MASTER OF SCIENCE PROGRAM IN CLINICAL AND POPULATION TRANSLATIONAL SCIENCE

THE DIVISION OF PUBLIC HEALTH SCIENCES
IN ASSOCIATION WITH
THE TRANSLATIONAL SCIENCE INSTITUTE
WAKE FOREST UNIVERSITY

PROGRAM HANDBOOK

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Links to other sources of information are shown as underlined brown text**.**

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BACKGROUND AND PHILOSOPHY

The Master of Science degree in Clinical and Population Translational Science (CPTS) was initiated in the fall of 2008, and replaces the Health Sciences Research Master of Science program. The CPTS program is co-administered by the Division of Public Health Sciences and the Wake Forest University Translational Science Institute (WFU TSI). The CPTS program complements our graduate education programs in Molecular Medicine and Translational Science (MMTS), also based in the WFU TSI. These programs are among a small number of similarly structured graduate programs in the United States, placing them on the cutting edge of graduate education.

Major changes have occurred in basic, clinical and community-based research in the last several years. In the past, basic, clinical and community-based researchers operated in separate domains, often without substantive interactions. This model of research conduct has contributed to barriers in the translation of knowledge into improved human health at the community level. At present, and increasingly in the future, it will be necessary for scientists to be able to collaborate effectively across the research spectrum to accelerate the translation of knowledge into improvements in human health.

The importance of developing new research models, and training researchers with the skills needed to create and participate in these models, was recognized by the National Institutes of Health in the Clinical and Translational Science Award program. To enable our graduates to meet this challenge, our program will provide students with a firm foundation across the spectrum of clinical and translational science, depth of expertise in clinical and population research, and development of skills that will enhance their capacity to participate in multidisciplinary team science. Students in the CPTS program will interact with students in the MMTS program in core courses and a research practicum to develop an understanding of the spectrum of research and skills in collaborative team science.

Within the field of clinical research, morbidity and mortality have been the primary outcomes assessed to evaluate treatment effectiveness. However, patient and provider satisfaction, health-related quality of life, health care expenditures, and cost-effectiveness are now evaluated with great regularity. This shift in emphasis is being driven, in part, by the changing health care system, which is demanding more complete information on physician practice patterns, clinical/patient outcomes, and the cost-effectiveness of therapies across a wide range of medical conditions. In addition, health outcomes and services are becoming more central to the funding structures of health care research. For example, the National Cancer Institute will not readily consider funding medical research unless it includes measurement of health-related quality of life and economic impacts. These factors are also becoming more central in the drug approval process, making the assessment of these outcomes more critical in the pharmaceutical industry.

In response to these changes, academic medical centers are redesigning their clinical delivery systems to conform to a system configured around capitated payment and fixed populations of patients in defined communities. Physicians and other health care professionals are also being asked to assume roles quite different from the traditional roles for which they were trained. Among these new roles are the responsibility for the delivery of cost-effective health care and preventive services to communities, the allocation of scarce health care resources, and the assessment of medical treatment effectiveness, including the evaluation of patient outcomes such as health-related quality of life. Academic research in the health care area also requires a broader combination of skills to more effectively examine the etiology, detection, prevention, and treatment of disease, in order to better inform the health care delivery system. Increasingly, multidisciplinary teams of researchers are required to address the complex research questions of importance in clinical research.

Within the field of community-based research, the linkages between public health and medical approaches to improving population health are increasingly recognized. The Medicine and Public Health Initiative, an alliance of the American Public Health Association and the American Medical Association, has focused on engaging leading medicine and public health organizations and individuals in efforts to reshape health education, research and practice. The clinical and population translational scientists of tomorrow must be prepared to conduct the research needed to advance methods for putting results we know into practice; to help determine gaps in coverage or in emphasis; to help assess ethical aspects of this research; to contribute to the determination of the long term cost-effectiveness of specific lines of research; to help develop public policy regarding areas of research development and implementation; and to help members of all health professions to become aware of and to utilize the most important research conclusions as they appear.

The combination of epidemiology; statistics; and clinical, health services, and community research methods into one program will provide students will the skills necessary to translate discoveries generated during laboratory research to human populations and to conduct research aimed at enhancing the adoption of best practices in health care settings and the community. Students also will be prepared to function in multidisciplinary teams that will conduct the translational research of the future.

PROGRAM OVERVIEW

The Master of Science (MS) Degree in CPTS is co-administered by the Division of Public Health Sciences and the Wake Forest University Translational Science Institute. Faculty members provide expertise and conduct research across the spectrum of basic, clinical, population, and translational research. The program is managed by two program co-directors and a program coordinator, with additional leadership provided by a small group of program faculty who form an Executive Committee. The program follows the policies and procedures of the Wake Forest University Graduate School of Arts and Sciences (Bowman Gray Campus).

Formal coursework for the CPTS graduate program emphasizes biostatistics, epidemiology, and clinical, health services, and community research, along with the responsible conduct of research and scientific communication. Students in the CPTS program also will participate in a shared course with students in the Molecular Medicine and Translation Science (MMTS) Program to develop an understanding of the spectrum of translational science. Competencies addressed by the formal CPTS coursework include the ability to:

- Develop meaningful and feasible research questions based on literature review and appropriate biological and psychosocial conceptual frameworks.
- Design and implement studies to answer research questions, with appropriate balancing of competing considerations involved in decisions about study design; participant sampling and recruitment; and approaches to data collection.
- Perform and interpret statistical analyses based on a foundation of statistical literacy, with graduates able to perform basic analyses on their own and prepared to collaborate with statisticians for more complex analyses.
- Conduct research in a responsible and ethical manner.
- Communicate scientific concepts orally and in writing, including through grant applications, protocols, manuscripts, abstracts, and presentations.
- Collaborate productively in the context of multidisciplinary scientific teams comprised of basic, clinical, and population scientists.

The course sequence and course descriptions are provided below.

In addition to formal coursework, all students pursuing a Masters degree in CPTS will be required to design a thesis of publishable quality that is closely aligned with the student's interests and career objectives. The thesis provides a capstone experience in which students apply the knowledge and skills obtained during their formal coursework. Further information about thesis requirements is provided in multiple following sections, beginning here.

Students pursuing an MD degree at the Wake Forest University School of Medicine can incorporate the CPTS MS into their medical training, typically between the second and third years of medical school.

A certificate in Clinical and Translational Sciences is available to doctoral students, post-doctoral trainees, and faculty at Wake Forest University or affiliated institutions. The certificate will be awarded after completion of an approved course of study, developed as described below.

ADMISSION STANDARDS AND PROCEDURES

The CPTS Program is open to individuals who already hold or are pursing advanced degrees, such as the MD, DVM, ScD, PhD, DDS, DSN, MMS (Physician Assistants), or MSN who are seeking training in the clinical and population aspects of translational research. The program also may be appropriate for qualified applicants with at least a BA or BS in a social science, public health, or other health-related field, although additional post-baccalaureate course work may be required. For applicants without an advanced degree, previous experience in a health-related field is highly desirable. All applicants must provide GRE, MCAT, or USMLE scores, to be forwarded by the testing institution directly to the Dean of the Graduate School. Applicants already affiliated with Wake Forest University as faculty, staff, or students should include a letter of recommendation from the Chair of the applicants' major department.

In addition to the aforementioned standards that pertain only to the CPTS Graduate Program, all prospective students should consult the Graduate School Bulletin of Wake Forest University for official policies and procedures applicable to all graduate programs.

The application deadline is January 15th, although late applications may be accepted with the permission of the program co-directors. In addition to the required written materials, applicants typically are interviewed by phone. Upon admission, all students must matriculate at the beginning of the subsequent fall semester. Applications must be filed electronically through the Graduate School's web site.

FINANCIAL CONSIDERATIONS

The Graduate School sets tuition and fees, and provides information regarding financial aid. The CPTS has a limited number of tuition scholarships available, and cover a portion of the tuition costs for students in formal training programs. An application to the program also serves as an application for a tuition scholarship, and students will be notified about the scholarship at the same time they receive their admission decision. Full-time students have preference for tuition scholarships, although part-time students are eligible and can request a scholarship.

All students are responsible for covering their living expenses through employment, formal training programs, financial aid, or other means.

All entering full-time CPTS graduate students receive a laptop computer with wireless capacity and standard software. The computer also will include SAS statistical software with a license active through the first semester. Students are responsible for renewing their SAS license thereafter. Students involved in formal training programs typically can have their program pay for this license. Students who are not in a formal training program should contact the CPTS program coordinator to discuss options for renewing the license. Part-time students will need to make their own arrangements for a computer and necessary software; a laptop is preferred given the need to access the internet and complete statistical analyses and other activities during class sessions.

All students are required to have health insurance. A common health insurance plan and support toward its premium will be provided by the Graduate School for students who do not have access to insurance. Students also must undergo a physical examination at Employee Health and submit required documentation.

INTERNATIONAL STUDENTS

International applicants and students are welcome to the CPTS program. Students are responsible for obtaining the necessary visas and following all other regulations and policies. Students also must demonstrate that they have sufficient funds to support themselves while in the United States. Assistance with visa issues can be obtained from Ms. Susan Pierce (spierce@wfubmc.edu). The WFU Center for International Studies provides information about regulations, housing, and local services.

PROGRAM REQUIREMENTS AND RELATED INFORMATION

All prospective students should consult the Bulletin of the Wake Forest University Graduate School for official policies and procedures of the graduate program. The following description of degree requirements pertains to special standards of the CPTS Graduate Program.

MS PROGRAM

For students pursing the MS, alone or in combination with another degree, a minimum of one year of full-time work or its equivalent in residence is required for the master's degree. Normally the program will require two years of full-time work or its equivalent. The degree must be completed within six years of beginning the program. Part-time status is available on a limited basis with the approval of the program directors.

A student's course of study is designed in consultation with the program directors and thesis advisor, based on the student's training, experience, and long-term career goals. The course of study must include a minimum of 30 semester hours of graduate credit, although additional coursework may be required. The minimum requirement can include no more than six hours of research credits.

JOINT MD/MS DEGREE PROGRAM

Students pursuing an MD degree at the Wake Forest University School of Medicine can incorporate the CPTS MS into their medical training. Students typically finish the first two years of medical school and then matriculate in the MS degree program, after which they return to conclude their final two years of medical school.

CERTIFICATE PROGRAM

The certificate program requires completion of a minimum of 12 hours of course work in clinical and translational sciences. Courses typically are selected from the CPTS course sequence described below. The program of course work is designed by the certificate student in collaboration with the program directors and one to three other faculty advisors with expertise relevant to the student's interests.

FACULTY ADVISING

Prior to matriculating in the program, both masters and certificate students will work with one of the program directors to identify a faculty advisor. The designated program director and faculty advisor will then guide students' enrollment in coursework. In addition, the program director and faculty advisor also will assist students in forming a thesis committee. After coursework is completed, it is expected that the students will be mentored by their faculty advisor and thesis committee members.

COURSEWORK

The program is designed for full-time students, although students may receive approval from the program co-directors to pursue their degree on a part-time basis. Full-time students complete their course work in three semesters in the first year, with the second year devoted to completing the thesis. Courses typically are held on Tuesdays and Thursdays. All courses meet on the Bowman Grey campus, typically at the Medical Center or Piedmont Plaza. The typical course sequence for the first year of the CPTS program appears below. Course registration is handled by the Graduate School.

Table 1: CPTS Coursework

Fall (13 hours total)	Spring (12 hours total)	Summer (6 hours total)
Foundations of CPTS (CPTS 701, 3 hours)	Clinical Trial Methods (CPTS 742, 3 hours)	Research Grant Preparation (CPTS 741, 3 hours)
Epidemiology (CPTS 720, 3 hours)	Measurement Methods in CPTS (CPTS 744, 1 hour)	Team Science Practicum (CPTS 705, 3 hours)
Introduction to Statistics (CPTS 730, 4 hours)	Applied Linear Models (CPTS 732, 4 hours)	
Social and Behavioral Theories in CPTS (CPTS 748, 2 hours)	Health Services Research Methods (CPTS 708, 3 hours) *OR* Community Research Methods (CPTS 746, 3 hours)	
Ethics and Reponsibility in CPTS I (CPTS 703, 1 hour)	Ethics and Reponsibility in CPTS II (CPTS 704, 1 hour)	

Students who wish to pursue individualized study in area of particular interest to them may arrange with a CPTS faculty member to do so for credit through an elective course.

Students with a strong interest in genetics, usually those in a training program with a genetic focus, may petition the program directors to modify their course requirements to accommodate their interest. Typically Molecular Biology (Biochemistry 73, 3 hours) replaces Social and Behavioral Theories in CPTS in the fall and Genetic Epidemiology (CPTS 726, 3 hours) replaces the Health Services or Community Research Methods course.

A student may petition the program directors and course instructor for exemption from a required course. The student must provide syllabus or description of the course along with a copy of a transcript indicating that the student has successfully completed a similar course. Alternatively, the student may be allowed to prove competency in the subject matter through examination by the course instructor. All requests will be reviewed on a case-by-case basis.

In addition to the required coursework, students are encouraged to attend and participate in seminars, journal clubs, and similar events sponsored by the Division of Public Health Sciences, Translational Science Institute, and their home department. Such attendance typically does not receive academic credit, although attendance could be incorporated into a for-credit course of individual study arranged by the student with a CPTS faculty member.

PROGRESS IN COURSEWORK AND ADMISSION TO DEGREE CANDIDACY

Satisfactory progress in course work requires that students maintain a “B” average or higher, equal to a 3.0 on a 4.0 scale. Students' performance will be reviewed each semester by the program directors in order to ensure adequate progress in the degree program. Students experiencing difficulty in any aspect of the program, including failure to maintain a "B" average or inadequate progress on the thesis, may be required to devise a written plan with their advisor and the program directors. This written plan would outline the steps to be taken in a given time frame to restore the student’s good standing in the short-term and ultimately to meet all program requirements. Students whose average does not meet these standards will not be permitted to advance to thesis work nor will a certificate be awarded.

After completing their coursework, and prior to beginning their thesis, students pursuing the masters degree must be admitted to degree candidacy by the Dean of the Graduate School. The application for candidacy is submitted by the program directors on a standard form. Upon completion of coursework and admission to degree candidacy, students must be continuously enrolled until they graduate. Enrollment is achieved by registering for courses, research hours, or as “Thesis Only” or “Graduate Fee.”

THESIS COMMITTEE FORMATION AND FUNCTION

After being admitted to degree candidacy, a thesis committee should be formed to advise each masters student on their thesis. The faculty advisor and one of the program directors will assist the student in identifying committee members and obtaining their commitment to serve. The thesis committee is made up of the faculty advisor, who will serve as the thesis committee chair, a statistician, and one to two other faculty members, ideally including at least one clinician. Students must notify the program directors of their committee membership by completing and returning the Approval of Thesis Committee for CPTS Program form.

In addition to meeting to approve the thesis proposal and again for the thesis defense, the student should meet regularly with the faculty advisor and other committee members as needed to ensure the progress of the student during the course of the thesis work. The student, faculty advisor, or any committee member can initiate a request for a meeting. If the student, faculty advisor, or any committee member has concerns about the function of the committee, they should contact one of the program directors.

SELECTION OF THESIS TOPIC

An important goal of the CPTS Master's Program is that thesis research serves directly to advance the scientific and professional careers of the students. Students should therefore choose a topic that will further their career objectives and be publishable in their major field of interest. The thesis topic may require primary data collection or rely on second data analysis from an ongoing or completed study or another source of existing data. Students should work closely with their faculty advisors to select thesis topics.

APPROACH TO AND FUNDING FOR THE THESIS

The thesis represents the culmination of the students' graduate training and thus students are expected to complete their theses independently, albeit with the advice and support of their thesis committee. Students are responsible for all written drafts and revisions, and should complete as much of the statistical analysis as possible.

Thesis preparation costs generally are born by the student and their department, training program, and thesis committee members' intramural or extramural research support. Extremely limited funds to assist with thesis preparation costs are available through the CPTS program; contact one of the program directors for more information.

THESIS PROPOSAL AND APPROVAL

Each student must prepare a thesis proposal and have it approved by their thesis committee. The thesis proposal consists of three elements:

1. A literature review demonstrating the student has sufficient background knowledge to pursue the proposed work and can use this knowledge to craft a rationale for the proposed specific aims. The literature review also will form the basis for the first chapter of the written thesis.

2. A statement of specific aims for the proposed work, in which the aims address one or more important scientific questions and are feasible within the scope of a masters thesis.

3. A set of skeleton ("mock") tables and/or figures that will serve as the basis for the presentation of results.

There are no page requirements or limitations for the thesis proposal. A typical proposal might include 10 to 15 double-spaced pages of literature review plus approximately 5 to 10 pages of skeleton tables.

The thesis committee must convene and formally approve the student's thesis. After reviewing and discussing the thesis proposal, the student and thesis committee should complete the Approval of Thesis Proposal form. This form and a copy of the thesis proposal should be forwarded to the program coordinator.

THESIS COMPONENTS

Students are encouraged to approach thesis preparation as an expanded manuscript preparation process, which facilitates submission of their work for publication. This preferred approach requires a three chapter thesis. The first chapter includes a detailed literature review that builds on the literature review presented as part of the thesis proposal. The second chapter takes the form of a journal article to be submitted upon completion of the thesis defense. The third chapter contains ancillary analyses and an expanded discussion that often includes suggestions about future research to address remaining questions.

Students have the option to complete a traditional thesis. This would include four chapters: Introduction, Methods, Results, and Discussion. While the Introduction would be comparable to the first chapter of the preferred approach, the other chapters would be expanded versions of chapters two and three of the preferred approach. Submitting a manuscript from a traditional thesis typically requires substantial additional revisions after completion of the thesis; therefore, this approach is not encouraged.

Either form of thesis should open with a title page, acknowledgements, and table of contents. In addition, the final section should include appendices and the student's curriculum vita. Appendices would include any material relevant to the thesis, such as questionnaires or a data dictionary.

THESIS FORMAT

The most important principles of thesis formatting are that the document be neat, error free, and consistently and clearly organized. Students should refer to the guidelines published by the WFU Graduate School regarding the required format and style of the thesis document, as well as requirements for review of the thesis format by the Graduate School. In the guidelines documents, students should take particular note of instructions regarding the physical appearance of the thesis document, presentation of illustrations, and contents of the opening (prefatory) pages. Students approaching the thesis as an expanded manuscript should include the chapters mentioned above rather than the traditional chapter mentioned in the Graduate School guidelines. For the expanded manuscript form of a thesis, each chapter should include a bibliography at the conclusion of the chapter rather than a cumulative bibliography.

FINAL EXAMINATION AND EXAMINATION COMMITTEE

The final examination for the master's degree is an oral defense of the student's thesis project. The 90 minute examination will cover the student's knowledge about the thesis and related areas. The defense generally opens with an approximately 30 minute presentation of the thesis work by the student, followed by a question and answer period. While most students defend successfully the first time, students may be re-examined one time. Scheduling of the examination is handled by the CPTS program coordinator.

The Examination Committee consists of at least three members of the WFU Graduate Faculty, who will be appointed by the Dean of the Graduate School upon recommendation by the Co-Directors of the CPTS Program. The Examination Committee typically includes all of the members of the Thesis Committee plus an Examining Committee Chair. The Chair is a graduate faculty member not affiliated with the student's master's thesis project, but who has content expertise in the topic area. This person is selected by the Dean of the Graduate School with input from the CPTS Co-Directors. The Examining Committee Chair polls the committee members 10 days before the examination to determine the acceptability of the thesis for defense and runs the oral examination.

THESIS TIMELINE

Thesis timelines vary widely based on students' other commitments and thesis proposal. Deadlines established by the Graduate School also shift from semester to semester. Students are thus encouraged to consult regularly with their faculty advisor and the program co-directors to ensure they are on schedule to graduate. The following table outlines key steps and recommended dates linked to the three available graduate dates. The recommended dates should be regarded as minimums; students should allow additional time if possible.

Table 2: CPTS Thesis Timeline

	Desired Graduation Date*		
Step	May	August	December
Identify faculty advisor	Prior to matriculation		
Admission to degree candidacy	Upon completion of coursework		
Form thesis committee	Within one month of admission to degree candidacy, preferably sooner		
Obtain approval of thesis proposal**	Mid-October	Mid-March	Mid-June
Submit complete draft of thesis to thesis committee	Early February	Early May	Early September
Submit Intent to Graduate Form to Graduate School	Early February	Early June	Early September
With support of faculty advisor and thesis committee, request formation of an Examination Committee and scheduling of the oral defense	Early March	Early June	Early October
Submit revised, final draft of thesis to Examination Committee and the Dean of the Graduate School	Early April	Early July	Early November
Defend thesis at final (oral) examination	Early May	Early August	Early December
Submit final thesis and any other required paperwork per requirements of the Graduate School (they provide a checklist when reviewing the draft thesis)	Early May	Early August	Early December

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*The Graduate School Academic Calendar includes specific dates and should be consulted by students planning to graduate in the current academic year.

**Students who elect to undertake primary data collection may need to seek approval of their planned study in advance of this date, as data collection likely will lengthen the time needed to complete the thesis. Students using data from existing studies also may need to request approval of their analytic idea through committees overseeing publications and presentations (aka, P&P committees).

THESIS COMPLETION POLICY

For the CPTS program, the thesis represents a capstone experience in which students demonstrate the competencies they have acquired during their coursework. The opportunity to prepare and hopefully publish a first authored manuscript for their thesis also provides students an entrée to their independent research career.

To maximize students' success with their thesis and retention of competencies requires steady progress toward thesis completion, as newly-acquired knowledge and skills may diminish as thesis completion is delayed. More importantly, delays prevent students from moving on to more independent work and may limit their ability to compete for extramural career awards and research funding. Finally, providing thesis mentoring represents a substantial and often uncompensated commitment for our faculty; thesis delays can make these commitments unduly burdensome.

Bearing in mind these important considerations, the CPTS program requires that:

1. Students who have completed their coursework must demonstrate progress on their thesis each semester. Progress will be assessed for all thesis only students at the end of each fall, spring, and summer term, via a brief on-line survey of each student and, if selected, their thesis mentor. The CPTS Program Co-Directors will review the results and provide each student and their mentor with confirmation of acceptable progress or notification of concerns. Students with concerns raised in two consecutive semesters will be asked to provide a mentor-endorsed plan for completing their thesis within one year. This policy applies to all students in any status in the CPTS and predecessor programs housed within the Division of Public Health Sciences.

2. Students must complete their thesis within two years of finishing their coursework, with an option to request no more than two one-year extensions from the CPTS Program Co-Directors (see form below). Thus the absolute maximum time allowed to thesis completion will be four years after coursework is completed, an exception to the Graduate School's overall policy of six years. Acceptable reasons for an extension will vary and may include delays in acquiring desired data or departure of a thesis mentor from the faculty. Moving on to another training program or a new position generally will not be considered an acceptable reason for an extension to be granted. Extensions must be requested before the end of the semester in which the student otherwise would be required to complete their thesis. This policy applies to all students who matriculated in the CPTS Program as of the fall semester in 2009 (not to students in predecessor programs housed within the Division of Public Health Sciences).

GRADUATE SCHOOL OPPORTUNITIES

The Graduate School supports a number of events and provides opportunities for professional development. This includes a Graduate Student Association and a research day at which students compete for prizes, as well as travel awards to support presentation of results at professional meetings. Students are encouraged to make full use of these resources.

ETHICAL CODE OF CONDUCT

All students are required to adhere to the highest ethical standards in completing their coursework and thesis. Student misconduct will not be tolerated, and may lead to the expulsion of the student from the CPTS Program. Misconduct includes but is not limited to: cheating on exams or other course work; stealing school and/or other students' property; vandalism; plagiarism and/or failure to cite/credit other professionals for their published work; falsifying data; computer misuse as specified by WFU; or failure to report an honor code violation by another student to the WFU Graduate School or CPTS Program Director(s). Suspected ethical misconduct will be referred to the CPTS Program Director(s) for investigation.

COURSE DESCRIPTIONS

The typical schedule and sequence of courses is shown above. Students not enrolled in the CPTS masters or certificate program, or who do not meet stated prerequisites, may enroll in these courses only with the permission of the instructor.

Other graduate level courses may be taken as electives. Students should consult their faculty advisor and the program co-directors before registering for such an elective.

CPTS 701, Foundations of Clinical and Translational Science, 3 hours: This course will provide students with a foundation in clinical and translational sciences, including an introduction to the research methods used in genomics, gene expression studies, proteomics, metabolomics, animal models of human diseases, clinical research, epidemiology, health services research, and community research. Students will develop skills needed to conduct clinical and translational research, collaborate in teams comprised of basic, clinical and population scientists, and translate research findings into clinical and population application. [NOTE: This course is shared with Molecular Medicine Translational Science Students.]

CPTS 703 and 704, Ethics and Responsibility in CPTS I and II, 1 hour each: This two course sequence covers professional ethics and responsibility for students in the CPTS program. The courses pursue three main objectives: (1) to introduce students to the culture, people and norms of biomedical research in the United States, (2) to identify points of ethical and/or professional conflict and tension in the research world, i.e. moments where incorrect decisions are at risk of being made, (3) to help students

develop ethical reasoning skills and a strategy for making appropriate, responsible decisions that are consistent with a high commitment to professionalism and social responsibility. Students will also be required to complete the Collaborative Institutional Training Initiative (CITI) Human Research On-Line Curriculum as part of this course.

CTPS 705, Team Science Practicum in Clinical and Translational Science, 3 hours: This elective course will provide students with practical, hands on experience working on a collaborative multidisciplinary translational study. Students will work with a multi-disciplinary investigative team on an ongoing projects in the Translational Science Institute (through the Participant and Clinical Interactions Resource, the Primate Center, etc.). Students will become familiar with the study protocol and procedures, including mechanisms for protection of animals or human subjects. They will participate in study conduct, review and interpretation of study data and prepare a written report and oral presentation describing the practicum experience. Students will develop skills in the conduct of team science. Students who have not identified a research team by the end of the first spring semester will be strongly encouraged to enroll in this course.

CPTS 708, Health Services Research Methods, 3 hours: This course introduces students to the basic financing, organization and delivery of health care services, and explores the relationships between patients, providers and the health care system. The course then focuses on the methods of health services research, including observational and experimental research designs, economic evaluation, technology assessment, comparative effectiveness, evidence-based medicine and quality improvement. Consideration is given to the appropriate use of and techniques for primary data collection and secondary data analysis, approaches to establishing research collaborations in health care settings, and ethical issues unique to health services research. Specific emphasis is placed on the translation on innovations into health care practice and policy, and the role of health services research in this process.

CPTS 720, Epidemiology, 3 hours: The course will provide students with a foundation in the history, concepts, and methods of epidemiology. Topics include measurement of exposure and disease, prevalence, incidence, association, and sensitivity/specificity analyses. Measurement error, bias, confounding, effect modification, causality and policy implications are discussed. The following observational study designs are reviewed: cross-sectional, case-comparison, cohort, ecological and meta-analysis.

CPTS 726, Genetic Epidemiology, 2 hours: The course will present fundamental concepts and methods in genetic epidemiology. It will introduce various genetic epidemiology study designs in related and unrelated individuals and cover basic analysis, inferences, plus their strengths and limitations. Prerequisites = CPTS 720, Epidemiology; CPTS 730, Introduction to Statistics; and BICM 731, Molecular Biology.

CPTS 730, Introduction to Statistics, 4 hours: The course is an introduction to statistical concepts and basic methodologies that are prevalent in biomedical literature. It includes discussion of such topics as descriptive statistics, probability, sampling distributions, hypothesis testing, simple linear regression, correlation, one-way analysis of variance,

categorical data analysis, survival analysis, sample size and power analysis, and nonparametric methods.

CPTS 732, Applied Linear Models, 4 hours: The topics of the course include statistical concepts and basic methodologies related to the general linear model and its extensions. The basic statistical procedures discussed in the course include simple and multiple linear regression, analysis of variance and covariance, logistic regression, and repeated measures analysis. Emphasis is given to proper application and interpretation of statistical methods and results. Prerequisite = CPTS 730, Introduction to Statistics.

CTPS 741, Research Grant Preparation, 3 hours: This course is designed to provide students with the knowledge and skills to develop grant proposals to pursue funding in their areas of interest. Topics covered include: the role of external funding in biomedical research; how to identify public and private sources of funding; required components in any type of grant submission; and human subjects and budgeting considerations. During the course, students develop a research proposal for peer review and critical discussion.

CPTS 742, Clinical Trial Methods, 3 hours: This course will provide students with detailed knowledge of clinical trials methodology from Phase I through Phase IV Trials and beyond. Topics to be covered include: why trials are needed; specification of the trial question(s); basic trial designs; identification of the appropriate study population, interventions, and response variables (including morbidity, mortality and patient-oriented outcomes); the randomization process; masking; sample size issues; issues in data analysis; recruitment/retention/adherence issues; trial monitoring and interim analyses, assessing/reporting adverse effects; interpreting trial results; meta-analyses; and post-marketing surveillance.

CPTS 744, Measurement Methods in Clinical and Population Science, 1 hour: Students will learn how to develop data collection forms, including surveys and medical record review forms, with particular attention to developing forms that are both user-friendly and reduce measurement error. Students will be introduced to the basic concepts of item development and manuals of procedure. Applications of course concepts will occur in the Clinical Trial Methods, Health Services Research Methods, and Community Research Methods courses.

CPTS 746, Community Research Methods, 3 hours: This course introduces students to the theories, principles, and methods of community research including community-based research and community-based participatory research (CBPR). It also explores the ecological relationships among individuals, environments, and social systems. Topics covered include, but are not limited to, partnerships, community experimental research designs, quantitative and qualitative research, community-based program evaluation, and ethical issues particularly relevant to community research. This course focuses on the translation of knowledge into effective community application within and in partnership with communities.

CPTS 748, Social and Behavioral Theories in Clinical and Population Translational Science, 2 hours: Successful translation of research into practice requires an understanding of how change occurs at the individual, social network, health systems, and community levels. This course will cover behavioral, social, and organizational theories that are useful in developing interventions and for the translation of research findings into clinical and community settings. Examples of theoretical frameworks to be included are: the Biopsychosocial Model, Social-Ecological Theory, Social Capital, Diffusion Theory, the Transtheoretical Model of Change, the PRECEDE-PROCEED, and the Theory of Reasoned Action.

CPTS 750, Thesis Research, 1 to 6 hours: Research directed towards the thesis. May be repeated for credit.

CPTS 766, Individual Study in Clinical and Population Translational Science, 1 to 4 hours: This offering will provide students with opportunities to pursue advanced topics in their individualized areas of interest with guidance from expert faculty. Potential examples of content areas include, but are not limited to, bioethics, cancer, cardiovascular disease, infectious disease, group randomized trials, qualitative methods, psychometrics, economic analysis, nutritional epidemiology and nutrigenomics, pharmacoepidemiology and pharmacogenomics. Individual studies may also be arranged to provide bench, community or health services research "lab" time for a student interested in translation of knowledge between settings (lab, clinic, healthcare delivery system and community). May be repeated for credit. Permission of instructor required for all students.

PROGRAM LEADERSHIP AND FACULTY

Faculty from Public Health Sciences teach most of the courses in the CPTS program and also serve on thesis committees. Other Graduate School Faculty may serve as instructors or thesis committee members after consultation with the CPTS program co-directors. Faculty who are not currently appointed to the Graduate School will need to work with the CPTS program co-directors to arrange a permanent or temporary appointment before serving on a thesis committee.

Program Co-Directors

GEIGER, ANN M., Public Health Sciences/Social Sciences and Health Policy (AB, Harvard-Radcliffe College; MPH, University of Michigan School of Public Health; PhD, University of Michigan Rackham Graduate School).

GOFF, DAVID C., Public Health Sciences/Epidemiology & Prevention (BS, Duke University; MD, University of North Carolina Medical School; PhD, University of Texas-Houston School of Public Health).

Program Coordinator

BEANE, JOAN, Public Health Sciences/Social Sciences and Health Policy

Executive Committee

ARCURY, THOMAS, Family & Community Medicine (BA, Duquesne University; MA, University of Kentucky; PhD, University of Kentucky).

BISCHOFF, WERNER, Infectious Diseases (MA, MD, Medical School Georg-August-University; MS, Wake Forest University School of Medicine; PhD, University of North Carolina at Chapel Hill).

BYINGTON, ROBERT, Public Health Sciences/Epidemiology and Prevention (BS, Loyola College; MPH, University of Texas School of Public Health; PhD, University of Texas School of Public Health).

DANIEL, KURT , Fourth Year Fellow, Masters of Epidemiology/General Cardiology (BS, Trinity University; DO, Oklahoma State University College of Osteopathic Medicine; MS, Wake Forest University School of Medicine).

IP, EDWARD, Public Health Sciences/Biostatistical Sciences (MA, Stanford University; PhD, Stanford University).

KEMPER, KATHI, Pediatrics (BA, University of Chicago; MD, University of North Carolina at Chapel Hill; MPH, University of North Carolina at Chapel Hill).

NICKLAS, BARB, Internal Medicine/Gerontology and Geriatric Medicine (BSE, N.E. Missouri State University; MS, Iowa State University; PhD, University of Maryland).

RHODES, SCOTT, Public Health Sciences/Social Sciences and Health Policy (BA, College of William & Mary; MPH, University of South Carolina School of Public Health; PhD, University of Alabama School of Public Health).

TOOZE, JANET, Public Health Sciences/Biostatistical Sciences (BA, Earlham College; PhD, University of Colorado Health Sciences Center; MPH, Harvard University).

VITOLINS, MARA, Public Health Sciences/Epidemiology and Prevention (BA, Albertson College of Idaho; MPH, Loma Linda University; DrPH, Loma Linda University).

APPROVAL OF THESIS COMMITTEE FOR CPTS PROGRAM (Form)

The thesis committee for _____ will include:

Committee Chair:

_____ _____ _____
Printed Name Signature Date

Statistician (or individual with requisite quantitative skills):

_____ _____ _____
Printed Name Signature Date

Content Experts (1-3 persons):

_____ _____ _____
Printed Name Signature Date

_____ _____ _____
Printed Name Signature Date

_____ _____ _____
Printed Name Signature Date

Student's Signature:

_____ _____ _____
Printed Name Signature Date

Approved by:

_____ _____ _____
Program Director Signature Date

(Notification of Committee Chair sent to Susan Pierce: Date_____)

Submit this form to Joan Beane, SSHP, 2nd Floor, Piedmont Plaza II, Room 214, 716-9513, jbeane@wfubmc.edu

APPROVAL OF THESIS PROPOSAL FOR CPTS PROGRAM (Form)

The thesis proposal of _____ has been reviewed by his/her thesis committee. The consensus of the committee is: (check one)

_____ Proposal is accepted as written as of our meeting on _____
(Date)

_____ Proposal is accepted with the condition that the attached revisions are completed and approved by the committee chair by _____
(Date)

_____ Proposal is rejected and must be resubmitted

Thesis Committee Chair's Signature:

_____ _____
Printed Name Signature

Committee Members' Signatures:

_____ _____
Printed Name Signature

_____ _____
Printed Name Signature

_____ _____
Printed Name Signature

_____ _____
Printed Name Signature

Student's Signature:

_____ _____
Printed Name Signature

****** Student or Thesis Advisor: Please attach a copy of the final thesis proposal. ******

Please submit this form and the thesis proposal to Ms. Joan Beane, SSHP, 2nd Floor, Piedmont Plaza II, 716-9513, jbeane@wfubmc.edu

REQUEST FOR EXTENSION TO COMPLETE THESIS FOR CPTS PROGRAM (Form)

Student

I have been unable to complete my thesis within two years of completing my coursework and am thus requesting my (check one) ☐ first or ☐ last (second) extension. I understand that this extension grants me one additional year from the date of my request in which to complete my thesis. I also understand that a student can be granted a maximum of two extensions of one year duration each, after which the student will not be permitted to defend their thesis and graduate, and will be formally withdrawn from the program by the Graduate School of Arts and Sciences.

I have attached a one paragraph statement describing the circumstances that have prevented me from completing my thesis within two years and a timeline showing how I plan to complete my thesis in the coming year

_____ _____ _____
Student Printed Name Signature Date

Thesis Mentor

I have reviewed and agree with this request for an extension, including the attached statement and timeline. I am prepared to continue mentoring this student for an additional year.

_____ _____ _____
Mentor Printed Name Signature Date

Program Director

This request is:

☐ Approved without comment
☐ Approved with comment, please see attached.
☐ Disapproved with comment, please see attached.

_____ _____ _____
Program Director Printed Name Signature Date

Submit this form and the required attachments to Joan Beane, SSHP, 2nd Floor, Piedmont Plaza II, Room 214, 716-9513, jbeane@wfubmc.edu