Clinical Research

Department of Clinical Research
Campbell University
College of Pharmacy & Health Sciences
Department of Clinical Research
180 Main Street
Buies Creek, NC 27506
910-814-5755

Mission Statement
The mission of the Department of Clinical Research is to educate and train students to meet existing and future clinical research needs; and, to provide leadership to the clinical research industry. The Department of Clinical Research supports the broad mission of Campbell University and the College of Pharmacy & Health Sciences.

Academic Programs
The Department of Clinical Research offers a Bachelor and Master of Science in Clinical Research degrees as well as a minor. The Master of Science in Clinical Research degree is offered as an online program. The Clinical Research Program is located forty-five minutes from North Carolina’s Research Triangle Park, one of the world’s largest and most dynamic research centers. Many world-class research hospitals and organizations in this area look to Campbell’s clinical research graduates when recruiting new talent.

Bachelor of Science in Clinical Research (BSCR)
The Bachelor of Science in Clinical Research degree is ideally suited to prepare students for entry-level jobs in the clinical research industry. Students in the program are required to complete an internship in the clinical research field, which provides them with networking opportunities, potential jobs, and experiential training. The department collaborates with sites primarily located throughout North Carolina and neighboring states to facilitate their placement. Students may choose an internship site based on their future career goals, including academics, clinical settings or research management sites. Many BSCR graduates gain employment as a direct result of their internship experience.

Online Master of Science in Clinical Research (MSCR)
The Master of Science in Clinical Research degree is an online program. The program is designed to educate students in literature evaluation, study design, research methodologies, data management, and statistical analysis and interpretation. The online environment offers enhanced interaction between peers, faculty and industry professionals. The MSCR program culminates with a research project based on the students’ therapeutic interest. Students may work independently or collaborate with another MSCR student. The faculty serve as research project advisors throughout the entire research project experience. This degree prepares graduates to enter the field in positions including data managers, medical writers, clinical research monitors, study coordinators, regulatory affairs specialists, Institutional Review Board (IRB) administrators and project specialists. In addition, many graduates pursue professional degrees within the medical and health sciences fields.

3+2 Program
The Department of Clinical Research provides an avenue for students to earn both their Bachelor of Science and Master of Science in Clinical Research degrees. While the traditional time to earn both degrees is six years, the 3+2 program places students on a fast track toward completing two degrees in five years, by utilizing two summer sessions. By virtue of pursuing both degrees, the program offers students a competitive edge in the job market and rapid career advancement. Consideration for acceptance into this program, students must meet the following requirements:
- GPA of 3.0 or higher
- GRE verbal ≥ 50th percentile, quantitative ≥ 50th percentile, analytical writing ≥ 3.0
(a written request may be made for the consideration of PCAT/MCAT/LSAT/GMAT score.
- All MSCR course prerequisites. See admissions requirements. Summer only admission for 3+2 program.

Clinical Research Minor
Students pursuing degrees in multiple disciplines will benefit from additional education in Clinical Research to augment their major field of study. These disciplines/programs include: Nursing, Biology, Chemistry, Exercise Science, Pre-Med, Pre-Law, Healthcare Management, Business Administration, and Psychology. To complete the Clinical Research minor, students must complete 19.5 credit hours of prescribed clinical research courses.

The following courses will comprise the Clinical Research Minor:

<table>
<thead>
<tr>
<th>Courses</th>
<th>Credit Hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>CLNR 324 - Intro to Biostatistics</td>
<td>3</td>
</tr>
<tr>
<td>CLNR 330 - Regulatory Affairs I</td>
<td>2</td>
</tr>
<tr>
<td>CLNR 334 - Scientific Literature Seminar I</td>
<td>1</td>
</tr>
</tbody>
</table>

Admissions Policies

BSCR Matriculation
The students in the pre-pharmacy or equivalent program can declare their major and matriculate into the BSCR degree program. It should be noted that BSCR students are required to complete a semester-long internship. Most internships are completed at external companies that serve as experiential training sites for CPHS. These institutions may require criminal background checks, substance abuse screenings and/or more stringent immunization requirements. All BSCR students are subject to these types of screenings and the results will be evaluated as detailed in the Criminal Background Check and Substance Abuse Testing policies and procedures outlined in this academic bulletin.

MSCR Matriculation
The MSCR program is a fully online, year round program with applicants considered for Summer and Fall I terms. While the Department operates on rolling admission, individuals should submit their applications by the following deadlines:
- Summer Admission: March 31
- Fall 1 Admission: June 30

The following requirements and standards are designed to ensure scholastic and professional success in the College’s MSCR degree program. Applications for admission to the MSCR degree program are evaluated by the Department of Clinical Research’s admissions committee. Acceptance into the graduate program is based on the overall record and ability of the applicant.

There are three pathways to admission to the MSCR program. Applicants may be considered in one of the following categories:

1. Graduate of a Bachelor’s program
These applicants are required to have completed their undergraduate degree, from a regionally accredited college or
university, prior to matriculation and enrollment in any graduate coursework. Individuals may apply prior to completion of their undergraduate degree and gain acceptance contingent upon completion of the degree.

2. **Campbell University undergraduate student pursuing BSCR/MSCR 3+2**

Qualified applicants may apply to the MSCR program with the understanding the students will not have a completed degree prior to enrolling in MS coursework as defined in the academic bulletin. Accepted applicants would complete the BS and MS degrees in a five year period as outlined. Please note: The MS degree cannot be conferred upon the students in this category until the requirements of bachelor’s degree are met.

3. **PharmD/MSCR dual degree applicant**

An applicant with acceptance into the doctor of pharmacy (PharmD) program may apply for the MSCR program to pursue the PharmD/MSCR dual degree. Since matriculants to the PharmD program are only required to have completed 64 hours of prerequisites, and not required to have an undergraduate degree, these MSCR applicants may enter the program with or without completion of an undergraduate degree prior to enrollment. Accepted applicants have been accepted into both degree programs and normally pursue the degrees over a five year time period. Students without an undergraduate degree cannot graduate with the MSCR until completion of the requirements of doctor of pharmacy degree or bachelor’s degree is met.

It should be noted the Admissions Committee continues to review the results of pending coursework, test scores and behavior during the admissions and matriculation process. The Admissions Committee reserves the right to rescind the offer of admission due to poor performance or unprofessional behavior.

**Admission Requirements**

- Bachelor’s degree or higher from a regionally accredited college or university (Exceptions: BSCR/MSCR 3+2 and PharmD/MSCR applicants)
- GPA of 3.0 or higher
- GRE verbal ≥ 50th percentile, quantitative ≥ 50th percentile, analytical writing ≥ 3.0 (a written request may be made for the consideration of PCAT/MCAT/LSAT/GMAT scores)
  - GRE School Code: 4575
  - Department Code: 0626
- TOEFL > 100 (internet-based) or IELTS > 7.0, with no individual band score below 6.
  - Institution Code: 5100
- All required academic coursework must be completed at a regionally accredited college or university. All prerequisite courses must be completed with earned grades of “C” or higher.

**Prerequisites**

- Anatomy & Physiology (must be completed prior to enrolling in CLNR 519 Physical & Clinical Assessment)
- Statistics (must be completed prior to enrolling in the Biostatistics course sequence)
- Science Courses (12 hours including 2 lab courses must be completed prior to matriculation)

**Application Process**

1. Complete application with required $50 fee
2. Submit all official college transcripts
3. Submit GRE scores (a written request may be made for the consideration of PCAT/MCAT/LSAT/GMAT scores) and TOEFL/IELTS scores (if applicable)
4. Submit two professional/academic letters of recommendation
5. Qualified applicants will be contacted for an interview

*It is strongly recommended the PharmD/MSCR Dual Degree students plan to start their MSCR curriculum in the Summer Term.

**Policies**

1. Matriculating students may enroll in MSCR courses before they have completed any program prerequisites. However, students must complete prerequisite coursework specified for any MSCR course prior to enrollment as indicated in the prerequisite section above.
2. Those who have earned a terminal doctoral degree (e.g. PhD, MD, DO, DPT or PharmD) at a regionally accredited institution in the United States are not required to submit a GRE or other test scores.
3. Students not seeking a degree can register for courses if they:
   - Submit a completed application form and application fee.
   - Have earned a bachelor’s degree (or higher) from a regionally accredited college or university with a GPA of 3.0 or higher.
   - Submit official transcripts of all college/university work attempted.
   - Submit GRE scores, having achieved a verbal score ≥ 50th percentile, quantitative score ≥ 50th percentile and an analytical writing score ≥ 3.0 (a written request may be made for the consideration of PCAT/MCAT/LSAT/GMAT scores).
   - GRE School Code: 4575
   - Department Code: 0626
   - Submit two letters of recommendation.
   - Receive the permission of the MSCR Admissions Committee.
   - Non-native English speakers must submit TOEFL (>100, internet based) or IELTS (>7.0, with no individual score below 6) scores.
   - Institution Code: 5100

Note: A maximum of 6 credit hours (not to exceed three courses) of MSCR courses that do not require a prerequisite may be taken.*

Non-degree-seeking students are encouraged to register as early as possible. However, in cases where demand for a class exceeds capacity, degree-seeking students will have priority over non-degree seeking students, which may result in a non-degree seeking student being removed from the course. Credit for any course(s) taken by non-degree seeking students who enroll in the program will be valid for up to five years following course completion.

*This includes clinical research core courses numbered 505, 515, 517, 519, 525, 530, 552, 561 and elective courses numbered 539, 541, 550, 555, 560, 574, 593 and 595.

Note: A maximum of 6 credit hours based on previous didactic coursework may be requested for exemption or transfer by submitting the appropriate form (with supporting documentation) to the Course Director. Subsequent approval by the Department Chairman and the associate dean for academic affairs is required.

**International Students**

- International applicants are eligible for admission if they have completed a bachelor’s degree or higher. International applicants must have their transcripts evaluated by WES or AACRAO to be considered for admission.
- This program is completely online with no residency required; therefore, international applicants are not eligible to receive US student visas.
- If English is not the applicant’s native language, applicants must submit official scores for the TOEFL (>100 internet based) or IELTS (>7.0, with no individual band score below 6). Applicants who have completed their undergraduate degree in English in the U.S. are not required to submit English proficiency test scores.
Refund Policy
Reference the General Information section of this bulletin for more information regarding the CPHS refund policy.

Academic Standards

BS in Clinical Research
Academic standards for undergraduate programs are specified in Campbell University’s Undergraduate Academic Bulletin.

MS in Clinical Research
Academic Probation
Students in the MSCR program are subject to academic probation for:
1. Failing to maintain a cumulative GPA of 3.0 or greater in all MSCR
2. Earning a final grade of less than C in any MSCR course. Students earning less than a C must repeat course and earn a grade of C or above

Any occurrence of either of the above will result in academic probation not to exceed one academic year. In addition, students must complete an academic contract to acknowledge their academic probation.

Academic Dismissal
Students in the MSCR program are subject to academic dismissal for:
1. Failure to complete all coursework within 5 years of beginning the program or 61 attempted credit hours, whichever comes first.
2. Failure to maintain a cumulative GPA of 3.0 or greater for any 10 consecutive MSCR credit hours.
3. Failure to successfully remediate (receive a C or above) a course in which a grade less than C was earned.

Policies & Procedures
A maximum of six credit hours based on previous didactic coursework may be requested for exemption or transfer by submitting the appropriate form (with supporting documentation) to the course director. Subsequent approval by the department chairman and the associate dean for academic affairs is required.

Transfer credit from equivalent coursework may be conditionally granted. When requesting a transfer, students must include:
• Previous course name and graduate level number
• Semester course was taken

• Educational institution where course was taken
• Syllabus for the course
• Transcript with grade for course (in applicant file at Campbell)

When transferring, the course director will make a recommendation regarding possible equivalency directly to the chairman of the department and the associate dean for academic affairs. Final decisions regarding course equivalencies will be made jointly by the chairman of the department of Clinical Research and the associate dean for academic affairs. The total number of transfer credits granted per student will follow the policies of Campbell University’s College of Pharmacy & Health Sciences and the Southern Association of Colleges and Schools Commission on Colleges.

Grade Appeals
For information regarding grade appeals, reference the College’s Policies & Procedures at the beginning of this bulletin.

The MSCR program will not approve a request to participate in commencement ceremonies unless all credit hours have been completed.

Curriculum

BS in Clinical Research
Semester 1
Courses Credit Hours
CHEM 111/111L - General Chemistry I 4
BIOL 111/111L - Basic Biology 4
ENGL 101 - Academic Writing 3
CHRS 125 - Intro to Christianity 3
PE 185 - Lifetme Wellness 2
PHAR 100 - Pre-Pharmacy Seminar* 1
CUC 100 - Connections 0.5
Total 17.5

Semester 2
Courses Credit Hours
CHEM 113/113L - General Chemistry II 4
BIOL 221/221L - Anatomy & Physiology 4
ENGL 102 - Academic Writing & Literature 3
MATH 122 - Calculus 4
THEA 115 – Public Speaking 3
CUC 100 - Connections 0.5
Total 18.5

Semester 3
Courses Credit Hours
CHEM 227 – Organic Chemistry I 4
BIOL 334 – Microbiology 4
PHYS 221 – General Physics I 4
LANG 201 – Foreign Language 3
MATH 160 – Statistics* 3
CUC 200 - Connections 0.5
Total 18.5

Semester 4
Courses Credit Hours
CHEM 228 – Organic Chemistry II 4
BIOL XXX – Biology Elective^ 3/4
HIST 1XX – Western Civilization I or II 3
Humanities Elective (see listing) 3
ECON XXX– Econ. Elective 3
CUC 200 - Connections 0.5
Total 16.5-17.5

Semester 5
Courses Credit Hours
CLNR 341 – Medical Terminology 1
CLNR 363– New Product Development 2
CLNR 364 – Principles of Clin. Research 2
CLNR 324 – Introduction to Biostatistics 3
CLNR 451 – Sci. & Technical Writing 3
A/M/T 131 - Intro to Art, Music, Theatre 3
Total 15.5

Semester 6
Courses Credit Hours
CLNR 328 – Introduction to Pharmacology 4
CLNR 330 – Regulatory Affairs I 2
CLNR 442 – Interpersonal Skills 2
CLNR 379 – Physical & Clinical Assessment 2
CLNR 334 – Scientific Literature Seminar I 1
ENGL 20X – Literature I or II 3
Total 16

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Humanities Elective (see listing) 3
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CLNR 364 – Principles of Clin. Research 2
CLNR 324 – Introduction to Biostatistics 3
CLNR 451 – Sci. & Technical Writing 3
A/M/T 131 - Intro to Art, Music, Theatre 3
Total 15.5

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CLNR 442 – Interpersonal Skills 2
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CLNR 334 – Scientific Literature Seminar I 1
ENGL 20X – Literature I or II 3
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and rapid career advancement. By virtue of pursuing both degrees, the program offers BY virtue of utilizing two summer sessions. The 3+2 program places students on a fast track toward completing two degrees in five years. While the traditional time to earn both degrees is six years, the 3+2 program reduces this time to earn both degrees is six years, the 3+2 program reduces this time to five years by utilizing two summer sessions. By virtue of pursuing both degrees, the program offers students a competitive edge in the job market and rapid career advancement.

NOTE: Please refer to our website at www.campbell.edu/cphs for the most up to date curriculum information.

3+2 Program
The Department of Clinical Research provides an option for students to earn both their Bachelor of Science and Master of Science in Clinical Research degrees. While the traditional time to earn both degrees is six years, the 3+2 program places students on a fast track toward completing two degrees in five years by utilizing two summer sessions. By virtue of pursuing both degrees, the program offers students a competitive edge in the job market and rapid career advancement.

Humanities electives: CHRS: 202, 212, 224, 236, 251, 322 or higher; PHIL 121; ENGL 201 – 206; HIST 1xx – 4xx; LANG 221, 222, 241, 242

Social science electives: CRIM, ECON, GEOG, POLS, PSYC, SOCI, COMM 240

***Students are required to submit and pass a criminal background check and drug screen prior to the start of internship

CLINICAL RESEARCH

<table>
<thead>
<tr>
<th>Semester 7 Courses</th>
<th>Credit Hours</th>
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<tbody>
<tr>
<td>CLNR 465 – Manag/Monitor Clin. Trials II</td>
<td>2</td>
</tr>
<tr>
<td>CLNR 440 – Regulatory Affairs II</td>
<td>2</td>
</tr>
<tr>
<td>CLNR 450 – Data Management Seminar II</td>
<td>3</td>
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<tr>
<td>UNIV XXX – Humanities/Social Science Elective (see listing)</td>
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<td>Elective</td>
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Total credit hours earned = 130.5 - 132.5 Note: Please refer to our website at www.campbell.edu/cphs for the most up to date curriculum information.

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<th>Semester 7 Credit Hours</th>
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Semester 1

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<tr>
<td>CHEM 111/111L - General Chemistry I</td>
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<td>BIOL 111/111L - Basic Biology</td>
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<td>ENGL 101 - Academic Writing</td>
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<td>CHRS 125 - Intro to Christianity Seminar</td>
<td>3</td>
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<tr>
<td>PHAR 100 - Pre-Pharmacy Seminar</td>
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<tr>
<td>CUC 100 - Connections</td>
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<td>Total</td>
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Semester 2

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<th>Courses</th>
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<tbody>
<tr>
<td>CHEM 113/113L – General Chemistry II</td>
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<tr>
<td>BIOL 221 – Human Anatomy &amp; Physiology</td>
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<tr>
<td>MATH 122 – Calculus</td>
<td>4</td>
</tr>
<tr>
<td>ENGL 102 – Academic Writing &amp; Literature</td>
<td>3</td>
</tr>
<tr>
<td>PE 185 – Lifetime Wellness</td>
<td>2</td>
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<tr>
<td>CUC 100 - Connections</td>
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<td>Total</td>
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Semester 3

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<tr>
<td>CLNR 101 - &gt;Intro to Clinical Research</td>
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<td>CHEM 227 – Organic Chemistry I</td>
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<td>BIOL XXX – &gt;Biology Elective</td>
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<td>A/M/T 131 – Intro to Art, Music, or Theatre</td>
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<td>UNIV XXX - Humanities Elective (see listing)</td>
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Semester 4

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<td>CHEM 228 – Organic Chemistry II</td>
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<td>BIOL XXX – &gt;Biology Elective</td>
<td>3/4</td>
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<tr>
<td>ENGL 20X - Literature I or II</td>
<td>3</td>
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<tr>
<td>MATH 160 - &gt;Statistics</td>
<td>3</td>
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<tr>
<td>UNIV XXX - Social Science Elective (see listing)</td>
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<td>CUC 200 - Connections</td>
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Semester 5

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<td>CLNR 341 – Medical Terminology</td>
<td>1</td>
</tr>
<tr>
<td>CLNR 363 - New Product Development</td>
<td>2</td>
</tr>
<tr>
<td>CLNR 364 – Principles of Clin. Research</td>
<td>2</td>
</tr>
<tr>
<td>CLNR 324 – Introduction to Biostatistics</td>
<td>3</td>
</tr>
<tr>
<td>CLNR 451 – Sci. &amp; Technical Writing</td>
<td>1.5</td>
</tr>
<tr>
<td>THEA 115 - Public Speaking</td>
<td>3</td>
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<tr>
<td>Total</td>
<td>15.5</td>
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Semester 6

<table>
<thead>
<tr>
<th>Courses</th>
<th>Credit Hours</th>
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<tbody>
<tr>
<td>CLNR 328 – Intro. to Pharmacology</td>
<td>4</td>
</tr>
<tr>
<td>CLNR 442 – Interpersonal Skills Seminar</td>
<td>2</td>
</tr>
<tr>
<td>CLNR 338 – Scientific Literature Seminar</td>
<td>2</td>
</tr>
<tr>
<td>UNIV XXX - Humanities/Social Science Elective (see listing)</td>
<td>3</td>
</tr>
<tr>
<td>LANG 20X - Foreign Language</td>
<td>3</td>
</tr>
<tr>
<td>HIST 1XX - Western Civ. I or II</td>
<td>3</td>
</tr>
<tr>
<td>Total</td>
<td>17</td>
</tr>
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Summer 1

<table>
<thead>
<tr>
<th>Courses</th>
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<tr>
<td>CLNR 505 - Principles of Clin. Research</td>
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<tr>
<td>CLNR 515 - New Product Development</td>
<td>1.5</td>
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<tr>
<td>CLNR 519/L – Physical &amp; Clinical Assessment w/lab</td>
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<td>CLNR 561 – Healthcare Economics</td>
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Semester 7

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<tr>
<td>CLNR 525 - Medical Ethics</td>
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<td>CLNR 559 - Man./Mon. Clinical Trials</td>
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Fall I

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<td>CLNR 517 - Biostatistical Inference</td>
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<tr>
<td>CLNR 568 - Project Management</td>
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Spring I

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<td>CLNR 518 - Intro to Biostats. Model.</td>
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<td>CLNR 520 - Adv. Data Management</td>
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Spring II

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<td>CLNR 530 - Regulatory Affairs</td>
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<td>CLNR 566 - Adv. Study Design/Ana.</td>
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Summer 2

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<tr>
<td>CLNR 420 - &gt;Senior Internship</td>
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<tr>
<td>CLNR 416 - Senior Seminar</td>
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<tr>
<td>CLNR 568 - Project Management</td>
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Electives

With approval from the course instructor and associate dean of academic affairs, PHAR courses may serve as electives.

*Permission of instructor required.

Federally supported financial aid requires a minimum of 2 credit hours per academic term.

NOTE: Please refer to our website at www.campbell.edu/cphs for the most current curriculum and tuition information.
Course Descriptions

CLNR 101 - Introduction to Clinical Research
Credit: 1 Hour
This course is designed to provide a broad understanding of clinical research and a basic overview of the clinical research industry. The course provides students with a basic understanding of key clinical research topics allowing students a foundation to continue their pursuit of a degree in clinical research and a career in the clinical research industry.

CLNR 324 – Introduction to Biostatistics
Credit: 3 Hours
This course, which focuses on statistical methods in health sciences, is intended to provide the student with basic knowledge of descriptive statistics, graphing data, probability theory, normal and other common distributions, sampling and estimation, hypothesis testing, ANOVA and other selected statistical methods.

CLNR 326 – Principles of Clinical Biochemistry
Credit: 3 Hours
This course discusses the basic biochemical principles of quantitative analysis utilized in common clinical laboratory tests. An introduction to interpretation of abnormal clinical laboratory values is presented. Quantitative aspects of nutrition are presented, and regulatory effects of various hormones are described. Prerequisite: CHEM 227 & 228

CLNR 328 – Introduction to Pharmacology
Credit: 4 Hours
The basic principles of drug action are covered through discussion of the responses of biological systems to drugs and chemicals. Emphasis is placed on understanding mechanism of action through detailed exploration of receptor-mediated events (pharmacodynamics). The course considers the quantification of drug action as well as the absorption, distribution, metabolism, and elimination of xenobiotics (pharmacokinetics) and how these and other factors relate to drug action. Prerequisite: Required: BIOL 221, CHEM 227; Recommended: CHEM 228

CLNR 330 – Regulatory Affairs I
Credit: 2 Hours
This course provides the student with an overview of the regulatory affairs universe, with emphasis on requirements for initiating clinical trials, developing pharmaceutical products, and gaining approval for worldwide marketing applications. This is the first of two required regulatory affairs courses in the BSCR program. Prerequisites: CLNR 363 & 364

CLNR 334 – Scientific Literature Seminar I
Credit: 1 Hour
This course is the first in a two-part series. The skills developed in this class will be further refined in CLNR 336, Scientific Literature Seminar II. This interactive class introduces students to literature searching and critical analysis techniques. Skills in critical analysis of the scientific literature will be developed in small group discussion of scientific papers chosen by the faculty and students. These skills are applied in the form of written and oral presentations of projects developed by researching the current biomedical and pharmaceutical literature. Prerequisite: CLNR 451

CLNR 336 - Scientific Literature Seminar II
Credit: 1 Hour
This interactive class is a continuation of CLNR 334, Scientific Literature Seminar I. The class focuses on the continued application of skills relating to literature searching and critical analysis techniques, skills that were introduced in CLNR 334. These skills are applied in the form of two solo oral presentations. For the first presentation, students will prepare a brief presentation on a scientific research paper of their own choosing and use PowerPoint to make visual aids to supplement their presentation. The second will be a seminar-style presentation on a health-related topic, again using PowerPoint to generate slides as visual aids. Prerequisite: CLNR 334

338 Scientific Literature Seminar (3+2 Program)
This interactive class is combination of CLNR 334, Scientific Literature Seminar I and CLNR 336, Scientific Literature II. This interactive class introduces students to literature searching and critical analysis techniques. Skills in critical analysis of the scientific literature will be developed in small group discussion of scientific papers chosen by the faculty and students. These skills are applied in the form of written and oral presentations of projects developed by researching the current biomedical and pharmaceutical literature. In addition to learning how to apply these skills with a team, complete comprehension of these skills are applied in the form of two solo oral presentations. For the first presentation, students will prepare a brief presentation on a scientific research paper of their own choosing, and use PowerPoint to make visual aids to supplement their presentation. The second will be a seminar-style presentation on a health-related topic, again using PowerPoint to generate slides as visual aids.

CLNR 341 – Medical Terminology (Online)
Credit: 1 Hour
This course is designed to introduce students to the language of the clinical research and medical communities. Instruction will engage students and provide them an opportunity to learn, understand, and apply the terminology in context of clinical research and medical settings.

CLNR 363 – New Product Development
Credit: 2 Hours
New Product Development provides an introductory overview of the process of developing a molecule into a therapeutic agent. This course provides an overview of the process from discovery through regulatory approval and introduction to the market place. A perspective of the interaction required between Research & Development and marketing in order to insure product success in a regulated environment will be provided. Students will be provided with the background necessary to pursue a wide range of additional courses leading to degrees in clinical research.

CLNR 364 – Principles of Clinical Research
Credit: 2 Hours
This course will provide a broad understanding of clinical research-definition, methodology, conduct and applications. The course will explore basic elements of clinical research including the hierarchy of clinical design, clinical trial conduct, and safety surveillance. Application of clinical trial knowledge to specific medical practice issues will also be explored.

CLNR 365 – Managing & Monitoring Clinical Trials I
Credit: 2 Hours
This introductory course has been designed to provide both a theoretical and practical overview of the principles of managing and monitoring clinical trials. Lectures will focus on the practical aspects of study set-up activities (i.e., study planning issues, data collection strategies, selecting investigators), study conduct activities (i.e., subject recruitment issues and enrollment strategies, obtaining informed consent, monitoring both patient and safety data quality and integrity and conducting site visits for study initiation, periodic monitoring and multiple site closings), and study termination activities. The course also covers responsibilities of sponsors, clinical monitors, clinical research organizations, investigators and institutional review boards. In-class activities will allow students to gain a greater appreciation of operational issues associated with various clinical research-related regulatory documents by working with...
case studies related to the content studied. Lectures are based on U.S. regulations and guidelines, as well as international good clinical practices and significant clinical research-related documents.

Prerequisites: CLNR 363 & 364

CLNR 379 & 379L – Physical & Clinical Assessment with Lab
Credit: 2 Hours
This course is designed to introduce students to the basic principles of medical terminology, history taking, the basic techniques of physical examination assessment, and diagnostic test data.
Prerequisite: BIOL 221

CLNR 416 – Senior Seminar
Credit: 1 Hour
This course is designed to prepare the student for real world practices. The student will learn and review research, presentation and public speaking techniques and utilize these to prepare a research paper and presentation. This course culminates in a presentation day where each student will present their research information and internship experience to the Department of Clinical Research and honored guests.
Co-requisite: CLNR 420

CLNR 420 – Senior Internship
Credit: 14 Hours
This course is an experiential learning system, which allows the BSCR students an opportunity to gain hands on experience in the clinical research profession. Students and participating institutions are matched to provide a comprehensive work experience. The internship is designed for a BSCR candidate to develop strong clinical research skills while improving his/her knowledge in the field of clinical research.
Prerequisite: Completion of all GCC & BSCR courses and at least a 2.0 major and cumulative GPA
Co-requisite: CLNR 416

CLNR 440 – Regulatory Affairs II
Credit: 2 Hours
This course builds upon concepts developed in Regulatory Affairs I and provides more detailed and broader coverage of the terminology and concepts that address the regulation of the pharmaceutical industry by the Food and Drug Administration, with an emphasis on the drug, biologic and veterinary product development and approval process.
Prerequisites: CLNR 363, 364 & 330

CLNR 442 – Interpersonal Skills
Credit: 2 Hours
In this course, students will learn about the various factors involved in developing good interpersonal speaking and writing skills including: self-awareness, understanding individual differences, goal setting, listening and providing feedback, teamwork, leadership development and motivating others, delegation, negotiation, conflict resolution, interviewing, and presentation skills. The course will provide a forum for group discussions and writing exercises.

CLNR 450 – Data Management
Credit: 3 Hours
This introductory course covers topics such as the role of data management in clinical trials and the duties of the Clinical Data Coordinator. Topics include organization, collection, review, and tracking of data. Coding of data and standardized terminology are also considered. The course will also include instruction utilizing modern electronic data collection methods.
Prerequisites: CLNR 363 & 364

CLNR 451 – Scientific & Technical Writing
Credit: 1.5 Hours
Scientific and Technical Writing is a required course for Clinical Research majors designed to enable students to effectively and accurately write a variety of technical documents used in pharmaceutical-related industries.

CLNR 465 – Managing & Monitoring Clinical Trials II
Credit: 2 Hours
This course will continue to build upon concepts introduced and developed in CLNR 365, Managing and Monitoring Clinical Trials I. Additional material will be added as appropriate, and students will achieve a greater depth of knowledge and understanding about topics covered in the first course.
Prerequisites: CLNR 363, 364, 365

CLNR 504 – Special Research in Clinical Research
Credit: 1-2 Hours
This course will introduce the graduate student to the scientific inquiry process used in clinical and scientific research. This involves application of the scientific process including but not limited to: literature evaluation, literature search, design of project, development of written and verbal skills, data acquisition and analysis, use of web-based systems and data and project management.

CLNR 505 – Principles of Clinical Research
Credit: 1.5 Hours
This course will provide a broad understanding of clinical research - definition, methodology, conduct and applications. The course will explore the basic elements of clinical research including the hierarchy of clinical trial design, clinical trial conduct, and safety surveillance. Application of clinical trial knowledge to specific medical practice issues will also be explored.

CLNR 510 – Pharmacokinetics
Credit: 2 Hours
Pharmacokinetics involves the rates of liberation, absorption, distribution, metabolism, and excretion of drugs and chemicals in the body. A basic course in pharmacokinetics examines these principles from the mechanistic, mathematical, and graphical perspectives, and provides a scientific approach to rational drug selection and therapy. The principles governing liberation, absorption, distribution, metabolism, and excretion will be presented. The rates or kinetics of these processes, and the mathematical methods associated with pharmacokinetics, will be examined. Application of theoretical principles will be extended to examine drug product equivalency, dosage regimen design, and dosage adjustment in renal and/or liver failure. This course is co-listed as PHAR 410
Prerequisites: PHAR 304 & 314
Permission of instructor required.

CLNR 515 – New Product Development
Credit: 1.5 Hours
New Product Development provides an introductory overview of the process of developing a molecule into a therapeutic agent, as well as an overview of the process from discovery through regulatory approval and introduction to the market place. This course will provide a perspective of the interaction required between Research & Development and marketing in order to ensure product success in a regulated environment. It is designed to provide students with the background necessary to pursue a wide range of additional courses leading to degrees in clinical research.

CLNR 517: Biostatistical Inference
Credit: 2 Hours
This course is intended to provide students with the basic knowledge of estimation, hypothesis testing, sample size and power analysis, and other selected statistical methods including two sample tests, contingency table inference and odds rations. Applications of the
methodology and interpretation of results is the primary focus of the course.
Prerequisite: CLNR 324, MATH 160 or approved general Statistics course

CLNR 518 – Introduction to Biostatistical Modeling
Credit: 2 Hours
This course is intended to provide students with an introduction to and basic knowledge of statistical modeling; including one-way analysis of variance (ANOVA) and, simple and multiple linear and logistic regression.
Prerequisite: CLNR 517
Acceptable Co-requisite: CLNR 520

CLNR 519 & 519L* – Physical & Clinical Assessment with Lab
Credit: 2 Hours
This course is designed to introduce the student to medical terminology, medical history taking, basic physical examination techniques, and diagnostic tests commonly used in clinical research protocols.
Prerequisite: Anatomy & Physiology
*Dual PharmD/MSCR students are required to attend a seated lab on main campus

CLNR 520 – Advanced Data Management
Credit: 2 Hours
This advanced course covers in detail topics such as the role of data management in clinical trials and the duties of the Clinical Data Coordinator. Topics include organization, collection, review, and tracking of data. Coding of adverse drug experiences, drugs and disease states, and standardized terminology are also considered.
Prerequisites: CLNR 505 & 515
Acceptable Co-requisite: CLNR 518

CLNR 525 – Medical Ethics
Credit: 2 Hours
This course will use a combination of lectures, interactive discussion, case presentations, and student presentations to explore the field of medical ethics. The course will primarily focus on medical ethics as it relates to clinical research. However, medical ethics in clinical practice may also be addressed. Historical cases as well as current events will be extensively used to highlight key principles of medical ethics. During the course, students will satisfy the requirement of human subjects training required for clinical investigators by the National Institutes of Health.

CLNR 528 – Pharmacogenetics
Credit: 2 Hours
Population genetics, disease state prevalence, and population variances in response to drug therapy are covered in this course. The impact of pharmacogenetics on the future of clinical trials will be considered.
Prerequisites: CLNR 505, 515 & 518
This course is co-listed as PHAR 594 and PHSC 564.

CLNR 529 – Epidemiology
Credit: 2 Hours
This course presents an overview of epidemiology and how the field augments clinical research. The course emphasizes an introduction to the application of epidemiological methods. The primary goal of the course is to orient students to the field of epidemiology and foster an appreciation for the methods used to do observational studies in “real world” settings.
Prerequisites: CLNR 505 & 518

CLNR 530 – Regulatory Affairs
Credit: 3 Hours
This course provides the student with an overview of the regulatory affairs universe, with emphasis on requirements for initiating clinical trials, developing pharmaceutical products, and gaining approval for marketing applications. Emphasis will be placed on the practical application of regulations in the commercialization of health care products. This will include data submission requirements, quality procedure regulations, marketing considerations, and post-approval requirements including safety reporting.
Prerequisites: CLNR 505 & 515

CLNR 539 – Medical Genomics
Credit: 2 Hours
This course starts by teaching basic genomics and molecular biology. Attention then focuses on the benefits of this knowledge in biomedical research and medicine. Examples of topics discussed include pharmacogenomics and toxicology, an awareness of the ethical, legal, and social implications of genomic research, and the potential future implementation of Precision Medicine and Information-based Medicine.

CLNR 541 – Behavioral Medicine
Credit: 2 Hours
This elective course will examine the pathophysiology, diagnosis, pharmacology, treatment guidelines, and current literature for a variety of psychiatric disorders. The course will cover current controversies surrounding clinical research and evidence-based decisions in psychiatry. Topics will include the following: schizophrenia, bipolar disorder, depression, and other psychiatric disorders.

CLNR 550 – Introduction to Public Health
Credit: 2 Hours
The course provides a comprehensive examination of the basic and critical issues in public health for pharmacists. The course content includes a basic knowledge base of public health issues, an exploration of the various roles that pharmacy can provide in offering public health services, and examples of unique applications to pharmacy practice. Issues in public health care are examined both from the pharmacy perspective and the traditional public health viewpoint.

CLNR 552 – Scientific Communications
Credit: 2 Hours
This course briefly reviews fundamental communication skills, and then teaches scientific communication in both written and verbal forms. Regulatory documentation, abstracts, posters, manuscripts, and professional reports are covered. Oral presentation skills are also covered. Interpersonal skills are developed in team project work.

CLNR 555 – Special Populations in Clinical Research
Credit: 2 Hours
This course will cover topics and issues associated with conducting clinical research in special populations and vulnerable populations. The populations reviewed will include pediatrics/adolescent, geriatrics, obstetrics/women issues, and ethnic minorities. Current regulatory mandates and guidance will be covered and issues unique to each special population will be discussed such as measurement challenges, recruitment, ethics, and IRB issues.

CLNR 559 – Advanced Managing & Monitoring of Clinical Trials
Credit: 3 Hours
This course provides an in-depth introduction to the principles of managing and monitoring clinical trials. The varied environments in which clinical research is conducted are described and the roles of the different personnel involved in a clinical trial will be detailed. Students will be introduced to the elements of clinical trial protocols and data collection strategies. The course will provide an overview of regulations relevant to clinical trials including responsibilities of sponsors,
investigators, institutional review boards, and contract research organizations. In addition, the course will cover selection of investigators, conduct of investigator meetings, procedure for site monitoring visits (study initiation, periodic monitoring, close-out and study termination), patient enrollment issues, safety monitoring, case report form review, and data management. Students will become familiar with Good Clinical Practices (GCPs), Standard Operating Procedures (SOPs), the quality assurance process (QA), and FDA audits. Prerequisites: CLNR 505 & 515

**CLNR 560 – Pharmacoeconomics**  
Credit: 2 Hours  
Students will become aware of the various tools, methods, and strategies to evaluate the economic contribution of specific drug therapies at a variety of levels. Rising health care costs will force decisions to be made regarding the overall cost implications as well as the effectiveness of the technology. The application of such pharmacoeconomic analyses to clinical practice and pharmaceutical care will be instrumental to pharmacy’s success in our future health care delivery. This course will be presented utilizing a parallel learning model whereby students will be asked to give and receive information about pharmacoeconomics. This course is co-listed as PHAR 561.

**CLNR 561 – Healthcare Economics**  
Credit: 2 Hours  
This course will give participants an in-depth international perspective on health care economics. This perspective will be delivered by starting at the macro-economic, global level and then narrowing the focus of study to numerous national health care systems and landmark case studies. All case studies will be aimed at measuring the economic impact of specific health care crises. Each case will be preceded by the description of cultural values that impact health care delivery and government response in the event of a health care crisis.

**CLNR 562 – Preclinical Drug Development**  
Credit: 2 Hours  
This course provides students with an overview of the process of classical and modern drug development. The course will also provide a perspective of the interaction of research, development and marketing activities in a regulated environment. Particular emphasis is placed on promising approaches expected to lead to novel therapies and drug delivery systems within the next decade. A focus on currently drug discovery is included.

**CLNR 566 – Advanced Study Design & Analysis**  
Credit: 3 Hours  
This course presents a selection of study designs and statistical analyses that are most relevant to clinical research. The course will also present research question development, endpoints, database utilization and sample size calculation. The course emphasizes the application of these topics beyond just understanding the concepts. The role of clinical research in providing the evidence for Evidence-based Medicine is considered. The primary goal of the course is to present the concepts that are crucial to prepare students for CLNR 690/695 Research Project I/II, and develop the knowledge for the central importance of statistical thinking in clinical research (from initial conceptualization of the study, through design, statistical analysis plans, statistical analysis, and interpretation), rather than to become experts in computation. Prerequisite: CLNR 505, 515  
Acceptable Co-requisite: CLNR 518

**CLNR 568 – Project Management**  
Credit: 2 Hours  
This course will introduce the generic concepts of professional project management that should be applied while managing projects in several industries. The full life cycle of a project will be studied including project initiation, planning, execution, control and closeout. The project manager’s role in developing and maintaining the timeline, budget, and quality of a project will be defined. Students will be exposed to the principles of project management as it applies specifically to clinical research. While managing an individual clinical trial will be covered, the broader perspective of managing new drug development projects in the pharmaceutical industry will be a major focus. In the latter, the project manager integrates basic research, pharmacology, toxicology, chemical development, analytical development, pharmacokinetics, metabolism, clinical research, and marketing aspects for delivering a new product to the marketplace. Prerequisite: CLNR 505, 515 & 559

**CLNR 573 – Evidence-Based Medicine**  
Credit: 2 Hours  
This course will trace formulation of relevant questions from clinical cases through the methodology required to search the clinical literature for critical information. Students will be exposed to the process of evaluating the validity and usefulness of this information in order to incorporate it into clinical practice. Prerequisites: CLNR 505, 515 & 518

**CLNR 574 – Integrated Drug Safety**  
Credit: 2 Hours  
This course provides students with a comprehensive introduction to the many facets of contemporary pharmaceutical and biologic drug safety. A lifecycle development approach is taken, whereby discussions of drug safety considerations during in silico simulation modeling, drug discovery, in vivo and in vitro nonclinical research, preapproval clinical research, and post marketing surveillance are fully integrated.

**CLNR 578 – Biopharmaceutics**  
Credit: 3 Hours  
This course presents the biological and physiochemical factors of the body, drugs and dosage forms that influence drug availability, disposition and pharmacological and toxicological responses. This course is co-listed as PHAR 314. Permission of instructor required

**CLNR 581 – Pharmaceutical Compliance & Quality Assurance**  
Credit: 2 Hours  
This course is designed to provide an overview of the process of compliance and quality assurance activities within the Pharmaceutical Industry. Emphasis will be placed on auditing fundamentals, audit processes and tools, quality program management as well as FDA compliance activities. Students may be exposed to a variety of industry experts during the course. Emphasis will also be placed on Good Manufacturing Practices (GMP), Good Laboratory Practices (GLP) and Good Clinical Practices (GCP). Students will gain a practical knowledge of Quality as a scientific discipline. Prerequisites: CLNR 505, 515, 530 & 559

**CLNR 593 – Leadership Development**  
Credit: 2 Hours  
This course is intended for students who are contemplating a management/leadership career track. The lectures present fundamental skills of organizational behavior and leadership that are essential to effectively managing and leading both direct reports and project teams. The course involves lectures supported by video presentations, group discussion, and role play. Participant materials can be retained by the student for future use/reference in the workplace. The course contains both theoretical content, as well as an examination of processes involved in human behaviors in the health care organizational setting. Due to the heavy emphasis on process, participation and group-intensive instructional approaches are used in the course; there are three primary student goals for the course: Demonstrate mastery of the content as specified in the course objectives; apply the theories to case studies and develop an understanding of your own managerial style.
CLNR 595 – Bioterrorism & Mass Public Health Threats
Credit: 2 Hours
This course provides an overview of current issues related to bioterrorism and mass threats to public health. Details of specific risks of threat entities and their treatment will be taught. An emphasis is placed on response planning and preparation. Cross listed as PHAR 595

CLNR 606 – Clinical Research Seminar
Credit: 2 Hours
This seminar is intended to assist the student in developing critical thinking skills in clinical research design and analyses of data. The course will reinforce learning of experimental methods in clinical research by analyzing manuscripts in the published literature. Students will learn criteria for quality that will allow them to distinguish those studies with the strongest validity. They will apply statistical methodology and knowledge of study design that they acquired in previous courses. Students will develop an understanding of the limitations of data and study design. The skills developed in this course will assist those students who will be writing their own manuscripts. The course will also prepare students to report on their research project. Prerequisites: CLNR 505, 515, 518 & 566 Co-requisite: CLNR 690

CLNR 690 - Research Project I
Credit: 1 Hour
This course is the first part of the four-part Research Project course, which comprises CLNR 690, 691, 694, and 695. The student will utilize prior didactic experience in the Clinical Research Program to propose, design, and conduct the research project. The research project must involve patient-oriented research, including: epidemiologic and behavioral studies, health outcomes research, and/or health services research. The project will be conducted under the supervision of the Course Director. Students will have an internal faculty advisor who is a full-time faculty member in the Department of Clinical Research, as well as a Statistician faculty member of the Department of Clinical Research assigned to advise them throughout the project. In this course, students will develop a written Research Proposal, and once approved, will develop this into a full Research Protocol. In later research project courses, the student will ultimately conduct the study and present study results. Prerequisite: CLNR 690

CLNR 691- Research Project II
Credit: 2 Hours
This course is the second part of the four-part Research Project course, which comprises CLNR 690, 691, 694, and 695. The student will utilize prior didactic experience in the Clinical Research Program to propose, design, and conduct the research project. The research project must involve patient-oriented research, including: epidemiologic and behavioral studies, health outcomes research, and/or health services research. The project will be conducted under the supervision of the Course Director. Students will have an internal faculty advisor who is a full-time faculty member in the Department of Clinical Research, as well as a Statistician faculty member of the Department of Clinical Research assigned to advise them throughout the project. In this course, students will further develop a written Research Proposal, and once approved, will develop this into a full Research Protocol. In later research project courses, the student will ultimately conduct the study and present study results. Prerequisite: CLNR 690

CLNR 694 - Research Project III
Credit: 2 Hours
This course is the third part of the four-part Research Project course, which comprises CLNR 690, 691, 694, and 695. The student will utilize prior didactic experience in the Clinical Research Program to propose, design, and conduct the research project. The research project must involve patient-oriented research, including: epidemiologic and behavioral studies, health outcomes research, and/or health services research. The project will be conducted under the supervision of the Course Director. Students will have an internal faculty advisor who is a full-time faculty member in the Department of Clinical Research, as well as a Statistician faculty member of the Department of Clinical Research assigned to advise them throughout the project. In this course, students will finalize their Research Protocol, obtain IRB approval/exemption (as appropriate) and develop a Data Analysis Plan for their project. In the last research project course, the student will analyze their data and present study results. Prerequisite: CLNR 691

CLNR 695– Research Project IV
Credit: 2 Hours
This course is the fourth part of the four-part Research Project course, which comprises CLNR 690, 691, 694, and 695. The student will utilize prior didactic experience in the Clinical Research Program to propose, design, and conduct the research project. The research project must involve patient-oriented research, including: epidemiologic and behavioral studies, health outcomes research, and/or health services research. The project will be conducted under the supervision of the Course Director. Students will have an internal faculty advisor who is a full-time faculty member in the Department of Clinical Research, as well as a Statistician faculty member of the Department of Clinical Research assigned to advise them throughout the project. In this course, students will validate study data, conduct their statistical analysis, present study results, and write/submit a final Study Report. Prerequisite: CLNR 694

Campbell University College of Pharmacy & Health Sciences reserves the right to make changes in the curriculum or policy of any program as it deems necessary.