraduate students are strongly encouraged to attend in person; however, remote participation is available via online meeting access. Graduate students may attend either in-person or via online meeting access.

University-level orientation is separate from the clinical research orientation, as it emphasizes other aspects of academic life. Both are useful and encouraged.

#### **3.3.1 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 2.3.3) and will readily comply with agency and Clinical Research Program policies and standards relative to information security. Formal documentation is required for undergraduates, due in part, to the internship requirements.

For graduate students, it is implied, as a condition of enrollment in the program, that you have read and agree with the terms of the Confidentiality Statement (Clinical Research Student Handbook, section 2.3.3) and will readily comply with agency and Clinical Research Program policies and standards relative to information security. Formal documentation is required for undergraduates.

### 3.4 Grading Policies

The Clinical Research 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 you invest in this class (and this class only) - they are not personal judgments and are nothing to be ashamed of.
- Grades do not determine how your instructors interact with you – Your instructors do not judge you or your potential based on the grade you receive.
- Your 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 this Canvas Learn course. Your 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.

Your 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. It is not prudent to 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 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.

#### 3.4.1 GRADING SCALE

Clinical research faculty have adopted a 10-point scale letter grade scale for all degree programs, excluding courses that are graded categorically (e.g., pass/fail). 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 %	C = 70 - 79 %	F = < 60%
B = 80 - 89 %	D = 60 - 69 %	

Any concerns/questions relating to an assigned grade on a test, quiz or written assignment must be made in writing within 10 days after the test/quiz date or assignment due date. The instructor will provide feedback on a timely basis after the written concerns have been received. Under no circumstances will confirmed, individual assignment grades be discussed after the final semester grades have been posted.

It is good practice to assume that make-up work or bonus (extra credit) work will not be incorporated into the clinical research courses unless specified in the syllabus. Therefore, it is important to monitor your progress throughout the semester.

### **3.4.2 GRADE APPEAL PROCEDURE**

Any student considering a grade appeal should understand that each faculty member has the academic freedom and responsibility to determine grades according to any method chosen by the faculty member. However, prejudiced or capricious academic evaluation by a faculty member is a violation of a student's rights and valid grounds for a grade appeal.

Any student who contests a course grade must 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 procedures outlined below. These procedures are not to be used in cases involving student academic dishonesty that are addressed by the UNCW Code of Student Life.

An appeal must be made in writing no later the last day of the next succeeding regular semester. Grades not appealed by that time become permanent. Undergraduate students must present the appeal in writing to the Associate Director of Undergraduate Programs. Graduate students must present the appeal in writing to the Associate Director of Graduate Programs.

The written statement shall limit itself to citations of evidence pertaining to the valid grounds for the appeal. By conferring with the student and the instructor, the Associate Director will seek resolution by mutual agreement.

Failing such resolution, the Associate Director will transmit the written appeal to the Director of the School of Nursing, 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 of Academic Affairs and Student Services, who will convene the CHHS Grade Appeals Committee.

The Grade Appeals Committee must consist of the convening Associate Dean, and five faculty members appointed by the Associate Dean. 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 supports the student's appeal, it will prescribe the method by which the student will be reevaluated. The grade resulting from the prescribed reevaluation is final and may not be further appealed.

### **3.4.3 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/assignments, points are deducted for any graded activities containing **any text messaging language, misspelled words, or incorrect grammar.**

#### **3.4.4 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. ***Please review the Netiquette Guidelines.***

### **3.5 Communication with Instructor**

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 confirming the meeting.

Students should expect that, in most instances (not all), instructors will respond to student inquiries within 72 hours, Monday through Friday. Students are referred to the course syllabus for specific communication plans.

### **3.6 Student Involvement in Research and IRB Review**

All student 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) website.

Students are encouraged to evaluate their research projects (i.e., capstone, independent study) for the need for IRB approval or review.

### **3.7 Student Representation and Organizations**

#### **3.7.1 CLINICAL RESEARCH COUNCIL AND COMMITTEES**

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

#### **3.7.2 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, Registered Student Organizations.

The Student Association of Clinical Research (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. Demonstrate a foundational understanding of clinical research methodologies described in study protocols with emphasis on study design, operational aspects, and regulatory compliance.
2. Integrate knowledge and skills gained in the basic sciences to the planning, implementation, and evaluation of clinical research.
3. Apply and explain scientific and regulatory concepts related to the development, design, and analysis of clinical studies for biopharmaceutical and medical device product development.
4. Evaluate ethical issues, including the protection of human subjects and the evaluation of safety in the conduct of clinical studies, in the context of underlying regulations and guidelines.
5. Explain processes and rationale for clinical study operations in the context of Good Clinical Practice and other relevant guidelines and regulations (e.g., study management, monitoring, safety management, handling of investigational products, data management)
6. Describe the collection, flow, and management of data through a clinical study and the role of statistics and informatics.
7. Interpret statistical results from the published studies in the peer reviewed literature and clinical study reports.
8. Demonstrate leadership, professionalism, oral and written communication, and team work skills in clinical research.

### **4.2 Application/Admission Process**

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

##### **4.2.1.1.1 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: July 1, 2017 application deadline: any courses taken Spring 2007 or prior are not valid.  
December 15, 2017 application deadline: any courses taken Summer 2007 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 SSC for further information.

#### 4.2.1.1.2 GRADE POINT AVERAGE

The grade point average (GPA) for application evaluation purposes will be calculated based on all completed 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.

#### 4.2.1.1.3 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.

#### **4.2.1.2 ADMISSION DECISIONS**

Admissions decisions are made by a committee of faculty members. One of three outcomes are assigned for each student:

- Full Admit: Students are not considered a full admit until they have successful completion with a grade of “C” (2.00) or better of all but one prerequisite courses and maintaining a cumulative GPA of at least 2.50.
- Conditional Admit Status: Students who have more than one prerequisite course remaining will be considered conditional admits until they finish all but one prerequisite.
  - If a student has more than one prerequisite course left at the start of the fall semester, they will not be allowed to continue in the program.
  - If a student does not complete their final prerequisite prior to the start of the summer between the 1<sup>st</sup> and 2<sup>nd</sup> years of the program, they will not be allowed to start the Clinical Research internship that fall.
- Denied: Students denied admission are eligible to re-apply in subsequent semesters.

#### 4.2.1.2.1 ADMISSION DEFERRAL

Acceptance into the Clinical Research Program is valid for one year. Students must submit a new application according to current admission policies to be reconsidered unless extenuating circumstances have been reviewed and confirmed with the Clinical Research Program Coordinator and SSC Advisor.

## **4.3 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:

### ***4.3.1.1 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).

### ***4.3.1.2 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.

### ***4.3.1.3 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.

### ***4.3.1.4 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 actually 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 her/his 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.

#### **4.3.1.5 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.

#### **4.3.1.6 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.

#### **4.3.1.7 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 SSC website for contact information (<https://uncw.edu/oss/index.html>) to obtain procedure details.

#### **4.3.1.8 REGISTRATION**

Students register for courses through mySeaport.

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.

#### **4.3.1.9 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 of Undergraduate 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 appeal process is summarized in this document (section 3.4.2). For additional assistance/information, contact the Program Coordinator or Director of the Student Success Center.

#### **4.3.1.10 TIME LIMITS FOR DEGREE COMPLETION**

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

## **4.4 Academic Performance**

### **4.4.1 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.

#### **4.4.1.1 MINIMUM PASSING GRAD FOR COURSES IN THE MAJOR**

A letter grade of 'C' or higher is required for all pre-requisite and major course 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.

#### **4.4.1.2 REPEATING COURSES**

Students not meeting the requirements of a C or better in major courses (or "pass" for pass/fail courses in the major) are allowed two opportunities to the course. Specifically, the student may repeat 1 course a maximum of 2 times 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 designee and availability of space in the course. This does not apply to pre-requisite courses which are addressed in the undergraduate academic catalogue.

#### **4.4.1.3 GRADE POINT AVERAGE (GPA)**

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

#### **4.4.1.4 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.

#### **4.4.1.5 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 grade for all courses designated in the Program of Study for the first year in the Program before enrolling in the internship courses (CLR 496, 497).

#### **4.4.1.6 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.

#### **4.4.1.7 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 immediately. Following advisement from the Program Coordinator, the student will be responsible for identifying a suitable internship site for completing the Program requirements.

#### **4.4.1.8 HONOR CODE VIOLATIONS**

Violation of UNCW’s Academic Student Honor Code may result if 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.

#### **4.4.1.9 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-apply for

admission to 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-apply to the Program.

#### **4.4.1.10 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 reapply for admission.*

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.

## **4.5 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 this course, students obtain an 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. 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.

### **4.5.1 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.

### **4.5.2 RESPONSIBILITIES**

#### **4.5.2.1 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.

#### **4.5.2.2 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.

##### **4.5.2.2.1 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.

#### **4.5.2.3 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.

#### **4.5.2.4 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.

#### **4.5.2.5 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.

#### **4.5.2.6 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 survey will be sent to preceptors via email). The internship courses also have an online learning component.

#### **4.5.2.7 STUDENT INJURIES AT INTERNSHIP SETTINGS**

If a student obtains an injury 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 might provide emergency care, but 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 Program Coordinator and student are responsible for completing the appropriate incident reporting forms of 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.

## **4.6 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 either 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 make certain that every student who intends to graduate from the university registers for those courses that are required for a degree. **The student,**

**however, must assume the final responsibility for meeting the graduation requirements set forth in the university catalogue.**

#### **4.6.1 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 **one course of up to four 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 seventh 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 2 graduate programs in clinical research: MS in Clinical Research Management and Product Development (36 credits) and the Post-baccalaureate Certificate in Clinical Research Operations (18 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, in the following areas:

Change of Name and Address

Email

Family Educational Rights and Privacy Act (FERPA)

Graduation

Indebtedness

#### Graduate Grading

- Academic Grievance Procedure
- Application for Admission to Candidacy and for the Degree
- Auditing Policy for Graduate Students
- Degree Time Limits
- Double Counting of Courses in Degree Programs
- Final Examination Policy
- Foreign Language Requirement
- Grade Appeal Procedure
- Grades of Incomplete
- Master's Degree Examination
- Minimum Competency Requirement
- Policy on Repeating Courses
- Retention by Appeal
- Retention Policy
- Transcripts

#### Registration

- Adding, Dropping
- Cancellation of Course Registration
- Continuous Registration Policy
- Credit for Approved Combined Degree
- Courses Approved for Undergraduate Credit Only
- Directed Individual Study
- Experiential Learning
- Extension Courses
- Course Credit
- Full-Time Status
- Graduate Courses Taken for Undergraduate Credit
- Graduate Courses Taken as an Undergraduate to Later Apply to a Graduate Degree Program
- Graduate Internships
- Leave of Absence
- Non-degree Credit
- Registration for Thesis
- Transfer of Course Credit
- UNC Online
- Web Registration

- Withdrawal Policy for Graduate Students

#### Student Conduct

- Academic Honor Code
- Class Attendance
- Code of Student Life
- The UNCW Honor Pledge
- Policy Statement on Illegal Drugs
- Student Gender-Based/Sexual Misconduct Policy

Release of "Directory Information"

Safety and Health Program

### 5.1.1 GRADUATE STUDENT RESOURCE BOOKLET

The resource provides additional information for graduate students.

[https://uncw.edu/gradschool/currentstudents/documents/graduate\\_student\\_resource\\_manual-fall\\_2017.pdf](https://uncw.edu/gradschool/currentstudents/documents/graduate_student_resource_manual-fall_2017.pdf)

## 5.2 Orientation

Two separate orientations are available to students

- Graduate School Orientation (attendance is strongly recommended). Look for announcements about details in your email. Note that online or recorded viewing may be offered. Contact the Graduate School ([gradschool@uncw.edu](mailto:gradschool@uncw.edu)) for questions.
- Clinical Research Graduate Program Orientation (attendance is required)

Remote attendance (e.g., online, via Zoom, recorded) is offered for both events. Confirm with the organizer each year.

## 5.3 Academic Advisement

Each student is assigned an academic advisor, and this advisor is named on the student's degree audit.

## 5.4 Academic Performance

### 5.4.1 WITHDRAWALS

Graduate Students are required to complete a withdrawal form 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 deadline.

Withdrawing after the deadline results in a failure of the course. Complete Withdrawals

Students who need to drop one or more courses or must withdraw from all courses during a semester follow procedures in the Academic Catalogue for course and semester withdrawals.

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

### 5.4.2 LEAVE OF ABSENCE

Students who are withdrawing from a term and plan to return in a subsequent term, or students who are planning to not enroll for a future 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 he/she 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 can result in dismissal.* It is important to follow the rules for withdraw and leave of absence as specified by the Graduate School.

## 5.5 Retention Policy

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

- 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 falls below a 3.0 GPA 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 in order to begin any program-specific exit requirement. Students must have a minimum GPA of 3.0 before starting the capstone course.

Students who are dismissed from the program may reapply for admission after a one year waiting period following dismissal.

Repeating clinical research courses to improve a grade is not allowed. (All courses have “no repeat” classification.)

## 5.6 Graduation

### 5.6.1 APPLYING FOR GRADUATION

All graduate students planning to graduate with a degree or certification **must apply for graduation through SeaNet** by the dates specified by the Graduate School. Graduation occurs in May and December only. There is not a summer commencement. Students finishing during the summer must participate in the December commencement.

### 5.6.2 ATTENDING GRADUATION BEFORE COMPLETING REQUIREMENTS

Graduate students are not allowed to “walk” for graduation if degree requirements are outstanding. They must wait for the appropriate May or December graduation.

### 5.6.3 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 program coordinator. **It is the student’s responsibility to follow-up with his/her advisor or graduate 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.**

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 survey](#). The information collected will be analyzed to help improve and support graduate programs at UNCW. The survey is available through SeaNet (Student Services & Financial Aid / Student Records / Graduate Student Survey). The Clinical Research Faculty appreciate your feedback!

## **6 MASTER OF SCIENCE, 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 four 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.

### **6.1.1 STUDENT LEARNING OUTCOMES**

Upon completion of the M.S. curriculum core component , the new graduate will be able to:

- Describe the processes by which biopharmaceutical and device industry move products from pre-clinical development to regulatory approval and post-marketing studies with emphasis on key regulations, ethics, and good clinical practice
- Discuss approaches to ensuring high quality clinical study data across the design and implementation process, including protocol/case report form design, monitoring, data management, statistical analyses, and reporting
- Write professionally and scientifically
- Search, summarize, and synthesize the scientific literature; communicate findings effectively

In addition to the core learning outcomes, upon completion of the M.S. curriculum the new graduate will be able to:

- Identify key components in the forecasting and managing of resources necessary for the execution of clinical trial programs including budget, timelines, and deliverables
- Discuss product development strategies in the context of domestic, international, and foreign laws and regulations; guidance documents; good clinical practice; market factors/competition; and health care policy
- Describe primary differences in the regulatory approval processes for the US and the European Union, particularly in the context of health care policy, reimbursement, research ethics, and data privacy
- List sources for regulatory guidance for the evaluation of safety and efficacy of new biopharmaceutical and device projects in the areas of clinical development, product manufacturing, and clinical compliance
- Evaluate critical domestic and global regulatory and health care issues that challenge and influence biopharmaceutical product development
- Effectively assess and manage ethical clinical trial programs and biopharmaceutical development projects
- Forecast the resources necessary for developing and managing biopharmaceutical clinical research grants and trials as required and regulated by global regulatory agencies
- Discuss the objectives and rationale for late phase studies involving epidemiology, pharmacovigilance/drug safety concerns, pharmacoeconomics, psychometric/patient-reported

### **6.1.2 APPLICATION / 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 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 related industry of at least two 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 addressing the student’s career goals and associated interest in the degree program (not to exceed 2 pages, double spaced)
  - Three recommendations (at least one from a current or former employer)

A total of 36 credit hours is required and must include 12 credit hours of core courses, 21 credit hours of additional coursework, and 3 credit hours for the capstone project.

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 B or better; 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.

### 6.1.3 FAQ’S ADMISSION TO MS PROGRAM

Frequently asked questions (FAQs) are located on the School of Nursing – Clinical Research website (<https://uncw.edu/chhs/son/academic/clres-ms-faq.html>). These FAQs are updated regularly.

## 6.2 Academic Performance

Students must maintain a 3.0 GPA while enrolled in the M.S. in Biopharmaceutical Clinical Research 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.

## 6.3 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 courses (CLR 597). The project is a faculty-guided scholarly experience that provides *evidence of a student’s critical thinking, ability to integrate information, and understanding of research*. Students must split the 3 credits into 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 4 core courses and with instructor approval. Students must obtain permission in the previous semester by contacting the Program Coordinator, no later than March 15 of the preceding spring semester if Part 1 is taken in Fall, or October 15 of the preceding fall semester, if Part 1 is taken in Spring)

Students requiring additional time to complete their project may enroll in continuous enrollment in subsequent semester.

A capstone project requires research, involves an applied project that relates to the student's degree in Clinical Research and Product Development, and results in solving a specific business or scientific problem. A capstone project often addresses practical questions, such as how best to solve a real-world business problem. Projects require significant background research and data analysis, and/or formulation of a usable product.

A cumulative analysis of findings is required of each project. *The analysis must demonstrate an understanding of basic statistics and data manipulation.*

Each project must be accompanied by a technical report that describes or documents the background research performed including methodologies, references, and lessons learned.

Please note that a literature review alone is NOT an acceptable or rigorous capstone project.

The Capstone prerequisites are: CLR 501, CLR 510, CLR 520, and CLR 550.

The Capstone 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.

### **6.3.1 CAPSTONE COURSE STRUCTURE**

The capstone project is divided into two semesters (Part 1 and Part 2). More information is provided in detailed sections further in this syllabus. The project consists of the following milestones:

#### **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 proposal course instructor.

Projects that are 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. For example, students may conduct an industry-wide multi-CRO survey and analysis to address a problem facing the industry.

It is encouraged that you identify an expert external to the clinical research faculty that can help facilitate your data collection and analysis. If you are conducting your project at your workplace, this person may be an internal company preceptor. This expert will also be part of your committee. 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, which can also be facilitated by a company preceptor.

Regardless of location, the local Institutional Review Board (IRB) should approve the project as necessary (if conducting human subjects research). Please refer to the UNCW IRB policies to ensure compliance (<http://uncw.edu/research/compliance/human.html>).

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. Most importantly, a topic should require critical analysis by the student and consist of appropriate rigor and uniqueness to be publishable in the literature.

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

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

Part 1 of the Capstone project involves 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 the clinical research and product development industry.
  - b) Conduct a comprehensive literature review to define the current state of knowledge.
  - 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 proposed project (in person, unless approval received by the capstone coordinator) to the Clinical Research 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 has the option to 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 from the faculty to proceed to Part 2
- 3) Form project committee for Part 2.

## **Project Committee and Topic Alignment with Faculty-Approved Tracks**

The project committee will consist of two to three members, one of whom must be a full-time faculty member of the graduate faculty in the Clinical Research Program. The chair of the committee will be assigned based on alignment with faculty expertise and will be determined at the oral presentation of the proposal.

The second committee member is typically a full-time or part-time member of the clinical research faculty, but it may also be another member with subject matter expertise, upon approval of the course coordinator. The third member of the committee should be an expert member identified by the student (e.g. company preceptor).

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 exactly will you be doing?
- What data will you collect?
- 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)?

It is not uncommon for students to 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 good source for topic ideas is to collaborate with research active faculty in the Clinical Research Program. Information about faculty research is found here:

<https://uncw.edu/chhs/son/about/clrdirectory.html>.

## **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
  - 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.

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

A formal presentation of the project is required and must be scheduled in coordination with the student's committee. 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, committee members provide comments. The committee may ask the student additional questions regarding the purpose and overall implications and limitations of the project.

In some cases, an alternative presentation of your project (e.g. a conference presentation) can be substituted in lieu of a formal committee presentation. Such alternatives need to be approved by the committee and course coordinator. Regardless of final presentation format, all students should explore opportunities to disseminate project findings at symposia (poster or oral presentations) or journal article publications.

At the conclusion of the presentation, the committee 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 important details about revision processes.

## **Capstone Grading Scale**

The grading scale for CLR 597 is different from all other courses in this degree program. For CLR 597, each assessment (project milestone) will be graded numerically. CLR 597 is a pass/fail class, and numerical grades are transformed into pass/fail criteria as follows:

Pass = 70.00 - 100 %

Fail = < 70%

The final course grade will not be rounded. Per the UNCW Graduate School, if a graduate student fails a course, then they are dismissed from the graduate program.

## **7 POST-BACCALAUREATE CERTIFICATE IN CLINICAL RESEARCH OPERATIONS**

The Post-Baccalaureate Professional Certificate in Clinical Research Operations 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 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 experience to apply for the full MS program, or students who do not wish to pursue the lengthier MS degree.

The program requires 18 credit hours for completion and is provided completely online as asynchronous distance education extension program. The entire 18 hours into the full MS program, if accepted. However, all admission requirements such as the two years of experience (preferred) must be met for admission, in addition to a positive decision from the review committee.

With the exception of 3 courses, students in the certificate program take the same courses as the MS degree students:

- Certificate students without 2 years of experience are required to take
  - CLR 505 Getting Started in Clinical Research
  - CLR 506 Clinical Research Operations and Regulations
- Certificate students are not required (or allowed) to take CLR 597 – Capstone.

### **7.1 Student Learning Outcomes**

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

- 1) Explain the marketing approval process (pre-clinical to phase IV) for new drugs, biologics, and devices from operational, scientific, and regulatory perspectives.
- 2) Compare and contrast differences in the drug approval process in the U.S. to other countries and regions.
- 3) Distinguish each phase of product development in terms of overall objections, applicable study designs, populations studied, types of clinical endpoints, and connection to information included in the approved product labeling.
- 4) Select appropriate regulations and guidelines, used in the U.S. and abroad, to guide specific activities related to new biopharmaceutical and device product development from the site, sponsor, and subject perspectives.
- 5) Examine and critique approaches for ensuring high quality clinical trial data related to protocol and case report form design, site activities, monitoring, data management, statistical analyses, safety reporting, and development of regulatory reports.

- 6) Construct a model for forecasting and managing the resources necessary for the execution of clinical trial programs including budget, timelines, and deliverables.

## 7.2 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 graduate 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.

These admissions requirements apply only to the graduate certificate program in Clinical Research Operations.

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 are not automatically admitted into the MS program, nor are they automatically accepted into the MS program.

Experience is not weighted heavily in the Certificate admissions criteria; it is weighted heavily in the MS program. Certificate students are encouraged to gain clinical research experience prior to applying for the MS program, to be competitive.

The program requires a minimum of 18 credit hours. A certificate graduate student may enroll on either a part-time or a full-time basis. Students admitted to the program are 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. See Academic Catalogue for details.

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; 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.

The set of frequently asked questions (FAQs) are located on the School of Nursing – Clinical Research website (<https://uncw.edu/chhs/son/academic/clres-ms-faq.html>). Prospective students are encouraged to check the online list of FAQs for updates.

## **7.3 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.

### **7.3.1 TRANSFER CREDIT**

No transfer credit from another institution will be counted toward the completion of the certificate program.

## **7.4 Certificate Course Sequence**

The program requires a minimum of 18 credit hours. Students admitted to the program are 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.

### Track 1:

Students with less than 2 years of experience (who do not hold an undergraduate degree in clinical research) are required to take:

CLR 505 - Getting Started in Clinical Research Credit Hours: 3

CLR 506 - Clinical Research Operations and Regulations Credit Hours: 3

After successful completion of CLR 505 and CLR 506, students are required to take the 3 core courses and 1 of the additional courses listed below.

### Track 2:

Students with approximately 2 or more years of experience or an undergraduate degree in clinical research are required to take the 3 core courses and 3 of the additional courses listed below.

#### Core Courses:

CLR 501 - Clinical Research Monitoring and Ethics Credit Hours: 3

CLR 520 - Regulatory Affairs & Quality Management Credit Hours: 3

CLR 550 - Clinical Research Trial Design & Data Management Credit Hours: 3

#### Additional Courses:

CLR 510 - Advanced Scientific Writing & Interpreting Medical Literature Credit (3)

CLR 512 - Pharmacotherapeutics for Clinical Research and Product Development (3)

CLR 515 - Epidemiology and Safety (3)

CLR 525 - Current Issues in Global Regulatory Development and Management (3)  
(CLR 520 is a pre-requisite)

CLR 530 - Project Management in Clinical Research (3)

CLR 540 - Post-marketing Studies (3)

CLR 545 - Biopharmaceutical Technology Transfer & Intellectual Property Management (3)

CLR 555 - Innovative Drug Product Development (3)



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

## 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:

### 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 2.3.3) and will readily comply with agency and Clinical Research Program policies and standards relative to information security.

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## 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 Faculty wish you an enjoyable and successful experience in our programs!