

CLINICAL SCIENCE GRADUATE PROGRAM PHD STUDENT HANDBOOK

303-724-1214 (p)

https://cctsi.cuanschutz.edu/training/clsc#phd

Table of Contents

WELCOME!	5
PURPOSE OF HANDBOOK	5
MISSION	5
VISION	6
CORE COMPETENCIES	6
CLINICAL SCIENCE GRADUATE PROGRAM CORE FACULTY AND STAFF	7
Main Office Address:	7
CLINICAL SCIENCE PHD DEGREE PROGRAM	8
TRACKS WITHIN THE CLSC PROGRAM	8
Clinical Investigation (CI)	8
Competencies Specific to Cl	
HEALTH INFORMATION TECHNOLOGY (HIT)	8
Competencies Specific to HIT	9
HEALTH SERVICES RESEARCH (HSR), COLLABORATIVE PROGRAM WITH COLORADO SCHOOL OF PUBLIC HEALTH	9
CLINICAL SCIENCE PROGRAM CURRICULA	
Clinical Investigation Curriculum (students admitted during or after summer 2021)	10
Health Information Technology Curriculum (students admitted during or after Fall 2023)	
Academic Advisement	
STUDENT RESPONSIBILITIES & PROGRAM PLANS	
CLSC PHD STUDENT – CLINICAL INVESTIGATION TRACK PROGRAM PLAN (STUDENTS ADMITTED DURING OR AFTER SUMMER 2021)	
CLSC PHD STUDENT – HEALTH INFORMATION TECHNOLOGY TRACK PROGRAM PLAN (STUDENTS ADMITTED DURING OR AFTER FALL 2023)	
Transfer of Credits	
COURSE OFFERINGS	
Course Information	
Registration	
CLSC 7650 Guided Research Tutorial	
Sample Course Plan for CLSC 7650	
Grading within the CLSC Program	
INCOMPLETE GRADES	21
Canvas	22
Course Evaluations	22
THE PRELIMINARY EXAMINATION	
Course Requirements for Taking the Preliminary Exam	23
EXAM FORMAT	23
CLSC Program Honor Code and Grading Policy	24
Criteria Used for Grading	24
Preparation Tips and Study Guide	25
Biostatistics Section	25
Research Methods Section	25
Ethics Section	26
ACKNOWLEDGMENT OF NIH FUNDING ON CCTSI PUBLICATIONS AND PROJECTS	27
COMPREHENSIVE EXAMINATION, THESIS PROCESS AND THESIS DEFENSE	28
COMPREHENSIVE EXAMINATION AND EXPECTATIONS OF THESIS COMMITTEE	28
Expectations of the Student	
Expectations of the Research Mentor	
Expectations of Members of the Comprehensive Exam and Thesis Committee	
Expectations of the Comprehensive Exam and Thesis Committee Chair	
Graduate School Faculty Appointment	
- added oction, seekly, promote the seekly s	

Committee Composition for Clinical Investigation and Health Information Technology	30
COMPREHENSIVE EXAMINATION PLANNING PROCESS	
Admission to Candidacy	31
Requirements Prior to Scheduling the Comprehensive Examination	31
Scheduling	32
Comprehensive Examination Process/Content	
Thesis Proposal or NIH-like Submission Elements	33
Evaluation Criteria for the Paper/Written Element	33
Comprehensive Exam Structure	33
Examination Grading	34
Post Comprehensive Exam Requirements	35
Committee Meetings	35
APPROVAL OF THESIS PROPOSAL	
COMPREHENSIVE EXAMINATION CHECKLIST	37
CLSC COMPREHENSIVE EXAMINATION REPORT	39
Please submit completed form to: Galit.mankin@cuanschutz.edu	
CLSC COMPREHENSIVE EXAMINATION ATTENDANCE FORM	40
Thesis Committee Report	41
Thesis Chapter Content Requirements	43
Thesis Defense	
Guidelines for Doctoral Dissertations	
Doctoral Dissertation Checklist	51
Permission to Proceed to Defense	
CLSC PhD Dissertation\Thesis Defense Report	
CLSC PhD Program Checklist for Thesis Defense:	54
GRADUATE SCHOOL RELATED INFORMATION	56
I.D. BADGE AND PARKING INFORMATION	56
GUIDELINES FOR STUDYING	56
THE STRAUSS HEALTH SCIENCES LIBRARY AT ANSCHUTZ MEDICAL CAMPUS	56
Scholarship Information and Financial Aid	
HONOR CODE	
CLINICAL SCIENCE PROGRAM FREQUENTLY ASKED QUESTIONS	57

Welcome!

The overall goal of the University of Colorado Denver | Anschutz Medical Campus Graduate Program in Clinical Science (CLSC) is to train nationally competitive clinician/clinical translational scientists by providing a formal, structured, and rigorous educational program in the clinical and translational sciences. The Clinical Science Graduate Program was designed in response to the demand for well-qualified clinical researchers in academia and industry. The critical need for individuals capable of conducting rigorous, credible and relevant patient-based research within stringent ethical and regulatory guidelines, and translating the evidence for community application, is expected to continue to grow.

For doctoral students, there is a selected emphasis of study in one of the following three tracks: Clinical Investigation (CI), Health Information Technology (HIT), or Health Services Research (HSR). These three specialized tracks of clinical science are important areas of study for translational research activities in the evolving health care environment. In our program, training occurs across many disciplines to achieve proficiency in the areas of clinical science, clinical investigation and translation, and includes biostatistics, clinical epidemiology, clinical studies design, ethics, and grant writing. An important compliment to the rigorous training in the CLSC program is the formal mentoring with interdisciplinary faculty working in the clinical sciences. Graduates of our program are highly qualified and well-trained clinician/clinical scientists who will be nationally competitive for grant funding and career advancement in the health sciences.

Your feedback and perspectives of the CLSC program are important. We strive to provide the best academically rigorous program while simultaneously meeting the individual needs of students and seizing opportunities to enrich the educational experience. Please feel free to contact any of the Core CLSC Faculty or CLSC Program Administrator at any time. Our contact information is below. We have an open door policy and want to hear your thoughts both good and bad. Please feel free to contact Dr. Lisa Cicutto, CLSC Director, at any time by email (Lisa.Cicutto@cuanschutz.edu) or by phone at 303-398-1538.

Purpose of Handbook

The intent of the PhD Handbook is to provide key information to help you succeed in and benefit the most from the Clinical Science Graduate Program. This Handbook should be used in conjunction with the University of Colorado Denver | Anschutz Medical Campus Graduate School Policies and Procedures, the Course book, and other official documents prepared and distributed by the Clinical Science Program. (This would include documents developed for candidacy application, thesis preparation and graduation). It is expected that students will be familiar with and knowledgeable of these documents. To access the Graduate School Policies and Procedures, please go to https://graduateschool.cuanschutz.edu/forms-resources/resources.

As a general rule, the policies in effect at the time of admission govern a student's progression. The curriculum, course schedules, and offerings are subject to change. Courses are offered pending required minimum enrollment numbers. If curriculum changes are made, courses in the current curriculum will be offered for a specified period of time; students who decelerate or otherwise change their program plans may be asked to substitute another course for required courses being discontinued or with insufficient enrollment. All program plan changes will be discussed and approved by the student's Academic Advisor.

Mission

The mission of the Clinical Science Program is to prepare and train nationally competitive clinician/clinical translational scientists.

Vision

To provide a comprehensive knowledge base of translational research methods, theories, and techniques in clinical science in order to train and further prepare Clinician Scientists.

Core Competencies

To prepare students to perform state of the art translational research, graduates of the Clinical Science Graduate program will:

- Perform human research adhering to legal, ethical and regulatory principles and guidelines
- Critically appraise existing literature and sources of information
- Apply evidence based practice principals
- Accurately select, use and interpret commonly used statistics
- Apply appropriate study designs and methods to address research questions/hypotheses
- Identify and measure clinically relevant and meaningful outcomes
- Design and conduct research studies
- Publish research-based manuscripts to peer-reviewed journals
- Prepare and submit competitive grant proposals
- Provide constructive reviews and feedback to colleagues
- Demonstrate effective communication and leadership skills
- Participate in interdisciplinary collaboration

Clinical Science Graduate Program Core Faculty and Staff

Lisa Cicutto, PhD, MSCS, APN, RN (303) 398-1538

Program Director <u>lisa.cicutto@cuanschutz.edu</u>

Allan Prochazka, MD, MSc (303) 399-8020 ex 2144

Education Director <u>allan.prochazka@cuanschutz.edu</u>

Track Director, Clinical Investigation

Matthew R.G. Taylor, MD, PhD (303) 724-1400

Track Director, Clinical Investigation matthew.taylor@cuanschutz.edu

Cathy Battaglia, PhD, MSHA, RN (303) 724-6387

Track Director, Health Services Research catherine.battaglia@cuanschutz.edu

Collaborative CSPH and CLSC

Richard Lindrooth, PhD (303) 724-5165

Track Director, Health Services Research richard.lindrooth@cuanschutz.edu

Collaborative CSPH and CLSC

Heather Haugen, PhD (303) 483-4308

Track Director, Health Information Technology <a href="https://health.nicon.ni

James Crapo, MD (303) 398-1720

Program Director Emeritus crapoj@NJHealth.org

Galit Mankin, MSW T: (303) 724-1214

Program Administrator galit.mankin@cuanschutz.edu

Amanda Whiting T: (303) 724-1219

Program Assistant <u>amanda.g.whiting@cuanschutz.edu</u>

Main Office Address:

University of Colorado Denver | Anschutz Medical Campus Clinical Science Program Colorado Clinical & Translational Sciences Institute (CCTSI) Anschutz Health Sciences Building 1890 N Revere Ct., Room 6149 Campus Box B141 Aurora, CO 80045

Phone: 303-724-1214

Clinical Science PhD Degree Program

The overall goal of CLSC doctoral training program is to prepare nationally competitive clinician/clinical scientists that are able to translate across the discovery-community continuum. Students in our program are highly motivated and bright individuals that seek additional rigorous training to become leaders in their field and make significant contributions to improving the health of citizens. The program allows specialization in one of three tracks or areas of focus: Clinical Investigation, Health Information Technology, or Health Services Research.

The PhD program consists of successful completion of: didactic coursework, a Preliminary Examination, a Comprehensive Examination, and completion and defense of a thesis dissertation. In addition to the program-wide requirement of at least 30 credit hours of thesis work, the didactic coursework component includes 26-33 credit hours of required coursework plus 2-6 credit hours of elective coursework (exact coursework requirements vary by area) See the Clinical Science PhD Program Course Curriculum on the following pages.

Tracks within the CLSC Program

Clinical Investigation (CI)

Clinical investigation is the discipline by which physicians, clinicians and other health related disciplines translate knowledge gained in the basic sciences or the laboratory setting to develop prevention and disease management interventions and strategies to improve health outcomes. It can also involve translating knowledge gained about the efficacy of successful strategies and interventions conducted in the academic clinical setting to the community setting to improve health related outcomes. The mission of the Clinical Investigation Track is to train the next generation of clinician scientists who will pursue successful careers in clinical translational research. Clinical investigation is clearly a primary mission of academic medical and health centers, and properly trained clinicians and scientists are uniquely qualified to engage in investigative and translational studies. Within the CI Track, training occurs across many disciplines:

- Clinical trial design
- Biopharmaceutics and pharmacokinetics
- Biodiagnostics
- Laboratory-based molecular biology techniques that assist in bridging basic and clinical sciences

Competencies Specific to CI

Specific to the CI Track, graduates of the program will:

- Apply relevant study design methods commonly used in clinical translational investigative studies
- Interpret results from common molecular and cellular biology laboratory experiments
- Develop a well-designed, successful research thesis project relevant to the clinical and translation sciences and fields

Health Information Technology (HIT)

The Health Information Technology Track provides a background in clinical informatics: the study of how medical data and knowledge can be stored, analyzed, and delivered to facilitate research and to improve the quality, safety, and efficiency of care. Students will develop a fundamental understanding of the technical and organizational challenges particular to the field of health information technology and will train in evaluation and research methods. Graduates of the Health Information Technology Track will be prepared for leadership

roles in developing, implementing, and evaluating clinical informatics applications in academia, industry and clinical practice. Within the HIT Track, formal training occurs in the following cross disciplines:

- Electronic health records
- Decision support
- Telehealth
- Public health informatics
- Research informatics
- Standards and data integrity
- Privacy and security

Competencies Specific to HIT

Specific to the HIT Track, graduates of the program will:

- Demonstrate understanding of relevant standards and terminologies for communication and representation of health data
- Demonstrate understanding of major types of clinical and administrative information systems and how they are integrated
- Demonstrate understanding of computerized provider order entry (CPOE) and clinical decision support systems (CDSS), including
 - Success factors for implementation
 - Methods of encoding rules/logic
- Ability to assess and develop methods to protect privacy (e.g. HIPAA issues) and security (confidentiality, integrity, and availability) of health information
- Design appropriate research and evaluation studies in HIT, with understanding of both experimental and quasi-experimental research designs
- Ability to apply systems life cycle approach to HIT planning, analysis, design, implementation and evaluation, including translation of user needs into functional requirement
- Apply database concepts to the design and implementation of databases for clinical, research, and public health applications

Health Services Research (HSR), Collaborative Program with Colorado School of Public Health

The Health Services Research (HSR) PhD Program is a collaborative program between the Clinical Science Graduate Program and the Health Systems Management and Policy Department within the Colorado School of Public Health (CSPH). Please refer to the following website for additional information:

http://www.ucdenver.edu/academics/colleges/PublicHealth/Academics/departments/HealthSystems/Academics/Pages/PhDHealthServicesResearch.aspx

Clinical Science Program Curricula

The Clinical Science Program curricula for PhD degrees are shown on the following pages.

Clinical Investigation Curriculum (students admitted during or after summer 2021)

Note that course schedules may vary from term to term. To verify schedules and prerequisites for specific courses, please visit the CLSC courses and registration web page at:

https://cctsi.cuanschutz.edu/training/clsc#resource

Course Number	Course Title	Credits		
BIOS 6601*	Applied Biostatistics I	3		
BIOS 6602*	Applied Biostatistics II	3		
BIOS 6648 or	Design and Conduct of Clinical Trials or			
EPID 6626 or	Research Methods in Epidemiology (BIOS 6602 is a pre-requisite) or	3		
BIOS 6623	Advanced Data Analysis			
CLSC 6210 [†]	Research Seminars in Clinical Science	1		
CLSC 6270	Critical Appraisal Seminars in Clinical Science	1		
CLSC 7101	Grant Writing I	1		
CLSC 7150*	Ethics and Responsible Conduct of Research	1		
CLSC 7202	Clinical Outcomes and Applications	3		
CLSC 7300	Scientific Grant Review Process: CCTSI Proposals - Doctoral	1		
EPID 6630*	Epidemiology	3		
EPID 6631	Analytical Epidemiology	3		
	Required Clinical Investigation Course Credits	23		
	Elective Course Credits	7		
Minimum Number of Required Course Credit (Core + Electives)				
*CLSC 8990	Doctoral Thesis	≥ 30		

^{*} Courses required before Preliminary Exam (biostatistics, ethics, epidemiology). In addition, a second methods class is required (EPID 6626 or EPID 6631 or BIOS 6648 or BIOS 6623 or CLSC 6270 or CLSC 7202).

[†]CLSC 6210 is taken over 1 year typically during the second or third year of your PhD (after passing the Preliminary Examination but before completing the Comprehensive Examination).

^{*} Must take the following prerequisite classes and pass the preliminary exam prior to registering for CLSC 8990: BIOS 6601, BIOS 6602, BIOS 6648 or EPID 6626 or BIOS 6623 or EPID 6631, CLSC 7150, EPID 6630

Health Information Technology Curriculum (students admitted during or after Fall 2023)

Note that course schedules may vary from term to term. To verify schedules and prerequisites for specific courses, please visit the CLSC courses and registration web page at:

https://cctsi.cuanschutz.edu/training/clsc#resource

Course Number	Course Title	Credits
BIOS 6601*	Applied Biostatistics I	3
BIOS 6602*	Applied Biostatistics II	3
BIOS 6648 or	Design and Conduct of Clinical Trials or	
EPID 6626 or	Research Methods in Epidemiology (BIOS 6602 is a pre-requisite) or	
	Advanced Data Analysis <u>or</u>	3
BIOS 6623 or	Analytical Epidemiology	
EPID 6631		
CLSC 6210 [†]	Research Seminars in Clinical Science	1
CLSC 6270	Critical Appraisal Seminars in Clinical Science	1
HLTH 6071 or	Intro to Health Information Technology <u>or</u> Foundations of Healthcare	3
NURS 6286	Informatics	
NURS 6289	IT Systems Life Cycle	4
CLSC 7101	Grant Writing I	1
CLSC 7150*	Ethics and Responsible Conduct of Research	1
CLSC 7202	Clinical Outcomes and Applications	3
EPID 6630*	Epidemiology	3
NURS 6293 or	Database Management Systems (Informatics focus)	3
ISMG 6080	Database Management Systems (Information Systems focus)	3
	Required Health Information Technology Course Credits	29
	Elective Course Credits	1
	Minimum Number of Required Course Credit (Core + Electives)	30
*CLSC 8990	Doctoral Thesis	≥ 30

^{*} Courses required before Preliminary Exam (biostatistics, ethics, epidemiology). In addition, a second methods class is required (EPID 6626 or EPID 6631 or BIOS 6648 or BIOS 6623 or CLSC 6270 or CLSC 7202).

[†] CLSC 6210 is taken over 1 year typically during the second or third year of your PhD (after passing the Preliminary Examination but before completing the Comprehensive Examination).

^{*} Must take the following prerequisite classes and pass the preliminary exam prior to registering for CLSC 8990: BIOS 6601, BIOS 6602, BIOS 6648 or EPID 6626 or BIOS 6623 or EPID 6631, CLSC 7150, EPID 6630

Academic Advisement

Student Responsibilities & Program Plans

The student's responsibilities include:

- Becoming familiar with, and adhering to, the rules, policies, and procedures in place in the Clinical Science program, the Graduate School, and the University as outlined in available resources such as the respective handbooks, web sites and calendars.
- Preparing a research plan and timetable in consultation with the Research Mentor as a basis for the program of study, including any proposed fieldwork.
- Meeting with the Research Mentor and reporting regularly on progress and results of research project.
- Establishing a Comprehensive Exam and Thesis Committee, with the assistance of the Research Mentor, by the end of the second year of study.
- Maintaining good records of each stage of the research.
- Planning to complete the PhD degree requirements in 4 years (the Graduate School's maximum duration for PhD degree completion is 8 years)

Meeting with your Academic Advisor once a year to plan and discuss your progress through the program is crucial to a successful experience for you and is thus **mandatory**. Your Academic Advisor assists you with identifying and scheduling required coursework, identifying areas of research and collaborations, and selecting committee members for your thesis and comprehensive examination. They may even help save you money by progressing through the program in the most expeditious manner.

At the time of your admission to the program, an Academic Advisor will be identified.

- 1. The Academic Advisor will assist you in selecting and sequencing courses and planning other activities to progress through the program. The projected courses for meeting the degree requirements, plans for additional course requirements, and a projected date for completion of the Preliminary and Comprehensive Examinations and the Thesis Defense will be recorded on the Program Plan Form (See next pages). Students should visit with their advisor regularly (at least once per year) for discussions of research ideas, grant and course opportunities, and other advisement.
 - New students should familiarize themselves with the curriculum requirements prior to meeting with their Academic Advisor. In conjunction with their Academic Advisor, all new students should develop a proposed plan of study. Copies of the track-specific planning forms are provided (See below). These plans are to be maintained electronically and accessed securely via a link provided by the program administrator.
- 2. It is expected that every Clinical Science Graduate Program student, for every year that s/he is in the program, will have a program plan form completed or updated, approved by the Academic Advisor, and submitted electronically the first week of September. You may receive notices from your Academic Advisor of specific requirements and timelines for this process. This information is key for planning future course offerings and insuring completion of the program in a reasonable period of time. Accurate program plans help prevent unnecessary closure of classes due to low enrollment. Updated program plans are the responsibility of the student.
- 3. Program Plans for the PhD degrees are shown on the following pages. For returning-student program plans, visit the PhD Resources section of the CLSC website at https://cctsi.cuanschutz.edu/training/clsc#phd

CLSC PhD Student – Clinical Investigation Track Program Plan (students admitted during or after summer 2021)

Note that course schedules may vary from term to term. To verify schedules and prerequisites for specific courses, please visit the CLSC courses and registration web page at: https://cctsi.cuanschutz.edu/training/clsc#resource

STUDENT NAME:	DATE OF LAS	T REVISION:
Matriculation:	Research Mentor:	Advisor:

Courses				Semest	ers (Tern	ı Year)		
<u>Number</u>	Credits	<u>Description</u>						Credits
TC	TAL REQU	JIRED COURSE HOURS FOR DEGREE = 30	 	 			 	 Earned
	23	Required Courses						
BIOS 6601*	3	Applied Biostatistics I						
BIOS 6602*	3	Applied Biostatistics II						
BIOS 6648 or EPID 6626 or BIOS 6623	3	Design and Conduct of Clinical Trials or Research Methods in Epidemiology (BIOS 6602 is a pre-requisite) or Advanced Data Analysis						
CLSC 6210 [†]	1	Research Seminars in Clinical Science						
CLSC 6270	1	Critical Appraisal Seminars in Clinical Science						
CLSC 7101	1	Grant Writing I						
CLSC 7150*	1	Ethics and Responsible Conduct of Research						
CLSC 7202	3	Clinical Outcomes and Applications						
CLSC 7300	1	Scientific Grant Review Process: CCTSI Proposals- Doctoral						
EPID 6630*	3	Epidemiology						
EPID 6631	3	Analytical Epidemiology						
	7	Elective Courses			I.		•	

^{*}Courses required before Preliminary Exam (biostatistics, ethics, epidemiology). In addition, a second methods class is required (EPID 6626 or EPID 6631 or BIOS 6648 or BIOS 6623 or CLSC 6270 or CLSC 7202).

[†]CLSC 6210 is taken over 1 year typically during the second or third year of your PhD (after passing the Preliminary Examination but before completing the Comprehensive Examination).

Clinical Scier Student Nan		ogram: Cl	inical Inve	estigatio	n										
Thesis Credit Hours Indicate # of Thesis Credit Hours taken per Semester: Fa/Sp/Su-Year										Total Credits					
THESIS CICARTI	<u></u>		marcace #	indicate # Of Thesis Credit nodis taken per semester. Fa/sp/su-Tear											≥ 30
*CLSC 8990 Do															
Comp/Thesis C	ommittee N	<u>leetings</u>	Indicate tl	he Semes	ter in which C	<u>ommittee</u>	Meeting	gs are l	neld: Fa/	Sp/Su-Yea	<u>ar</u>				<u>Total</u> <u>Meetings</u>
Committee Me	etings Held														
<u>Exams</u>			Semester:	Fa/Sp/Su	ı-Year	NOT	<u>ES</u>								
Prelim Exam															
Comp Exam															
Thesis Defense															
Courses to Trai	nsfer – if app	olicable – m	ust be appro	oved by P	rogram and th	e Graduat	e Schoo	ol							
<u>Number</u>	<u>Credits</u>	Description	<u>n</u>				Substi	itutes F	<u>or</u>		Cre	edits Gran	<u>ted</u>		
	1	1									<u> </u>				
Pending succe for transfer, A schedule wou	AND passing	g the requi	red progra	m exami	nations (Prel	iminary E	xamina	ation, (Comprel	nensive E	-				of courses propose fense), this
Student's Approval Date: Track Director's Approval Date:															

Rev.5/18/23

CLSC PhD Student – Health Information Technology Track Program Plan (students admitted during or after Fall 2023)

Note that course schedules may vary from term to term. To verify schedules and prerequisites for specific courses, please visit the CLSC courses and registration web page at: https://cctsi.cuanschutz.edu/training/clsc#resource

STUDENT NAME: DATE OF LAST REVISION: **Matriculation: Research Mentor: Advisor:** Courses Semesters (Term -- Year) Number **Credits** Description **Credits TOTAL REQUIRED COURSE HOURS FOR DEGREE = 30 Earned Required Courses** BIOS 6601* 3 Applied Biostatistics I BIOS 6602* Applied Biostatistics II Design and Conduct of Clinical Trials or BIOS 6648[‡] **or** EPID 6626 or Research Methods in Epidemiology (BIOS 6602 is a 3 pre-requisite) or BIOS 6623 or Advanced Data Analysis or **EPID 6631** Analytical Epidemiology CLSC 6210[†] 1 Research Seminars in Clinical Science CLSC 6270 Critical Appraisal Seminars in Clinical Science HLTH 6071 or Introduction to Health Information Technology or 3 **NURS 6286** Foundations of Healthcare Informatics Management of Health Information Technology or NURS 6289 4 Information Life Cycle CLSC 7101 1 **Grant Writing I** CLSC 7150* 1 Ethics and Responsible Conduct of Research CLSC 7202 3 **Clinical Outcomes and Applications EPID 6630*** 3 **Epidemiology** Database Management Systems (Informatics focus) NURS 6293 or 3 ISMG 6080 Database Management Systems (Information Systems focus) **Elective Courses** 1

^{*}Courses required before Preliminary Exam (biostatistics, ethics, epidemiology). In addition, a second methods class is required (EPID 6626 or EPID 6631 or BIOS 6648 or BIOS 6623 or CLSC 6270 or CLSC 7202).

[†]CLSC 6210 is taken over 1 year typically during the second or third year of your PhD (after passing the Preliminary Examination but before completing the Comprehensive Examination).

Clinical Science PhD Program: Health Information Technology

Student Name:															
Thesis Credit H	<u>ours</u>		Indicate	Indicate # of Thesis Credit Hours taken per Semester: Fa/Sp/Su-Year											Total Credits ≥ 30
*CLSC 8990 Doc	•														
Comp/Thesis C	ommittee M	<u>leetings</u>	Indicate	the Seme	ster in wh	ich Comn	nittee N	leetings are	held: Fa/	'Sp/Su-Yea	<u>ar</u>				<u>Total</u> <u>Meetings</u>
Committee Med	etings Held														
			T = -	- 12 12		1		_							
Exams Prelim Exam			Semeste	r: Fa/Sp/S	<u>u-Year</u>		NOTES	<u>></u>							
Comp Exam															
Thesis Defense															
			l .												
Courses to Tran	nsfer – if app	olicable – m	ust be app	roved by I	Program a	nd the Gi	raduate	School							
<u>Number</u>	<u>Credits</u>	Descriptio	<u>n</u>					Substitutes	<u>For</u>		Cre	edits Gran	<u>ted</u>		
Pending successful completion of all planned courses (B or better in all courses), ≥ 30 thesis credit hours completed, approval and validation of courses proposed for transfer AND passing the required program examinations (Preliminary Examination, Comprehensive Examination and the Final Thesis Defense), this schedule would fulfill the requirements of the Clinical Science PhD Program (Health Information Technology Track).															
Student's Approval Date: Track Director's Approval Date:															

Transfer of Credits

Pending CLSC Program and Graduate School approval, transfer of up to 30 semester credits for the PhD may be coordinated. Transfer credit is defined as any credit earned at another accredited institution. The maximum amount of transfer work that may be applied toward a graduate degree at CU Denver | Anschutz Medical Campus is 30 semester hours for Ph.D. degree programs. The Graduate School accepts transfer credits only after approval of those transfer credits by the student's Program Director and the Dean of the Graduate School.

All courses accepted for transfer must:

- a. Be graduate level (M.S. / M.A. or Ph.D.);
- b. Have a grade of "B" or higher;
- c. Not have been applied toward an undergraduate degree or another graduate degree on the same level (e.g., Ph.D. to Ph.D.);
- d. Be validated by the Program Director if not taken within seven (7) years of the PhD comprehensive exam; and
- e. Be transferred prior to the term in which the Comprehensive Examination is taken.

Credit cannot be transferred until the student has established a satisfactory record of at least one term of enrollment at the CU Denver and earned a minimum 3.00 GPA. Transferred courses do not reduce the residency requirement but may reduce the amount of work required at CU Denver for the degree.

Transfer of Credits for Core CLSC Courses: Students must contact the current course instructor for each course that they are substituting (or attempting to transfer in) to determine that the course is comparable. This will involve submitting the course syllabus to the course instructor for review to assist with determining comparability. Students must copy/forward emails from the current course instructors identifying whether or not the course being transferred is comparable to the core CLSC course to Ms. Galit Mankin (galit.mankin@cuanschutz.edu).

Transfer of credits for elective courses into the CLSC program: Students will submit a copy of the course syllabus to their Academic Advisor for each course that they are seeking to transfer into the program and apply towards the degree. The Academic Advisor will review the materials in light of the focus of the student's program of research and level of academic rigor. Ms. Galit Mankin (galit.mankin@cuanschutz.edu) needs to be copied on or forwarded emails detailing the decision to recommend or not the transfer of credit hours.

Students wishing to transfer credits for courses taken over 7 years prior to completing the comprehensive exam need to be validated. The validation process is similar to the transfer of core credit hours. Students need to contact the course instructor for each of the courses taken more than 7 years ago to determine whether or not the course content has changed substantially since the student completed the course. Emails of the instructor's assessment must be forwarded or copied to Ms. Galit Mankin (galit.mankin@cuanschutz.edu).

The onus for contacting instructors, collecting course syllabus/syllabi for review, and the coordination of the review and communication process, as well as, paperwork is on the student.

Finally, a Graduate School form detailing the recommended courses for transfer is required to be signed by the program and submitted to the Graduate School. The Transfer of Credit form is not required for non-degree

credit transfers as these courses appear on the University of Colorado transcripts. Approval of the courses by the program and the Graduate School on the Application for Candidacy will constitute approval of the transfer of courses toward the degree.

It is not always a good idea to transfer in core credit hours for CLSC core courses, especially if they were completed several years ago. It is often wiser to repeat similar coursework so that you are well prepared for your preliminary and comprehensive examinations.

Course Offerings

Course Information

Course titles, credits and semester of offering are listed on the Course Offering Schedule available on the CLSC website:

https://cctsi.cuanschutz.edu/training/clsc#resource

Consultation of the Anschutz Medical Campus Graduate School Course Book is also recommended:

https://catalog.cuanschutz.edu

The semesters listed are the semester that each course is usually offered and is subject to change. Some courses require pre-requisites. Courses have a minimum enrollment of 5 students; a course with less than the minimum enrollment on the first day of the semester is subject to cancellation. The program reserves the right to provide a substitute course or modify the program plan for students who have decelerated or take less than 6 credit hours/semester.

Registration

Registration opens three to four weeks before the beginning of summer and fall semesters, and even earlier for spring semester. The student registration portal is found at https://portal.cusys.edu/UCDAccessFedAuthLogin.html. The Academic Calendar is posted on the CU Denver | Anschutz Medical Campus Graduate School's website at https://graduateschool.cuanschutz.edu/forms-resources/resources/resources/resources/resources/resources/resources/resources/resources/resources/resources/resources/resources/resources/resources/resources/">https://graduateschool.cuanschutz.edu/forms-resources/resour

The drop/add period ends one (summer) to two weeks (fall and spring) after the semester begins. Students remain responsible for full tuition and fees for any classes dropped after this period, and a \$60 late fee is charged for any class added after this period. Payment is due within 30 days of the beginning of the semester, regardless of your registration date. Note that new students are not allowed to register until after being cleared by the Graduate School. It is, therefore, essential that all the required forms, information and payments have been submitted to and approved by the Graduate School.

CLSC 7650 Guided Research Tutorial

A Guided Research Tutorial, also known as an independent study course, may be taken for 1-3 credit hours given that the requirements for doing so are fulfilled. Independent study courses (CLSC 7650 Guided Research Tutorial) cannot exceed 8 credit hours for the doctoral degree.

No required courses may be taken for credit as independent study.

Planning for the Guided Research Tutorial should begin at least one term prior to the term of planned enrollment. There are several steps that need to occur prior to enrollment.

- 1. First, discuss your intent and plan for the Guided Research Tutorial with your Academic Advisor to get preliminary approval.
- 2. Discuss with the proposed course instructor his/her availability to supervise your course of study and to review and agree on the course plan. Specifically, a course plan should be mutually developed and agreed upon and include:
 - proposed number of credit hours,
 - course objectives
 - course content covered, activities and the timeframe (outline),
 - assignments or outcomes/products of the course and due dates to the course instructor.
- 3. Determine the appropriate number of credit hours
 - Regular meetings need to occur with the course instructor
 - For instructional activities conducted by the faculty that require student participation, experimentation, observation or practice, the minimum number of weekly student-faculty contact hours is 2 hours for a 1 credit course, 4 hours for a 2 credit course and 6 hours for a 3 credit course throughout the semester.
 - For a private instruction—based course, there needs to be formal presentations in a one-to-one relationship between the student and the instructor weekly. Over the course of 15 weeks, there needs to be at least 7.5 hours with the instructor for a 1 credit hour course; 15 hours with the instructor for a 2 credit hour course; and 22.5 hours with the instructor for a 3 credit hour course.
- 4. Submit the course plan that has the approval (as evidenced by signatures or emails acknowledging approval) of the Academic Advisor and the course instructor to the Clinical Science Graduate office (galit.mankin@cuanschutz.edu) for approval by the Educational Director or the Program Director.

Steps 1-4 need to be completed prior to registering for CLSC 7650 Guided Research Tutorial. This is a closed registration course meaning that registration without a permission number is not allowed. The CLSC program must provide the students with the permission number in order to register.

Sample Course Plan for CLSC 7650

Clinical Science (CLSC) 7650 Guided Research Tutorial

Fall 2008

Student: Jane Kanduit

Primary Instructor: Onlywith Myhlp, MD

Credits: 3 hours

Course Focus: Manuscript Preparation, Writing and Submission of Pilot Study on Surviving a PhD and Avoiding

Bankruptcy

Course Objectives:

At the end of this course, I will be able to:

- 1. Perform literature searches related to surviving a PhD and avoiding bankruptcy
- 2. Synthesize and integrate the literature related surviving a PhD and avoiding bankruptcy by writing a literature review
- 3. Write a structured abstract related to pilot study re: surviving a PhD and avoiding bankruptcy
- 4. Describe and write the statistical analyses section of the manuscript
- 5. Prepare tables and figures that support the text in the manuscript for publication
- 6. List and discuss the pros and cons of possible journals to submit to and publish in
- 7. Submit a manuscript for peer-review publication on surviving a PhD and avoiding bankruptcy

Weekly Course Content Outline:

1-2	Review literature for guidance on publishing in scientific journals.
2-4	Perform literature search and review literature on surviving a PhD and avoiding bankruptcy.
3	Interview mentors and colleagues about strategies for publishing in the area
2-5	Identify appropriate journals for manuscript
5	Write Background/Introduction section
6	Meet with psychologist, stress physiologist, life coach and financial planner to seek advice in the write-
	up of methodology used in pilot study
7	Write Methods section
8	Meet with statistician about writing statistical analysis section and presentation of results
9-10	Write Results section (2 weeks)
10-11	Write Discussion and abstract
11-12	Solicit feedback on entire manuscript and draft cover letter to editor

Meeting Plans with Instructor:

- 1. Meet with Dr. Onlywith Myhlp, every week on Mondays at the VA hospital from 2:00- to 4:00 (2x15=30 hours).
- 2. Meet with psychologist, stress physiologist, life coach and financial planner (all co-authors) each for 1-2 hrs while writing the manuscript and perhaps again after completing first draft.

Assignments:

13-14 14-15

1. Outline of manuscript: Due week 3, 5% of final grade

Revise and incorporate comments

Submit to chosen journal

- 2. Introduction section: Due week 6, worth 15%
- 3. Methods section: Due week 9, worth 15% of final grade
- 4. Results section: Due week 11, 2% of final grade
- 5. Discussion and abstract: Due week 12, 20% of final grade
- 6. Cover letter and revised paper submitted: 20% of final grade

Grading within the CLSC Program

Standards for assigning grades are as follows:

Letter Grade	GPA	% Grade
Α	4.00	93-100
A-	3.70	90-92
B+	3.30	87-89
В	3.00	83-86
B-	2.70	80-82
C+	2.30	77-79
С	2.00	73-76
C-	1.70	70-72
D+	1.30	68-69
D	1.00	63-67
D-	0.70	60-62
F	0.00	<60

Any course grade below a B will not be accepted for credit hours applied to the PhD in Clinical Science degree.

The following activities will be considered academic dishonesty:

- Copying the work of current or past students or using solutions given to students in past semesters for any class assignments
- · Paying external parties to complete part or all of assignments or exams
- · Using material from other sources (such as websites, books and articles) without crediting the source

If a student is caught engaging in one of these activities, the program will enforce the standard penalty for academic dishonesty. The standard penalty for a first violation is an F on the assignment resulting in at least a one letter grade penalty for the course. The penalty for subsequent academic penalties can involve removal from the program.

Incomplete Grades

After the 10th week, courses may not be dropped unless there are special circumstances. As of Jan. 1st, 2009, students are able to request only the grade of "I," as "IW" (Incomplete Withdrawal) and "IF" (Incomplete Fail) are no longer allowed. The student must ask the instructor for an "I" grade if his/her circumstances warrant it. If this is the case, the student and the instructor must develop a written plan for the work that needs to be completed and the time frame for its completion. If the outlined work is completed according to the agreed upon time frame, the Instructor of Record must submit the work plan (work required and timeline) and the final grade using the grade change form (a.k.a. "Change of Record" or "COR" form). This form is available to faculty only from the CLSC Administrative Office. The Instructor of Record and the CLSC Program Director will need to sign the form, but at no time may this form be in the student's possession. If the agreed upon work is not completed by the agreed upon time frame, the course grade will be changed to an "F" (Fail).

Canvas

Canvas is used in almost all courses available through the CLSC Program. Course syllabi, notes, lectures, articles, discussion groups, and assignments can be found here. Online quizzes, exams, and assignments are also conducted on or submitted via Canvas. Canvas allows faculty, instructors, and trainers to easily upload course content; manage course communication; test students online; post multimedia materials; manage student grades online, and many other course-related functions. Using a common web browser, students can access the materials from home or work at their convenience. Canvas is primarily used for web-enhanced courses (traditional courses with Internet enhancement), and hybrid courses (courses that blend the traditional format with online).

Canvas can be accessed at http://canvas.cuonline.edu and accessed with your UCDenver email log-in. Upon enrollment, your registered courses will be attached to Canvas and content made available at the beginning of the semester.

For access assistance, please contact the UC Denver Online Help Desk at 303.315.3700 (Monday through Friday, 7:00 am – 7:00 pm), or email cuonlinehelp@cuanschutz.edu. The help desk provides email assistance 24 hours a day, 7 days a week. They guarantee a 24-hour response time to inquiries, but generally respond in much shorter time.

Course Evaluations

Ongoing student assessment is critical and is a required component of any Graduate School program to maintain accreditation. At the end of the semester students will complete an overall evaluation of the course and instructor. Students are asked to evaluate components of the course on a 1-5 scale (1-poor, 2-fair, 3-good, 4-very good, 5-excellent) and have the opportunity to add free text.

The Preliminary Examination

At the end of the first year of didactic course work, students will take a written Preliminary Exam to assess their comprehension of the educational concepts covered in the coursework. The Graduate School requires a Preliminary Examination to ensure that students are qualified for doctoral study. The purpose of the Preliminary Examination is to determine potential for successful completion of the program and to use the results in subsequent academic advising. The Preliminary Examination covers the core content areas of:

- Biostatistics
- Ethics
- Research Methods

The Preliminary Examination is held every year over a three-day period between the end of the spring and beginning of the summer terms (typically late May or early June). You will be asked to indicate your intent to take the examination about 3 months prior to the date of the Preliminary Examination. Students typically take the Preliminary Examination after completing the first year of required core courses.

Course Requirements for Taking the Preliminary Exam

CLSC Students:

For students starting the program *during or after* summer 2020, the following courses must be completed prior to taking the Preliminary Examination:

Biostatistics: BIOS 6601 and BIOS 6602

• Ethics: CLSC 7150

Methods: EPID 6630 plus one of the following

- CLSC 6270
- CLSC 7202
- EPID 6626
- BIOS 6648
- EPID 6631
- EPID 6623

Exam Format

The Preliminary Examination is **OPEN BOOK**. Students should feel free to use textbooks, reference materials, class notes, peer-reviewed publications, and credible websites.

Students may choose to complete the Biostatistics section in the classroom or at work/home (you are still obligated to report to the classroom the morning of the exam in order to sign the honor codes and receive the exam folder). The other two sections (content areas) can be completed off campus.

Since the examination is open book, students should remember to bring the necessary materials, such as biostatistics textbooks and class notes. The other two sections (content areas) can be completed at work/home. A printer will be available locally for printing.

On the morning of the exam, students will be given an exam folder. Once the seal is broken, students have committed to taking the exam in its entirety. Students will be asked to read the instructions completely and to ask questions prior to starting the exam. All questions raised will be answered openly and shared with all students. A failing grade will be given to any exam section not completed.

CLSC Program Honor Code and Grading Policy

Before beginning the exam, you must sign the honor code policy for each exam section and submit this to the CLSC Program staff.

All doctoral students taking the CLSC preliminary exam will be requested to sign the following statement for their work:

"As noted in the exam instructions, I have abided by the CU Denver | Anschutz Medical Campus Graduate School honor system whereby I have not used any reference material, computer files, or worked with any person in a manner that would unfairly advantage my performance on this Ph.D. Program in Clinical Science Preliminary Examination. Moreover, I will not share a copy of this Preliminary Exam (either the questions or my responses) with anyone without written preauthorization from the Ph.D. Program in Clinical Science administration."

Faculty members will be using a grading rubric for scoring each exam section. The pass/fail designation you receive will reflect faculty scores submitted for: 1) Research Methods, 2) Ethics, and 3) Biostatistics. In order to pass the Preliminary Exam, you will need to receive a passing designation in ALL three sections. If you fail any one, you will need to talk with the Program Director and your Academic Advisor to identify the next steps. If you fail any two or all three sections, you will be administratively withdrawn from the Clinical Science graduate program. Possible next steps include re-taking the failed section of the exam within a designated time period, completing additional courses before retaking the examination, or withdrawal from the program.

The scoring is as follows: 100 to 80 score = Pass Less than 80 = Fail

Historically, the most **common error** made is **not reading the instructions carefully** and/or **not answering ALL components** of each question. This exam process is the equivalent to writing academic papers. Ensure your thoughts are well thought out, articulated, and supported by references.

Skipping a question or a section of a question is not a wise choice. It is better to provide your best answer possible than no answer at all. You should respond in full sentences – not outline format. The use of tables and figures to illustrate points is encouraged. Overall writing style and correct use of spelling and grammar are taken into consideration during scoring. Organizing responses according to the sections of the examination questions and sub-questions (with headers) is a useful approach (and makes your exam easier to grade).

Criteria Used for Grading

ANALYSIS

- Identify and organize elements in ways that demonstrates a logical coherent response
- Explain the central issues, problems and "puzzles" with respect to the topic under discussion
- Identify and explain unstated assumptions, logical fallacies, and extraneous aspects of an issue, problem or position
- Project the implications of an issue, problem, or position
- Explain and compare alternative views

SYNTHESIS

- Present succinct summaries of ideas that reflect comprehension of the whole while building a deliberate message concerning the topic under discussion
- Convey abstract relationships that form conceptual wholes
- Integrate a variety of sources to form a foundation for the student's unique ideas

CRITICAL SCHOLARLY ABILITIES

- Demonstrate critical self-awareness and reflective thinking
- Provide succinct, complete and direct responses to the issues
- Demonstrate a breadth of knowledge of the topic under discussion that is consistent with the breadth covered in the entry doctoral level courses
- Interpret existing literature without misrepresentation
- Demonstrate the ability to defend a logical position without prejudice

Preparation Tips and Study Guide

At a minimum, it is suggested that you dedicate at least 40 hours of study time for the Preliminary Exam.

You should review the course reading materials, textbooks, and class notes, as well as spend time reviewing the literature.

Biostatistics Section

The objectives for the biostatistics section are three-fold:

- 1) To demonstrate your familiarity with fundamental concepts and elements of probability, descriptive statistics and hypothesis testing;
- 2) To demonstrate that you can define and carry out a basic design and analytic plan for a study; and
- 3) To demonstrate that you can use appropriate computer packages for design and analysis.

Students should be comfortable with the following concepts:

- Dichotomous and continuous variables
- Power of a statistical test
- Sample size calculation
- Power calculation
- Normal distribution
- Inference from two-way tables

Be sure that you are comfortable programming in SAS and PASS (or some statistical software that can be used for sample size/power calculations).

Research Methods Section

From your epidemiology and research methods course material, you should review study designs that are commonly used in the field of clinical science research. The primary objectives for the research methods section of the exam are to ensure that students have the ability to:

 Describe in detail each type of research design studied (providing definitions of key terms and appropriate examples);

- 2) Compare and contrast the strengths and weaknesses of various study designs, as well as in comparison to the randomized, controlled clinical trial;
- 3) Design and compare alternative design approaches to the randomized, controlled clinical trial; and
- 4) Select the best design to answer a clinical question or hypothesis and provide the rationale for the selection.

The questions in this section of the CLSC Preliminary exam will expect you to identify the "optimal" study design for a specific clinical question or hypothesis. Thus, you should examine each study design's applicability to different types of clinical science research questions. Be sure to highlight and discuss literature-based examples of how different study designs have been used successfully.

Ethics Section

The primary objectives for the ethics section of the exam are to ensure that students have the ability to:

- 1) Describe the COMIRB requirements for paperwork and approvals (based on COMIRB web site). Additionally, it is important that student can explain the common pitfalls to avoid (based on COMIRB reviewer criteria) in preparing an informed consent document for approval;
- 2) Explain the historical foundations of the current requirements for ethical review of human subjects research. Please review the seminal works (e.g., Declaration of Helsinki, the Nuremberg Code, and the Belmont Report) carefully to identify the basic ethical principles that should guide the conduct of human subjects research; and
- 3) Apply their knowledge of ethical principles and regulatory issues to be addressed in a human subjects research to a selected case study situation.

Acknowledgment of NIH Funding on CCTSI Publications and Projects

The Clinical Science graduate program is a CCTSI (Colorado Clinical & Translational Sciences Institute) - sponsored Training and Education Resource. Any publications, patents, projects, or other tangible outcomes (including MSCS thesis/Publishable paper and PhD thesis) that benefit from any CCTSI resources **must credit the CTSA Grant**.

The following language should be used when citing the grant:

"This project/publication is supported in part by NIH/NCATS Colorado CTSA Grant Number UL1 TR002535. Contents are the authors' sole responsibility and do not necessarily represent official NIH views."

In addition, publications should be registered with PubMed Central.

More information is available on the CCTSI website at https://cctsi.cuanschutz.edu/resources/grant-language

Comprehensive Examination, Thesis Process and Thesis Defense

Comprehensive Examination and Expectations of Thesis Committee

The PhD Thesis Examination Committee will examine the student for both the Comprehensive Examination, to qualify for PhD candidacy, and the PhD Thesis Defense Examination to complete the requirements of the PhD degree. Students select at least five members to serve on their PhD Thesis Committee. This committee will administer both the Comprehensive Examination and the Thesis Defense Examination. The PhD Thesis Committee is to be formed and meet once within 12 months of successful completion of the Preliminary Examination. Holding a comprehensive examination will fulfill the requirement of holding a full thesis committee meeting. The PhD committee is required to meet at least once per year until the student successfully passes the PhD Thesis Defense Examination. However, it is strongly advised that the PhD Thesis Committee meet two or more times/year. Following each Comprehensive Examination and These Committee meeting, documentation of the student's progress and areas discussed are to be forwarded to the CLSC Administrator (galit.mankin@cuanschutz.edu) using the Thesis Committee Report Form.

We encourage students to talk with a number of faculty members about possible topics during their first year of study. Following successful completion of the Preliminary Examination, the PhD Thesis Defense Examination must be formed and met within 12 months. Holding a comprehensive examination will count will fulfill the requirement of holding a full thesis committee meeting. Contact faculty you might want to work with or faculty in an area that interests you. Academic Advisors are a wonderful resource for networking and identifying potential Research Mentors and committee members. When meeting with various faculty, you are not making any commitment to work with that person nor they with you. Do not assume that you need to find a topic on your own, but also do not assume that you will be handed a topic to work on. It will be helpful if you have some interests or specific things to suggest as you are meeting with faculty.

When you have selected your Research Mentor, also known as the thesis supervisor, (the person you will work most closely with for your research project and thesis) and are fairly confident you have a good topic or specific area to work in, begin forming the committee. You and your Research Mentor should determine other faculty with whom you would like to work and who would add expertise needed for your project. When you have agreed on a list of possible members, meet with each of those people to describe your proposed work and request committee membership. You and your committee should meet as a group at least once every year, although every six months is preferable. You will also need to identify the Chair of your committee. The Research Mentor and Chair must be different. The Chair is responsible for monitoring the conditions and reporting their outcome to the Clinical Science Graduate Program and the Graduate School. Specifically, s/he will complete the Thesis Committee Report form (in the following pages) following each committee meeting and will chair both the Comprehensive Examination and the Thesis Defense Examination. It is the role of the Chair to complete and submit the Thesis Committee Report form. However, it is strongly encouraged that the student work with the Chair to ensure the process is completed.

Expectations of the Student

Good supervisory practice entails responsibilities not only of the Research Mentor but also of the student. When a student enters a doctoral program, that student commits time and energy necessary for research leading to a thesis that makes a substantial and original contribution to knowledge. It is the responsibility of the student to conform to University and program requirements and procedures. Although it is the duty of the Research Mentor to be reasonably available for consultation, the primary responsibility for keeping in touch rests with the student.

Expectations of the Research Mentor

Within the context of their role as Research Mentor, a faculty member's primary task is to guide and inspire his or her students to reach their scholarly potential. At the same time, each Research Mentor must try to ensure that each student is in compliance with the rules and regulations of the University. The Research Mentor and Comprehensive Exam and Thesis Committee members should promote conditions conducive to a student's research and intellectual growth and provide appropriate guidance on the progress of the research and the standards expected.

In order to provide good supervisory practice, Research Mentors will:

- Commit adequate time to meet regularly with students.
- Guide the student in the selection and planning of an original research topic that can be successfully completed within the expected time frame (4 years). The maximum time the Graduate School allows for completion of the PhD is 8 years).
- Establish with the student a realistic timetable for completion of various phases of the research project and write-up.
- Provide students with regular and timely provision of feedback and ensuring students adhere to the agreed upon timetable.
- Ensure that students have an understanding of the relevant theories and the methodological and technical skills necessary for the research.
- Establish with the student a Comprehensive and Thesis Committee by the end of the second year of the student's program (or earlier).
- Ensure that the committee meets with the student at least once a year, as a committee, and provides an annual written report of the student's progress.
- Make arrangements to ensure continuity of supervision during leaves or an extended period of absence.
- Encourage participation in departmental seminars.
- Encourage and assist students to attend and present work at local, national, or international conferences and to publish their work in appropriate peer-reviewed journals.
- Advise on and contribute to career development and professional development in academics, examples include: preparation of the CV, providing letters of reference, reviewing applications, and strategies for launching an academic career.
- Be honest with the student when academic performance is not meeting expectations.

Expectations of Members of the Comprehensive Exam and Thesis Committee

In order to provide good supervisory practice, Comprehensive Exam and Thesis Committee Members will:

- Commit adequate time to meet with students to advise and provide expertise.
- Provide input in the selection and planning of an original research topic that can be successfully completed within the expected time frame (4 years).
- Provide students with timely provision of feedback when requested.
- Ensure that students have an understanding of the relevant theories and the methodological and technical skills necessary for the research.
- Advise on and contribute to career development and professional development in academics, examples include: preparation of the CV, providing letters of reference, reviewing applications, and strategies for launching an academic career.
- Be honest with the student when academic performance is not meeting expectations.
- Attend Comprehensive Exam and Thesis Committee meetings at least once a year.

Expectations of the Comprehensive Exam and Thesis Committee Chair

- He/she is responsible for the completion and submission of the appropriate paperwork or forms and that these forms are scanned and e-mailed to Galit Mankin.
- He/she is responsible for chairing the committee meetings and examinations
- Specific to PhD students,
 - Complete the Comprehensive Exam: Approval of Thesis Proposal after successful completion of the Comprehensive Examination and the accompanying Graduate School form.
 - Ensure that the committee meets at least yearly and completes the Thesis Committee Report of the student's progress.
 - Ensures that prior that the Permission to Proceed to Defense form is completed when the student is scheduling the PhD Final Thesis Examination/Defense.
 - If conflicts arise between the student and the Research Mentor or committee members, the Chair will take the lead for resolution of conflicts and will notify the Program Director or Educational Director of the CLSC, as appropriate.

Graduate School Faculty Appointment

All members of the committee must have or be eligible for a Graduate School faculty appointment. A Graduate School faculty appointment listing is posted on-line at https://gs.ucdenver.edu/tbl gradfac curr.php

For a committee member who does not have a Graduate School appointment, students may request that the CLSC Program submit an appointment nomination to the Graduate School. To begin this process, the student must submit to Galit Mankin (galit.mankin@cuanschutz.edu) a CV of the nominee and a written explanation of what this potential member would contribute to the committee. The nomination requests must be submitted to the CLSC Program no less than two months before the planned comprehensive and thesis proposal examination date.

Committee Composition for Clinical Investigation and Health Information Technology

- The committee must contain at least 5 members.
- The majority of committee members must be CLSC faculty.
- At least 1 member must NOT be from the CLSC faculty.
- Your Research Mentor (the person you will work most closely with to develop and conduct your research project) is a member and MUST attend the Comprehensive Examination and the Thesis Defense Examination but is NOT allowed to chair the committee nor the exams.
- The Chair of the committee must be a CLSC core faculty member (This includes the Track Directors, Educational Director, Program Director and Program Director Emeritus). This individual will chair the Comprehensive Examination, your committee meetings, and the Thesis Defense Examination.

Following the above guidelines and with input from the Academic Advisor (Track Director) and Research Mentor, the student should prepare a list of proposed committee members for review and approval by the Clinical Science Program Director. This should be done at the latest two terms following passing of the Preliminary Examination (although it is encouraged that the committee be formed much earlier).

Following the above guidelines and with input from the Academic Advisor (Track Director) and Research Mentor, the student should prepare a list of proposed committee members for review and submit it for approval to Galit Mankin by e-mail, along with a copy to the Academic Advisor. This should be done at the

latest two terms following passing of the Preliminary Examination (although it is encouraged that the committee be formed much earlier).

Comprehensive Examination Planning Process

Admission to Candidacy

Graduate School Policies & Procedures apply to Comprehensive Exams of all CLSC PhD students. The purpose of the Comprehensive Examination is to provide the candidate with the opportunity to demonstrate mastery of a broad range of knowledge in clinical science. While specific courses completed by the candidate are important, their content has been tested as a portion of the grading process for the course. The Comprehensive Examination is not, therefore, a re-examination of course content but rather the integration and application of knowledge and skills. A form of evidence of this ability is the student's thesis proposal. The candidate should demonstrate synthesis of knowledge in the areas of:

- theory construction, analysis, and evaluation;
- research and analytic methods required to answer significant clinical science questions;
- existing and emerging knowledge in clinical science, the identified clinical science track and other contributing fields.

Before admission to candidacy for the PhD in Clinical Science, each student must pass a Comprehensive Examination in his/her selected track or field of concentration. This examination will include: 1) a written exam component, 2) a presentation of the thesis proposal that is open to the public, and 3) a closed oral exam on the proposal, related clinical science topics and synthesis of completed coursework. The format of the written exam requirement can take the form of an NIH-like grant or the first three chapters of the student's thesis.

Requirements Prior to Scheduling the Comprehensive Examination

- Preferably completed by the end of the student's third year.
- Successful completion of the Preliminary Examination.
- Completion of or current registration for all program-required, non-thesis coursework.
- Validation of any course work to count toward the degree that was taken more than 7 years before the Comprehensive Exam.
- A cumulative G.P.A. of 3.00 or higher for completed CLSC program coursework.
- Registration for a minimum of one credit during the semester of the examination.
- Attendance at the public presentation portion of at least one CLSC peer's Comprehensive Examination.
- A CLSC program-approved list of committee members, including the Research Mentor and Thesis Committee Chair.
- Ready to initiate the project. The student must submit the "Approval of Thesis Proposal Form" (signed by Chair & Mentor) to Galit Mankin at least 8 weeks before the exam.

- The student must have prepared a written research proposal in the form of an NIH grant submission or the first three chapters of a thesis that has already been read by your Research Mentor. Students are strongly encouraged to meet with their committee or its individual members prior to the Comprehensive Examination to determine general agreement regarding the content and form of the proposal.
- The student must submit his/her thesis proposal to all committee members and to Galit Mankin at least **8 weeks** before the exam.

All required paperwork must be completed and submitted to <u>Galit Mankin</u> **NO LESS THAN 30 DAYS** before the exam is held.

- University-wide Instructions and Forms for the Comprehensive Examination are available in the Student Services section of the Graduate School website:
 https://graduateschool.cuanschutz.edu/forms-resources/resources
 Please read all instructions carefully. An "Application for Admission to Candidacy" form must be submitted along with the "Request for Scheduling Exam" form.
- The paperwork requires the CLSC Program Director to review, approve and sign the form before the Graduate School will accept it.
- Any student who does not meet the Graduate School deadlines will be required to re-schedule his/her Comprehensive Examination. Therefore, we strongly recommend students begin the paperwork process NO LESS THAN 8 WEEKS before the planned exam date.

Extremely Important: Students must be registered at the time they take the Comprehensive Examination. Students who schedule their examinations after the last day of a given term must register in the subsequent term.

• In addition to the maximum 10 thesis hours that may be completed *prior* to the Comprehensive Exam (and *after* passing the preliminary exam), up to 10 additional thesis hours may be completed *during* the semester in which the Comprehensive Exam is taken.

Scheduling

- Due to limited faculty availability during the Summer semester, Comprehensive Exams will
 normally be held during Fall and Spring semesters. The Comprehensive Exam can be held in a room
 on the AMC campus or an AMC-affiliated campus or remotely by zoom.
- The Graduate School requires that students and committee members set aside 3 hours for the Comprehensive Exam.

Contact CU Denver | Anschutz Medical Campus Educational Support Services to reserve a room and any necessary audio-visual equipment (e.g., projector):

https://www1.ucdenver.edu/offices/office-of-information-technology/services/academic-technology-and-classroom-support

Comprehensive Examination Process/Content

All members of the committee must be present for the examination. One member, but not the chairperson or the student, may participate by interactive video or telephone. Any costs incurred to bring an outside member to campus or to connect the member by interactive video/telephone are the responsibility of the student. The examination form, indicating the pass, conditional pass, or fail status of the exam, must be signed by all committee members and returned to the Graduate School Office. Students might remind the chair of his/her

responsibility to obtain signatures from all committee members while present. *Graduate School policy requires* that the student never be in possession of the completed exam form; failure to comply with this requirement nullifies the exam results. The completed form should be scanned and e-mailed to the CLSC Administrative Office (galit.mankin@cuanschutz.edu).

The thesis proposal should describe the proposed topic, background and relevant literature, theoretical foundations, methods, and intended approaches. The student and the Research Mentor (and perhaps other committee members with whom the student may have worked closely) should work together to get the proposal in good shape, and then circulate it to the committee for comments. This process is meant to help assess the level of agreement between the student and the committee, describing expectations and scope of work. The PhD research project and thesis should show originality on the part of the student and be of peer-reviewed publishable quality.

Thesis Proposal or NIH-like Submission Elements

- 1) Cover letter/memo: Provide a list of the names of the Comprehensive Examination Committee, provide the date, time, location (including room number) and title of the proposal and oral presentation.
- 2) Chapter 1- Introduction: Provide a brief overview, conceptual framework, purpose, and problem statement of the proposal.
- 3) Chapter 2- Background/Review of the Literature: Perform a review of the literature that identifies, reviews, and critically appraises existing knowledge in the identified fields and topics. Gaps in evidence, knowledge and/or practice should be identified that the proposed project addresses.
- 4) Chapter 3- Study Hypotheses, Methods and Analysis Plan: Briefly present the proposed study's hypotheses/research questions, the methods proposed to address the hypotheses/questions and the accompanying analysis plan.

Evaluation Criteria for the Paper/Written Element

- Focuses on a substantive topic in clinical science that synthesizes theory, research and practice.
- Reflects breadth of knowledge in the field.
- Reflects understanding of the issues and problems related to the topic.
- Presents original ideas and sound rationale; the significance for clinical science is convincing.
- Discusses and suggests methods and approaches to the inquiry.
- Is concise, logical and readable.
- The content is well founded and accurate.
- Citation and documentation of sources used are accurate and comprehensive.

Comprehensive Exam Structure

The Comprehensive Examination has two components: 1) a formal, public presentation of the student's thesis (dissertation) proposal, and 2) a closed discussion with the exam committee during which the student is required to demonstrate in-depth knowledge of the methodological, clinical and social issues pertinent to the student's project and selected track.

The public presentation should last approximately 30-40 minutes, followed by an open question-answer session. Following the public presentation is a closed meeting with committee members. During this exam component, content from track-specific courses and the student thesis proposal will be covered (related

fields of study, methodology, statistics). Listed below are some examples of core content areas according to track.

- Clinical Investigation: Students will be expected to demonstrate their knowledge and understanding of the challenges and potential solution/approaches used in clinical investigations, research methods, and principles of clinical translation.
- Health Information Technology: Students will be able to present and discuss the goals and objectives for HIT in clinical, financial and administrative realms; describe the role of HIT in improving patient safety, quality, and operational efficiencies; and explain the major barriers to implementing HIT.

Prior to their own Comprehensive Exam, CLSC students must attend at least one of their CLSC peer's public presentation component of the Comprehensive Examination. Students are encouraged to attend more than one to become familiar with the process and to participate in the scholarly dialogue.

Examination Grading

There are three possible outcomes for the Comprehensive Exam:

- 1) Pass The student must receive affirmative (passing) votes from the majority of the committee members to pass.
- 2) Pass with conditions The committee may decide that although the student has passed the examination the student should complete additional work on the thesis proposal or coursework. Areas of additional work or other conditions will be specified on the examination form and must be completed to the satisfaction of the examination committee within 4 months of the examination. The committee chair is responsible for monitoring the conditions and reporting the outcome to the Graduate School and to the Clinical Science Program office. Failure to satisfy these conditions will result in failure of the examination.
- 3) Fail If the student fails the examination, per Graduate School Policies & Procedures, the student may be subject to immediate dismissal from the program. At the program's discretion, the student may be allowed to re-take the examination once. The re-examination will be in the form designated by the committee and must be completed within twelve (12) months. The original examination form noting the failure is signed by the committee and returned to the Clinical Science Program office. New examination forms will be generated when the examination is rescheduled. The student will be required to meet registration requirements and be registered during the term in which the repeat exam is taken.

Upon completion of the Comprehensive Examination, the Chair ensures completion of the proper forms. Please refer to the PhD Comprehensive Examination Checklist to ensure completion of all required Graduate School CLSC forms. These forms should be provided to the CLSC Administrative Offices (galit.mankin@cuanschutz.edu) These forms should never be in the student's possession. Copies will be kept in the student's file.

Post Comprehensive Exam Requirements

- After passing the Comprehensive Examination, students must register for at least 5 dissertation/thesis credits every semester (excluding the summer semester).
- The student must register for a minimum of 5 thesis credits during the semester in which he/she defends (summer is NOT excluded in this instance).
- A maximum of 10 thesis credits can be taken in any semester. Only 10 of the thesis credits taken prior
 to the Comprehensive Examination (and after passing the preliminary exam) may be counted towards
 the minimum 30 credit hours required.
- In addition to the maximum 10 thesis hours that may be completed *prior* to the Comprehensive Exam (and *after* passing the preliminary exam), up to 10 additional thesis hours may be completed *during* the semester in which the Comprehensive Exam is taken.

Important Note: There is some strategy required in taking thesis credits. Because of the continuous registration requirement, taking too many credits early may result in additional expense; however, if a student takes too few, it may limit how quickly the student can graduate.

Committee Meetings

Although it is expected that each student's Thesis Committee will meet at least yearly, it is highly desirable that the committee meet more regularly. The student should also meet with individual committee members more regularly to take advantage of the individual members' expertise for successful project completion. The Chair should complete and return the CLSC Thesis Committee Report Form to the CLSC Program Administrator immediately following each Committee meeting.

UNIVERSITY OF COLORADO DENVER CLINICAL SCIENCE GRADUATE PROGRAM

Approval of Thesis Proposal

The following members of	the Thesis Committee have approved th	e dissertation							
proposal submitted by Doctoral Candidate									
Chairperson									
·	Print name								
	Signature	Date							
Research Mentor	Print name								
	Signature	Date							

This form is to be submitted to the Clinical Science Graduate Program's Administrative Office: Galit.mankin@cuanschutz.edu

Clinical Science PhD Program Comprehensive Examination Checklist (Expectations of the Chair)

<u>2-4 days prior to</u> the Comprehensive Examination, ensure that you have received the necessary paperwork from Galit Mankin:

•	Graduate School Information/Instruction sheet	
•	Graduate School Confirmation Sheet	
•	Graduate School Comprehensive Examination Report form	
•	CLSC Comprehensive Examination Attendance form	
•	Student's completed coursework and grades record	
•	CLSC Comprehensive Examination Report form	

 Copy of Student's Thesis proposal - should be provided by the student directly to the committee members

If you have not received these documents, please contact Galit Mankin at galit.mankin@cuanschutz.edu or 720-848-6249

Day of the Comprehensive Examination

- 1. Have attendees sign-in using the CLSC Comprehensive Exam Attendance form
- 2. Introduce the student and the title of his/her thesis proposal
- 3. Explain the structure of the Comprehensive Examination
 - Open forum session will include PhD student's presentation (approx. 40-45 mins) followed by questioning (approx. 20-30 mins)
 - Closed session follows the open forum (only committee members and student)
- 4. Following the presentation and questioning, thank and dismiss attendees and begin the closed session (ONLY committee members and student)
- 5. Ask student to step outside room (10mins), while the examination committee discusses the following points:
 - i. Ensure all members have read the proposal
 - ii. Determine order and format of questioning
 - iii. Review student's coursework and grades
 - iv. Determine if there are major concerns of the candidate
- 6. Call student back into the examination room to begin closed session questioning
- 7. Once questioning is completed, ask student to step outside the room (10-15 mins) while committee deliberates.
- 8. Chair the committee member executive session
 - a. Determine examination grade: pass, pass with conditions, or fail
 - If pass with conditions, the conditions need to be clearly documented and a date by which the conditions must be met identified on paper (conditions must be satisfy within 4 months). This paper should be provided to the CLSC Program Administrator, Galit Mankin.

- b. Have committee members sign Graduate School Comprehensive Examination Report form
- c. Complete the CLSC Comp Exam Form with committee member input
- 9. Call the candidate back into the room to join the committee and share the results of the examination. If there are conditions, explain the steps that the student must complete and the timeframe for completion.
- 10. Remind the student that the CTSA grant must be cited in the finalized version of the student's Thesis. The following language should be used when citing the grant:

 "This project/publication is supported in part by NIH/NCATS Colorado CTSA Grant Number

 UL1 TR002535. Contents are the authors' sole responsibility and do not necessarily represent official NIH views."

In addition, publications should be registered with PubMed Central.

11. Return the completed Graduate School forms and the CLSC forms to CLSC: Galit.mankin@cuanschutz.edu

AT NO TIME IS THE STUDENT TO HAVE POSSESSION OF ANY OF THE GRADUATE SCHOOL FORMS

CLSC Comprehensive Examination Report

Stude	nt:	Date of Exa	am:
Chair:		Research Mentor: _	
Memb	pers in Attendance:		
			tion and review of the written thesis proposal and ollows towards CLSC core competencies:
1.	Understands legal, ethical a	and regulatory issues related	to clinical research and principles for Responsible
	☐ Exceeds expectations	☐ Meets expectations	☐ Below expectations
2.	Critically appraise existing ☐ Exceeds expectations		
3.	Accurately select, use and i ☐ Exceeds expectations		ntistics. Below expectations
4.	Apply and use appropriate ☐ Exceeds expectations		to address research questions/hypotheses. Below expectations
5.	Identify and measure clinic ☐ Exceeds expectations	,	
6.	Design and conduct clinical ☐ Exceeds expectations	lly and patient oriented rese ☐ Meets expectations	
7.	Demonstrate effective com ☐ Exceeds expectations	nmunication and leadership s	skills. □ Below expectations
8.	Participate in interdisciplin ☐ Exceeds expectations	ary collaboration. ☐ Meets expectations	☐ Below expectations
C	omments:		

Please submit completed form to: $\underline{\textbf{Galit.mankin@cuanschutz.edu}}$

24.

25.

CLSC Comprehensive Examination Attendance Form

SPEAKER:	
DATE: /	
ATTENDEES	(please PRINT name clearly):
1.	26.
2.	27.
3.	28.
4.	29.
5.	30.
6.	31.
7.	32.
8.	33.
9.	34.
10.	35.
11.	36.
12.	37.
13.	38.
14.	39.
15.	40.
16.	41.
17.	42.
18.	43.
19.	44.
20.	45.
21.	46.
22.	47.
23.	48.

Rev.5/18/23 Page 40

49.

50.

CLINICAL SCIENCE GRADUATE PROGRAM Thesis Committee Report

Stude	ent:	Date of N	Meeting:	
Resea	arch Mentor:	Dissertation	on Chair:	
Comn	nittee Members in Atter	ndance:		
1.	Has the student made If yes, attach student's	, , ,	YES NO	
	If no, explain the reaso			
2.	Please list publications last committee meetin	•	shed and/or grants subm	itted, or awarded since the
3.	Is there evidence that	the student is sufficiently c	committed to the researc	h? YES NO
4.	Does the student have ☐ Exceeds expectations	sufficient knowledge of th ☐ Meets expectations	ne current literature? ☐ Below expectations	☐ Unable to assess/Too early
5.	Is the student able to c ☐ Exceeds expectations	critically appraise evidence ☐ Meets expectations	and various sources of ir ☐ Below expectations	nformation? ☐ Unable to assess/Too early
6.		sufficient knowledge to ap rinciples for the Responsib □ Meets expectations	–	gulatory issues related to ☐ Unable to assess/Too early
7.	Did the student display analyses? ☐ Exceeds expectations	•		used statistics and forms of

8.	Did the student demonstrate the ability to use appropriate research design to address the research questions or hypotheses?				
	☐ Exceeds expectations	☐ Meets expectations	☐ Below expectations	☐ Unable to assess/Too early	
9.	Does the student have a ☐ Exceeds expectations	bility to identify and meas ☐ Meets expectations	sure clinically relevant ar ☐ Below expectations	nd meaningful outcomes? ☐ Unable to assess/Too early	
10.	Through the final resear	ch project, is the student	participating in interdisc YES NO	plinary research?	
11.	Has the student commu ☐ Exceeds expectations	nicated effectively (writte ☐ Meets expectations	n and oral) in committee ☐ Below expectations	e meetings? □ Unable to assess/Too early	
12.	What are the specific co	ncerns of the committee ।	related to the project/stu	udent?	
13. the ne	The committee recomm xt meeting.	ends the following activiti	es, experiments and/or រុ	goals to be accomplished by	
14.	Has the student been multiple of the student	ade aware of concerns, ex YES NO	spectations or recommer	ndations of the committee?	
15.	Are there any disagreem	nents within the committe YES NO	e or between committee	e members and the student?	
16.	Date by which next mee	ting should be held?			

This form is to be submitted to the Clinical Science Graduate Program's Administrative Office: Galit.mankin@cuanschutz.edu

Thesis Process

- 1. Form the committee: See above Comprehensive Examination and Thesis Committee Membership.
- 2. Draft a proposal: See above Comprehensive Examination Process/Content.
- 3. Conduct the research: The student will work with the Research Mentor and committee members to carry out the proposal. As things develop there will likely be some variation from the proposal, which is okay. Research involves collaboration. Some committees or individual members meet regularly (e.g., weekly) while others meet upon request. However, the student should not spend long periods of time working alone without talking with the Research Mentor this is a recipe for delay, expenses, and/or failure. Committees MUST meet at least once a year (preferably every six months), and complete a Thesis Committee Report form (found at the end of this section) to be submitted to the CLSC Administrative Offices. Students must register for at least five thesis hours each fall and spring semester extending through the semester of the thesis defense. The final grade for the thesis (thesis course credit hours) will be withheld until the thesis is completed and approved by the Graduate School; the student will receive a grade of "In Progress" (IP) until that time.
- 4. Write the thesis: The thesis must meet the formatting criteria outlined in CU Denver | Anschutz Medical Campus <u>Graduate School Thesis Specifications</u>. The student will draft his/her thesis and circulate it among committee members informally. The goal is for the student to incorporate all required changes/revisions to the draft thesis document PRIOR to the Thesis Defense Examination.

Thesis Chapter Content Requirements

There is some variation in chapters across theses, but all theses must contain the information listed below and adhere to the Graduate School requirements.

Chapter 1- Introduction: Provide a brief overview, conceptual framework, purpose, and problem statement of the project.

Chapter 2- Background/Review of the Literature: Perform a review of the literature that identifies reviews and critically appraises existing knowledge in the identified fields and topics. Gaps in evidence, knowledge and/or practice should be identified that the project addresses.

Chapter 3- Study Hypothesis/es or Research Questions, Methods, and Analysis Plan: Provide the study's overall purpose, research question(s) hypothesis/es, specific aims, and a detailed description of the research methodology and analytical approach used. Where appropriate, detailed lab protocols should be specified (but may be included in an appendix). A power calculation/sample size calculation would normally be included. If qualitative or exploratory work was involved to complement the primary hypothesis-driven study approach, these study aims and methods should be described also. Appendices are helpful to provide copies of instruments, calibration assessments, key diagnostic tests, clinical performance metrics, study data forms, study data definitions, survey instruments, or any other source documents related to the study. The student's thesis COMIRB application and (at a minimum) COMIRB approval documentation (including HIPAA documentation if appropriate) should be included as a separate appendix.

Chapter 4- Study Results: Tables, graphs, and a detailed summary of the study findings should be presented.

Chapter 5- Conclusion/Discussion: The project's conclusions are presented and a discussion of the implications (as related to the field of clinical science) provided. The impact on patient care should be

discussed. Strengths and limitations of the work are also described. Future research directions and/or research projects planned may be discussed in this chapter or an additional chapter.

Thesis Defense

- 5. Prior to scheduling your PhD thesis defense, all Thesis Committee members should agree that the student and the thesis are ready to proceed to defense. The CLSC Permission to Proceed to Defense form should be signed by committee members and returned to the CLSC Administrative Office (Attn: Galit Mankin).
- 6. Schedule thesis defense: Upon the request of the student and when all members of the committee have signed the **Permission to Proceed to Defense form**, a day and time acceptable to all committee members can be scheduled. Faculty signatures (electronic signatures are acceptable) on this form ensure that the full committee agrees that the student is ready to defend his/her final thesis. Students should plan on a meeting of at least four hours. The final draft of the thesis must be submitted to the CLSC Administrative Office (galit.mankin@cuanschutz.edu) and the committee members of the Thesis Defense Examination at least four weeks in advance of the planned defense date. The defense can be held in a room on the AMC campus or an AMC-affiliated campus or remotely by zoom.
- 7. Please note that the following forms need to be completed and submitted to CLSC Administrative Office.
 Allow a minimum of 4 weeks for the CLSC and the Graduate School to process the required forms:
 - 1) Request for Exam form (a Graduate School form)
 - 2) <u>Permission to Proceed to Defense form</u> (a CLSC program form)

Graduate School deadlines for graduation are listed in the <u>Deadlines and Forms section of the Graduate School website</u>. *It is crucial to check the Graduate School deadlines to ensure a smooth process.*Graduation packets containing all necessary instructions and paperwork are available from the Graduate School office or website.

Students must be enrolled for at least 5 thesis credits (CLSC 8990) during the semester in which the thesis defense is held.

Students should consult the graduate school several months before planning to graduate to ensure the necessary paperwork is complete.

8. Defend the thesis: The thesis defense is the official Graduate School final exam for the PhD degree.

Please plan to set aside 3 hours for the thesis defense. CU Denver-Anschutz Medical Campus Educational Support Services (https://www1.ucdenver.edu/offices/office-of-information-technology/services/academic-technology-and-classroom-support) is available for reserving a room and providing equipment (e.g., projector). Similar to the Comprehensive Examination, the thesis defense consists of an open-to-the-public oral presentation and question period followed by a closed session with the members of the examination committee. All CLSC Program faculty and students will be invited to attend the oral presentation. The public presentation should last approximately 50 minutes with 20-30 minutes available for open public discussion. All members of the committee must be present for the examination. One member, but not the chairperson or the student, may participate by interactive video.

At the thesis defense, a majority vote of the Comprehensive and Thesis Committee members is required. This committee will evaluate both the oral defense and written thesis. Following deliberations, the committee will vote to pass, conditionally pass (with modifications required to the written thesis draft), or fail a student for his/her thesis defense. If changes are required, final review and approval by the

Clinical Science Program PhD Student Handbook

committee chair (who will determine that the committee's stipulated modifications have been completed successfully) will be obtained. If a student passes the examination with conditions, those conditions must be satisfied within 60 days for the PhD degree.

9. Submit thesis: A current Format Guide for Theses and Dissertations is available on the <u>Graduate School</u> <u>website</u>. Your final thesis or dissertation must be uploaded by the published deadline in order to graduate in that semester. In addition, an electronic copy of your thesis MUST be submitted to the program within 60 days of your thesis defense date.

Clinical Science Program Guidelines for Doctoral Dissertations

Please review and follow the Graduate School Formatting Guidelines https://graduateschool.cuanschutz.edu/forms-resources/resources/

Length: Most range between 150-200 pages

General Outline for Doctoral Dissertation

Title

The title must be pertinent to your project, but it should also indicate a sufficient grasp of the subject matter to suggest a focused effort.

Abstract

The abstract is a brief summary of your proposal. It should include the research question to be answered, the proposed methodology and the key results. If more than one hypothesis is to be tested, this should be stated in the abstract. The abstract is typically written last. Abstract uses a structured format Background/ Rationale, Objective/Purpose, Methods, Results, Conclusion and is within the 350 words limit.

Chapter 1 Elements

Introduction

This is a *general* introduction to what the thesis is all about -- it is *not* just a description of the contents of each section. Briefly *summarize* the question (you will be stating the question in detail later), some of the reasons why it is a worthwhile question, and perhaps give an overview of your main results. This is a birds-eye view of the answers to the main questions answered and how this thesis adds value to the known literature.

What is the topic and why is it important? State the problem(s) as simply as you can. Try to step back mentally and take a broader view of the problem. How does it fit into the broader world of your area/discipline?

In the introduction, do not overestimate the reader's familiarity with your topic. You are writing for researchers in the general area, but not all of them need be specialists in your particular topic. The introduction should be interesting. If you bore the reader here, then you are unlikely to revive his/her interest in the methods chapter. For the first paragraph or two, tradition permits prose that is less dry than the scientific norm. Try to make the reader want to read the heavy bundle that has arrived uninvited on his/her desk. Go to the library and read several thesis introductions. Did any make you want to read on? Which ones were boring?

This section might go through several drafts to make it read well and logically, while keeping it short. For this section, it is a good idea to ask someone who is not a specialist to read it and to comment. Is it an adequate introduction? Is it easy to follow? There is an argument for writing this section---or least making a major revision of it---towards the end of the thesis writing. Your introduction should tell where the thesis is going, and this may become clearer during the writing.

Literature Review

The topic of the dissertation must be well grounded in the relevant theoretical and/or empirical literature related to the topic. This means that an extensive literature review needs to be conducted as the basis for the proposal and the dissertation, in defense of the chosen topic. The extent and type of literature search strategy should be discussed with your mentor. You should have a table or algorithm that describes your search strategy and results and approach to finding and reviewing the relevant research. This literature review must also widely and firmly support the research questions, the research design, and any hypotheses that may be tested.

Here you review the state of the literature relevant to your thesis. The idea is to *present* the major ideas right up to, but not including, your own personal brilliant ideas.

This section is organized by idea, and not by author or by publication.

Where did the problem come from? What is already known about this problem? What other methods have been tried to solve it?

Ideally, you will already have much of the hard work done, if you have been keeping up with the literature. If you have summarized those papers, then you have some good starting points for the review.

For example, when you start reading about a topic, you should open a spread sheet file, or at least a word processor file, for your literature review. Of course, you want the reference but you also write a summary (anything from a couple of sentences to a couple of pages, depending on the relevance). In other columns of the spread sheet, you can add key words (your own and theirs) and comments about its importance, relevance to you and its quality.

How many papers? How relevant do they have to be before you include them? Well, that is a matter of judgment. You are the world expert on the topic of your thesis: you must demonstrate this.

Problem Statement, Research Questions, Hypotheses

You need to describe the overall or general "problem" to be solved and the specific research questions and/or hypotheses to be answered. In either case, this section has three main parts:

- 1. a concise statement of the problem, the research questions/hypotheses that your thesis tackles [5].
- 2. justification, by *direct* reference to the Literature Review chapter, that your question is previously unanswered
- 3. discussion of why it is worthwhile to answer this question.

Item 2 above is where you *analyze/critically appraise* the information which you presented in the Literature Review. For example, maybe your problem is to "develop an algorithm capable of handling very large scale problems in reasonable time" (you would further describe what you mean by "large scale" and "reasonable time" in the problem statement). Now in your *analysis* of the state of the art you would show how each of the current approaches fails (i.e. can handle only small problems, takes too much time, requires very expensive software). In the last part of this section you would explain why having a large-scale fast algorithm is useful; e.g., by describing applications where it can be used.

You must make it clear in this section how what you want to do differs from what has been done before and how it builds upon the past work. You should also be able to show that the question you want to answer will further the state of knowledge in your field. Finally, the statement of problem should culminate in the identification of one or more testable hypotheses/research questions that you think will address the statement of

problem.

Chapter 2 Elements

Theoretical OR Conceptual Model

The dissertation must have a theoretical framework that is steeped in and builds upon the relevant knowledge base. Theoretical frameworks must contribute to conceptual or theoretical models that can be tested by theoretical or empirical means. The theoretical or conceptual framework should be used to motivate the hypotheses and the empirical specifications that are used to test hypotheses.

Study Design, Methods and Statistical Approach

The topic of the dissertation and the nature of the research question(s) or hypothesis(es) must lead the research design. Some questions/hypotheses may require different research designs. For example, some topics and research questions in the field are best suited to some form of qualitative research while others may be best suited to some form of quantitative research. Some topics may be best suited for some combination of qualitative and quantitative research. It is the nature and research questions that determines the appropriate research design.

Methods of data collection and techniques of analysis must be consistent with the research design. For example, if the research questions call for survey research, then they must conform to the best standards of survey research and subsequent statistical analysis. If the research questions call for an econometric model, then the methods of data collection and analysis must conform to the best standards of econometric modeling. If the research questions call for some form of qualitative research design, then the methods of data collection and analysis must conform to the best standards of a particular form of qualitative research. Data collection and analysis, whether quantitative or qualitative must build a strong bridge between conceptualization and operationalization. Standard Operating Procedures should be mentioned and provided in Appendices. Data collection instruments are also provided in the Appendices.

IRB and **IACUC**

Include COMIRB and other IRB submitted to and approved along with the protocol number(s) for all research involving human subjects/participants. For live animals, animal tissue or observational animal work, include your IACUC protocol number. Include your IRB and or IACUC submissions in Appendices.

Chapter 3 Elements

Results

Results of the research are presented clearly and address the research questions/ hypotheses. Styles for presenting results in your dissertation may vary. In general, there are 3 options:

- 1. Results are described through tables, figures, graphs, images and text.
- 2. Results are written as full manuscripts that are in submission-ready form as they would be submitted for publications (3 papers).
- 3. Published, In Press or submitted peer-reviewed manuscripts (3 papers) of your research results are presented in the results section or contained in the dissertation as separate chapters following chapter 2 (theoretical/conceptual framework and methods).

For students that choose option 3, dissertations that use the style of presenting/inserting three Published, In Press or submitted peer-reviewed manuscripts may choose to have each published paper serve as a separate chapter of the dissertation. The published papers must be re-formatted to follow the Graduate School Format Guide for Theses and Dissertations. (See above at the top of the document). In addition, for multi-authored papers, a description must be included that provides the full reference citation and describes the student's role and contributions. Students who use this approach may have shorter methods and final conclusions and discussion chapters. Students should discuss this option of the published papers for their thesis early in the process (before the Comprehensive Examination). In addition, it is important to consult with your thesis committee regarding expectations for the methods and final conclusions and discussion chapters. For this option, at least one peer-review paper is published or *in press* before the doctoral dissertation defense.

Last Chapter: Conclusions and Discussion

Generally, three things are covered in the Conclusions and Discussion section/chapter, and each of these usually merits a separate subsection:

- 1. Conclusions
- 2. Summary of Contributions and Implications
- 3. Limitations of Research
- 4. Future Research

Conclusions are *not* a rambling summary of the thesis: they are *short*, *concise* statements of the inferences that you have made because of your work. It helps to organize these as short numbered paragraphs, ordered from most to least important. All conclusions should be directly related to the research question stated in the Problem Statement, Research Questions, Hypotheses chapter.

The Summary of Contributions and Implications will be sought and carefully read by the examiners. Here you list the contributions of *new* knowledge that your thesis makes and how it builds on existing literature as well as how your work contradicts the previous work of others. Of course, the thesis itself must substantiate any claims made here. There is often some overlap with the Conclusions, but that's okay. You also want to highlight/discuss the implications of your work. This summary should be organized around your contributions to and implications for research/methods, theories/models/framework, and clinical practice.

The Future Research subsection is included so that researchers picking up this work in future have the benefit of the ideas that you generated while you were working on the project. Future work should relate to the clinical area, methods, and theory.

Dissertations that use the style of presenting three Published, In Press or submitted manuscripts approach has the last chapter presents and discusses linkages (i.e., similarities and differences) between the separate manuscripts that are included in the dissertation, striving as much as possible to present the document as representative of a coherent body of work. The conclusion chapter 'ties' everything together and helps the reader see how the various manuscripts, taken together, make a contribution to the knowledge base regarding the problem. The conclusion chapter should present/discuss research imperatives, or knowledge gaps, not visible when each manuscript is considered individually and should articulate an agenda for future research on the issues addressed in the dissertation. It should be clear the contributions to the literature made by the student's body of work in terms of research, theory, and practice as well as next steps to be taken or considered to move the state of the evidence forward.

References

The list of references is closely tied to the Literature Review. Most examiners scan your list of references

Clinical Science Program PhD Student Handbook

looking for the important works in the field, so make sure they are listed and referred to in the Literature Review. All references given *must* be referred to in the main body of the thesis. Note the difference from a Bibliography, which may include works that are not directly referenced in the thesis.

Appendices

What goes in the appendices? Any material which impedes the smooth development of your presentation, but which is important to your dissertation. Generally, it is material that is of too nitty-gritty a level of detail for inclusion in the main body of the thesis, but which should be available for perusal by the examiners to convince them sufficiently. Examples include data collection instruments, immense tables of data, lengthy statistical formulae or outputs or derivations, etc.

Doctoral Dissertation Checklist

- 1. The title is clear and concise.
- 2. Abstract uses a structured format Background/Rationale, Objective/Purpose, Methods, Results, Conclusion and is within word limit.
- 3. Include COMIRB/IRB protocol number(s) in your Acknowledgements and Methods Chapter/Section. For live animals, animal tissue or observational animal work, include your IACUC protocol number in your Acknowledgements and Methods Chapter/Section.
- 4. Problem is significant and clearly stated.
- 5. Review of the literature is efficiently summarized.
- 6. Limitations of the literature are highlighted and well defined.
- 7. Important terms are well defined.
- 8. Hypotheses or research questions are clearly stated and are testable, discoverable, or answerable.
- 9. Problem statement, hypotheses, or research questions derive from the review of the literature. Rationale for work is clearly articulated.
- 10. Research design is clearly and comprehensively described, and demonstrated to be related to the research questions, and/or hypotheses.
- 11. Theoretical or conceptual model/framework used to guide work is well described.
- 12. Methods of data collection are clearly presented and demonstrated to be related to the research questions/hypotheses.
- 13. Plans for analysis whether quantitative or qualitative are clearly stated and justified within the context of the research design.
- 14. Tables and figures are used effectively. Textual explanation of the tables/figures is provided along with the tables and figures.
- 15. Results of the research are presented clearly and address the research questions/hypotheses.
- 16. Major findings are discussed clearly and related to previous research.
- 17. Importance of the findings is explained.
- 18. The relationship between the research and the findings is demonstrated with tight, logical reasoning.
- 19. Conclusions are clearly stated.
- 20. Conclusions are based on the results.
- 21. Generalizations are confirmed.
- 22. Limitations and weakness of the study/body of work are discussed.
- 23. Implications of findings to clinical care, research, methods and theory are discussed.
- 24. Relationship of the study to previous research is clear.
- 25. Suggestions for future research are offered regarding clinical care, research, methods and theory.
- 26. References are included (usually > 75).
- 27. Data collection instruments are included in Appendices.
- 28. IRB submission in Appendices
- 29. Sentence structure, grammar, spelling, and punctuation are correct.
- 30. Thesis is clearly written.
- 31. Tone is unbiased and impartial.

*Grossly borrowed with some adaptations from J. E. Mauch and J. W. Birch (1998), *Guide to the Successful Thesis and Dissertation*, Marcel Dekker.

UNIVERSITY OF COLORADO DENVER | ANSCHUTZ MEDICAL CAMPUS PhD PROGRAM, CLINICAL SCIENCE GRADUATE PROGRAM

Permission to Proceed to Defense

Ву	for the Thesis Def	fense Examination.
Doctoral Candid	date	
Dissertation Chairperson		
	Print name	
	Signature	Date
Research Mentor		
	Print name	
	Signature	Date
Committee Member	P. i.	
	Print name	
	Signature	Date
Committee Member		
	Print name	
	Signature	Date
Committee Member		
	Print name	
	 Signature	 Date

Please submit completed form to: Galit.mankin@cuanschutz.edu

CLSC PhD Dissertation\Thesis Defense Report

Stude	nt:	Date of E	Exam:	
Chair:		Research	Mentor:	
Mem	bers in Attendance:			
	ne student's ability regarding the esentation and response to ques	· ·	taking into account the written thesi	s/dissertation, the
1. Applies legal, ethical and regulatory issues related to clinical research and principles for Responsible (onsible Conduct of	
	Research. ☐ Exceeds expectations ☐	Meets expectations	☐ Below expectations	
2.	Critically appraises existing liter ☐ Exceeds expectations	rature and sources of info] Meets expectations	rmation. ☐ Below expectations	
3.	Accurately select, use and inter ☐ Exceeds expectations	•		
4.		ly designs and methods to I Meets expectations	address research questions/hypoth	eses.
5.	,	relevant and meaningful on the sections	outcomes. ☐ Below expectations	
6.		nd patient oriented resear I Meets expectations		
7.		nication and leadership sk I Meets expectations	ills. □ Below expectations	
8.	Participate in interdisciplinary o ☐ Exceeds expectations ☐	collaboration. I Meets expectations	☐ Below expectations	
Type o	f research (select all that apply)	\square T0.5 \square T1 \square T2	$_{T3}\square_{T4}\square_{N/A}$	
	CLINICAL TRA	ANSLATIONAL RESEAR	RCH SPECTRUM	
Basi Scient Discov	tific Preclinical Insights		ctice for Population Gl	roved obbal salth

Comments:

Rev.5/18/23 Page 53

CLSC PhD Program Checklist for Thesis Defense:

Expectations of the Chair

<u>2-4 days prior to the Thesis Defense</u>, ensure that you have received the necessary paperwork from Galit Mankin:

•	Graduate School Defense Information/Instruction sheet	
•	Graduate School Thesis Defense Confirmation Sheet	
•	Graduate School Thesis Defense Results Report form	
•	CLSC Thesis Defense form	
•	CLSC Attendance Sheet	

- Copy of Student's Thesis should be provided by the student directly to the committee members
- Thesis/Dissertation Approval form Student is instructed to complete the form on-line (from the GS website), and bring it to the defense in order to obtain signatures from all the committee members. The handling of this form is the responsibility of the student.

If you have not received these documents, please contact Galit Mankin at galit.mankin@cuanschutz.edu or 720-848-6249

Day of the Thesis Defense

- 1. Have attendees sign in using the CLSC attendance sheet.
- 2. Introduce the candidate student and the title of his/her thesis.
- 3. Explain the structure of the Defense:
 - Open forum session will include PhD candidate's presentation (approx. 50-55 mins) followed by questioning (approx. 30 mins)
 - Closed session follows (only committee members and candidate)
- 4. Following the presentation and questioning, thank and dismiss attendees and begin the closed session (ONLY committee members and the candidate student).
- 5. Ask the candidate to step outside the room (5-10mins), while the examination committee discusses the following points:
 - Ensure all members have read the Thesis
 - Determine order and format of questioning
 - Determine if there are major concerns of the candidate
- 6. Call candidate back into the examination room to begin closed session questioning.
- 7. Once questioning is completed, ask student to step outside the room (10-15 mins) until asked to return.

- 8. Chair the Committee member executive session
 - a. Determine examination grade: pass, pass with conditions, or fail
 - If pass with conditions, the conditions need to be clearly documented and a date by which the conditions must be met identified on paper (conditions must be satisfied within 60 days), which is submitted to the CLSC Program Administrator, Galit Mankin.
 - b. Committee members sign Graduate School Thesis Defense Report form
 - c. Complete the CLSC Thesis Form with committee member input
- 9. Call the candidate back into the room to join the committee and share the results of the examination. If there are conditions, explain the steps that the student must complete and the timeframe for completion
- 10. Remind the student that the CTSA grant must be cited in the finalized version of the student's Thesis. The following language should be used when citing the grant: "This project/publication is supported in part by NIH/NCATS Colorado CTSA Grant Number UL1 TR002535. Contents are the authors' sole responsibility and do not necessarily represent official NIH views."

In addition, publications should be registered with PubMed Central.

10. Scan and e-mail the completed Graduate School forms and the CLSC forms to: Galit.mankin@cuanschutz.edu

AT NO TIME IS THE STUDENT TO HAVE POSSESSION OF ANY OF THE GRADUATE SCHOOL FORMS

Graduate School Related Information

I.D. Badge and Parking Information

New students will be contacted by email to receive a badge. The signing authority for the Graduate School will let you know when to contact the Badge Office at the Anschutz Medical Campus (AMC). A driver's license, state ID, or passport is necessary to have your photo taken and to receive your badge. The Badge Office is located in Building 500, Room N1207 behind the café and on the same floor as the bookstore. The Badge Office can be reached at 303-724-0399 and at IDAccessBadges@cuanschutz.edu.

Pay parking is available at the Anschutz Medical Campus. For maps, permits and rates, go to https://www.cuanschutz.edu/offices/facilities-management/parking-transportation-maps/parking

Guidelines for Studying

A good rule of thumb to remember is that for each credit hour of a course, you will spend about <u>double to</u> <u>triple</u> that number of hours each week doing work for the class. Thus, you will spend about 6-12 hours each week, out of class, on average, for a 3-credit-hour class. Students with less experience in the subject matter of a particular unit or course should anticipate a greater time commitment.

The Strauss Health Sciences Library at Anschutz Medical Campus

As a student in the CLSC Program, you have access to the outstanding state-of-the-art Anschutz Medical Campus' Health Sciences Library, which houses more than 2000 online journals, many information databases, computer workstations, group study rooms, and online text references. This is a valuable resource that is available to you for your professional use throughout your enrollment in the CLSC Program. We encourage you to read the materials from the Health Science Library and to explore the assistance available on the home page at: (https://library.cuanschutz.edu/). The "Online Information Rack" from the library also provides helpful information about the library and its online services. If you have questions about using the library, the librarians can be reached at 303-724-2152.

Scholarship Information and Financial Aid

No scholarship opportunities specifically designed to support students of the CLSC Program exist at this time. Financial aid information is available from the campus financial aid office: https://www.cuanschutz.edu/student-finances/financial-aid

Honor Code

Students are expected to review and follow the Graduate School Honor Code Guidelines and Academic Integrity Expectations: https://graduateschool.cuanschutz.edu/forms-resources/resources

Clinical Science Program Frequently Asked Questions

Where is the Graduate School located?

The Graduate School is located on the Anschutz Medical Campus in Aurora, CO at 13001 E. 17th Place in Building 500, Room W5107.

Where is the Clinical Science Program Administrative Office located?

The Clinical Science Program Administrative office is located on the Anschutz Medical Campus in Aurora, CO at 1890 N Revere Ct. in the Anschutz Health Sciences Building, Room 6149.

I am interested in the Clinical Science Program and would like to know more about the admissions requirements. Who do I contact?

Please contact Galit Mankin at 303-724-1214 or galit.mankin@cuanschutz.edu for more information.

What forms do I need to complete for exams/graduation?

Forms, deadlines and instructions for exams/thesis defense are located on the Graduate School website. See the Master's Resources page if you are a master's student. PhD students should refer to the PhD Resources page.

How can I verify that members of my committee have current Graduate Faculty appointments?

See the Graduate Faculty Directory for a list of faculty with current or expired appointments. New appointment paperwork is received on a regular basis from the programs. If a faculty member's appointment is showing as expired or they are not currently listed on the website, contact Galit Mankin, CLSC Program Administrator, to see if appointment paperwork has already been forwarded to the Graduate School or to request new appointment paperwork be completed.

What is the maximum number of credits I can transfer?

Master's degree students can transfer in 12 semester hours. Transfer credit is defined as any credit earned at another accredited institution. PhD degree students can transfer in 30 semester hours. Credits must meet the transfer credit requirements and be approved for transfer by the program and the assistant dean.

What opportunities are there for loan repayment for clinical researchers?

The NIH Loan Repayment Program (LRP) for Clinical Research is designed to recruit and retain highly qualified health professionals as clinical investigators, repaying lenders directly for the existing principal, interest, and related expenses of qualified government and commercial education loans obtained for undergraduate, graduate, and health professional school expenses. For more information, visit the LRP website.

Is financial support available for international students?

No student financial support [for either educational costs (e.g., tuition) and/or stipend support] is available through the Clinical Science Program. As part of the application materials required, all international applicants must document that adequate financial support will be available for the entire period of study. For additional information, please review the International Student Requirements for Graduate School admissions.

Who might I contact for a CLSC course billing-related question?

For billing questions, contact the UCD Anschutz Medical Campus Bursar's Office: https://www.cuanschutz.edu/student-finances/billing-payments