Trainee Handbook

Clinical and Translational Science Program
Medical College of Georgia

2008 Entering Class
May 2008

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Introduction

Hello and welcome to the Clinical and Translational Science (CTS) Program at the Medical College of Georgia (MCG). The faculty and staff of the CTS Program look forward to working with you as you undertake this exciting new phase of your research career.

The Department of Biostatistics at MCG offers programs leading to a Certificate in Clinical and Translational Science (CCTS) and a Masters of Clinical and Translational Science (MCTS). The primary objective of the CTS program is to enable health professionals to perform Clinical and Translational Research. The program is intended primarily for MCG faculty members, but clinical fellows and senior residents are also encouraged to apply. The Clinical and Translational Science curriculum includes didactic instruction in the core areas of biostatistics, epidemiology, and clinical research design; a mentored research project; and seminars on recent advances in clinical and translational science.

Upon completion of either the CCTS or MCTS programs, graduates will have developed the necessary skills for performing each of the following tasks:

- Effectively utilize human subjects in clinical trials,
- Perform basic analyses of clinical research data,
- Apply basic epidemiologic principles and tools in clinical research,
- Consider relevant ethical and legal issues when designing and conducting clinical research,
- Prepare research manuscripts for publication in research journals, and
- Prepare competitive grant proposals for extramural research funding.

This document describes the policies and guidelines specifically applicable to the Certificate and Masters programs in Clinical and Translational Science offered by the MCG Department of Biostatistics. Trainees should also refer to and follow the MCG Graduate Student Guide for Masters Degree Programs, which is a comprehensive reference on all policies and guidelines of the MCG School of Graduate Studies (SGS): http://www.mcg.edu/gradstudies/pdf/esmaster.pdf. Additional information is also available on the CTS Program website http://www.mcg.edu/research/biostat/CTS.html.

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Advisory Committee

Shortly after being admitted to the CTS program, the trainee will form an Advisory Committee consisting of at least 4 members, all but one of whom must be a member of the MCG Graduate Faculty. The trainee's primary research mentor (their Major Advisor) should be a member of the Graduate Faculty and will serve as chair of the Committee. The Committee must include at least one faculty member in the Department of Biostatistics, who will serve as the Biostatistics Mentor for the trainee. The composition of the Advisory Committee must be approved by the Director of the CTS Program. The Director will forward the list of committee members to the Dean of the School of Graduate Studies (SGS) for approval and formal appointment. Upon successful completion of the mentored research project, the trainee must present it to the Advisory Committee orally. This serves as the final examination and, for the oral defense of the research project to be successful, there may be no more than one member of the Committee who votes not to pass the trainee on the final exam. Please see the MCG Graduate Student Guide for Masters Degree Programs for various deadlines and further details http://www.mcg.edu/gradstudies/pdf/esmaster.pdf.

Plan of Study

Soon after entering the program, the CTS trainee should create a Plan of Study with the help of his/her Advisory Committee. The Plan of Study should include a list of all the courses he/she will be taking at MCG, including the required courses, electives, mentored research courses, seminar courses, and any other courses relevant to the trainee's degree program. The Plan of Study, and any subsequent changes in it, must be approved by the Director of the CTS Program. The Advisory Committee will evaluate the trainee's progress in the Plan of Study each semester until all courses listed in the plan are completed. Each semester, the trainee's Major Advisor should approve the courses to be taken during the next semester and give permission to register by signing in the appropriate place on the Plan of Study.

Curriculum for the Certificate in Clinical and Translational Science

To obtain the Certificate in Clinical and Translational Science, the trainee must complete 15 credit hours of didactic courses, 2 credit hours of clinical and translational science seminars, and 3 credit hours of mentored research. The CCTS can be completed in 1 year and courses taken while obtaining the certificate can be applied toward the Masters of Clinical and Translational Science for those who wish to continue. Upon successful completion of the required coursework and the mentored research project, the trainee will be awarded a Certificate in Clinical and Translational Science from the MCG School of Graduate Studies through the MCG Department of Biostatistics.

CCTS Curriculum (20 semester hours)

- Biomedical Statistics (3 hrs)
- Introduction to Epidemiology (3 hrs)
- Introduction to Clinical Trials (3 hrs)
- Design and Analysis of Observational Studies (3 hrs)
- Seminar in Clinical and Translational Science (2 hrs)
- Responsible Conduct of Research (1 hr)
- Scientific Communications (1 hr)
- Scientific Grant Writing (1 hr)
- Mentored Research in Clinical and Translational Science (3 hrs)

Curriculum for the Masters in Clinical and Translational Science

To obtain the Masters in Clinical and Translational Science, the trainee must complete the CCTS curriculum plus 1 additional required didactic course (3 credit hours), 2 additional credit hours of clinical and translational science seminars, 6 credit hours of elective courses, and 5 additional credit hours of mentored research. The MCTS can be completed in 2 years. Upon successful completion of the required coursework and their mentored research project, the trainee will be awarded a Masters of Clinical and Translational Science from the MCG School of Graduate Studies through the MCG Department of Biostatistics.

MCTS Curriculum (36 semester hours)

- Biomedical Statistics (3 hrs)
- Introduction to Epidemiology (3 hrs)
- Introduction to Clinical Trials (3 hrs)
- Design and Analysis of Observational Studies (3 hrs)
- Seminar in Clinical and Translational Science (4 hrs)
- Responsible Conduct of Research (1 hr)
- Scientific Communications (1 hr)
- Scientific Grant Writing (1 hr)
- Mentored Research in Clinical and Translational Science (8 hrs)
- Systematic Reviews (3 hrs)
- Electives (6 hrs)

Elective Courses for the Masters in Clinical and Translational Science

MCTS trainees must take a total of at least 6 credit hours of approved electives as part of their Plan of Study. Elective courses can be taken in any combination during the summer, fall and spring semesters, as long as the total credit hour requirement of 6

hours is satisfied. It is recommended that MCTS trainees take their electives in the 2nd year of the program and that they take no more than 8 credit hours of coursework in any semester.

Electives may be chosen from the following list, or other appropriate courses may also be selected. All electives to be included in the trainee's Plan of Study for the MCTS Program must be approved by the trainee's Advisory Committee and the Director of the CTS Program.

Biostatistics and Epidemiology
Categorical Data Analysis (3 hrs)
Epidemic Modeling (3 hrs)

Genomic Medicine
Fundamentals of Genomic Medicine (4 hrs)
Translational Genomics & Proteomics (3 hrs)
Functional Genomics & Proteomics using Animal Models (3 hrs)
Computational Methods in Genomics and Genetics (4 hrs)

Health Informatics
Public Health Informatics (3 hrs)
Healthcare Information Requirements and Standards (3 hrs)
Health Data Management & Knowledge Discovery (3 hrs)
Fundamentals of Health Promotion (3 hrs)
Introduction to Environmental Health (3 hrs)
Health Decision Support Systems (3 hrs)

Clinical Research
Qualitative Design and Analysis (3 hrs)
Critical Analysis of Health Behavior Theories for Research (3 hrs)
Theory and Research in Health Disparities (3 hrs)
Clinical Outcomes Research (3 hrs)

Recommended Course Sequence (Full-Time)

YEAR ONE

Summer Semester (6 hrs)

- STAT 7040 - Biomedical Statistics (3 hrs)
- STAT 8130 - Introduction to Epidemiology (3 hrs)

Fall Semester (8 hrs)

- STAT 8240 - Introduction to Clinical Trials (3 hrs)
- STAT 8390 - Seminar in Clinical and Translational Science (1 hr)

- STAT 8400 - Mentored Research in Clinical and Translational Science (1 hr)
- SGSS 8011 - Responsible Conduct of Research (1 hr)
- SGSS 8012 - Scientific Communications (1 hr)
- SGSS 8130 - Scientific Grant Writing (1 hr)

Spring Semester (6 hrs)

- STAT 8260 - Design and Analysis of Observational Studies (3 hrs)
- STAT 8390 - Seminar in Clinical and Translational Science (1 hr)
- STAT 8400 - Mentored Research in Clinical and Translational Science (2 hrs)

End of Year 1 - Following the successful oral defense of the mentored research project, the trainee is awarded the Certificate in Clinical and Translational Science.

YEAR TWO

Summer Semester (4 hrs)

- STAT 8360 - Systematic Reviews (3 hrs)
- STAT 8400 - Mentored Research in Clinical and Translational Science (1 hr)

Fall Semester (6 hrs)

- STAT 8390 - Seminar in Clinical and Translational Science (1 hr)
- STAT 8400 - Mentored Research in Clinical and Translational Science (2 hrs)
- Elective

Spring Semester (6 hrs)

- STAT 8390 - Seminar in Clinical and Translational Science (1 hr)
- STAT 8400 - Mentored Research in Clinical and Translational Science (2 hrs)
- Elective

End of Year 2 – Following the successful oral defense of the mentored research project, the trainee is awarded the Masters in Clinical and Translational Science.

Recommended Course Sequence (Part-Time)

A part-time option is available for both the CCTS and MCTS programs:

YEAR ONE

Summer Semester (3 hrs)

- STAT 8130 - Introduction to Epidemiology (3 hrs)

Fall Semester (3 hrs)

- SGSS 8011 - Responsible Conduct of Research (1 hr)
- SGSS 8130 - Scientific Grant Writing (1 hr)
- STAT 8390 - Seminar in Clinical and Translational Science (1 hr)

Spring Semester (1 hr)

- STAT 8390 - Seminar in Clinical and Translational Science (1 hr)

YEAR TWO

Summer Semester (3 hrs)

- STAT 7040 - Biomedical Statistics (3 hrs)

Fall Semester (5 hrs)

- STAT 8240 - Introduction to Clinical Trials (3 hrs)
- SGSS 8012 - Scientific Communications (1 hr)
- STAT 8400 - Mentored Research in Clinical and Translational Science (1 hr)

Spring Semester (5 hrs)

- STAT 8260 - Design and Analysis of Observational Studies (3 hrs)
- STAT 8400 - Mentored Research in Clinical and Translational Science (2 hrs)

End of the Certificate Program - Following the successful oral defense of the mentored research project, the trainee is awarded the Certificate in Clinical and Translational Science.

YEAR THREE

Summer Semester (3 hrs)

- STAT 8360 - Systematic Reviews (3 hrs)

Fall Semester (3 hrs)

- Elective

Spring Semester (3 hrs)

- Elective

YEAR FOUR

Summer Semester (1 hr)

- STAT 8400 - Mentored Research in Clinical and Translational Science (1 hr)

Fall Semester (3 hrs)

- STAT 8390 - Seminar in Clinical and Translational Science (1 hr)
- STAT 8400 - Mentored Research in Clinical and Translational Science (2 hrs)

Spring Semester (3 hrs)

- STAT 8390 - Seminar in Clinical and Translational Science (1 hr)
- STAT 8400 - Mentored Research in Clinical and Translational Science (2 hr)

End of the Masters Program - Following the successful oral defense of the mentored research project, the trainee is awarded the Masters in Clinical and Translational Science.

Clinical and Translational Science Seminars

All trainees are expected to attend all seminars that are offered through the CTS Program. These seminars are considered an essential part of the education of all CTS trainees. Although a trainee may not fully understand the content of every seminar, the cumulative effect of all such seminars is substantial and is an integral part of the preparation toward the future role as a clinical and translational researcher. The CTS Seminar Course Director always welcomes suggestions related to the seminar series (e.g., speakers, topics, etc.). CTS trainees are also encouraged to attend other seminars in related areas within the School of Graduate Studies, as well as seminars offered in the Schools of Allied Health, Dentistry, Medicine, and Nursing.

CTS Mentored Research Project

All CTS trainees should begin their mentored research no later than their first fall semester in the program. Trainees in the CCTS Program must register for a total of at least 3 credit hours of mentored research for the entire program, and trainees in the MCTS Program must register for a total of at least 8 credit hours of research. Registration for additional credit hours of mentored research may be required for successful completion of program requirements.

It is expected that the mentored research project that is a requirement of the CCTS program will culminate in a scientific paper that is suitable for submission to a scientific research journal. The mentored research project that is a requirement of the MCTS program is expected to culminate in a grant proposal that is suitable for submission to an extramural funding agency (NIH, RWJ, etc.). The Advisory Committee will make the

final determination as to whether the trainee's research project is sufficient to fulfill the requirements of the CCTS or MCTS program.

Transfer/Substitution/Waiver of Courses

A trainee must have a minimum of 20 graduate credit hours of coursework for the Certificate in CTS and 36 hours for the Masters degree. As a general rule, transferring/substituting courses from other institutions is strongly discouraged. Only graduate credits that have not been applied toward another degree are eligible for transfer. A trainee wanting to transfer or substitute courses from another institution must submit a request along with the transcripts to the CTS Program Director. The Director will evaluate the request and make the final decision regarding the transfer/substitution. Transfer/substitution of courses does not decrease the number of credit hours needed for graduation. These credit hours must be satisfied with elective courses approved by the Advisory Committee and the CTS Program Director.

A trainee entering the CTS program with substantial prior graduate-level coursework that is relevant to the CTS curriculum may waive up to 6 credit hours of coursework at the discretion of the CTS Program Director and the Advisory Committee.

A "Transfer/Substitution/Waiver of Course Form" must be completed and approved by the Director of the CTS Program, and forwarded to the School of Graduate Studies. As per SGS policy, a maximum total of 12 credit hours of graduate courses may be transferred/substituted/waived.

Grades, Academic Performance and Progress

Satisfactory progress toward a degree in the School of Graduate Studies requires that a trainee maintain a cumulative grade point average (GPA) of at least a 2.8 for all courses attempted. A **minimum** grade of C (or satisfactory in courses graded S and U) must be earned for each course applying toward the CTS certificate or degree, and a 2.8 cumulative GPA in all courses attempted toward the certificate or degree is required for graduation.

Academic Probation and Dismissal

Any trainee whose cumulative GPA for a degree program drops below a 2.8 is placed on academic probation. Such status is noted on the trainee's academic record (transcript). While on probation, the trainee **must** earn a minimum of a 3.0 each semester until the cumulative GPA is raised to at least a 2.8.

Trainees who fail to earn at least a 3.0 each semester while on probation shall be considered for academic dismissal from the School of Graduate Studies. Where circumstances warrant, upon recommendation of the CTS Program Committee, and approval of the Dean of the School of Graduate Studies, a trainee being considered for

dismissal under the provisions of this policy may be permitted to continue as a student on probation. In such cases, the trainee must earn at least a 3.0 each semester while on probation until a 2.8 cumulative GPA is achieved. Failure to do so will result in automatic dismissal from the degree program. The second dismissal will be final.

A trainee may be considered for dismissal if he/she fails to make timely progress toward the degree sought, or may be subject to additional required coursework. Any trainee dismissed from the CTS Program may appeal the action in accordance with School of Graduate Studies procedures.

Financial Support

The cost of either the CCTS or MCTS is anticipated to be completely covered under the MCG Tuition Assistance Program (TAP) for eligible full-time employees who have been with MCG for 6 months or longer. A TAP application form **must** be submitted by the appropriate deadline for each semester the trainee is enrolled in the program. A copy of this form is provided in this Handbook.

At the present time, there are no graduate assistantships or similar financial awards available to support graduate study in the CTS Program.

Academic Integrity and Judicial Procedures

The university recognizes honesty and integrity as being necessary to the academic function of the institution. Regulations promulgated in the interest of protecting the equity and validity of the university's grades and degrees and to help trainees develop standards and attitudes appropriate to academic life are contained in the MCG *Graduate Student Guide for Masters Degree Programs* http://www.mcg.edu/gradstudies/pdf/esmaster.pdf.

Understanding and adhering to the "Conduct of Research" policy as stated in the *Graduate Student Guide* are extremely important for all graduate students. CTS trainees are expected at all times to respond to assignments and research projects with original data, manuscripts and other work. Any deviation from this could result in a grade of F for the assignment and course and possible dismissal from the School of Graduate Studies.

Any possible violation by a trainee of the "Student Conduct Code," "Conduct of Research," or other institutional policies as stated in the *Graduate Student Guide,* must be reported to the Dean. The School of Graduate Studies follows all judicial procedures and proceedings as described in the *Graduate Student Guide* .

Leave of Absence

Registration in each semester indicates that a trainee is making progress toward his/her degree objective. Trainees who do not plan to enroll for an upcoming semester should request a leave of absence from the Associate Dean of the School of Graduate Studies, through the Director of the CTS Program. Failure to do so could result in being required to reapply for admission. A leave of absence does not modify a trainee's obligation to complete the Certificate Program within a three-year time limit, or the Masters degree within a five-year time limit. Any trainee granted a leave of absence by the School of Graduate Studies must withdraw from the Medical College of Georgia in accordance with the institutional Trainee Withdrawal Policy available at http://www.mcg.edu/students/Registrar/pdf/StudentWithdrawalPolicy.pdf.

Withdrawal from the School of Graduate Studies and University

A student who wishes to withdraw from his/her program should complete the procedures outlined on the Withdrawal Form available in the Registrar's office. Because of the federal aid policy and definitions, if a student who is registered for courses in a term and on the class roster as of the first day of class wishes to drop all courses that term, he/she must complete a Withdrawal Form. To re-enter the program, the student must complete a reactivation form, which may be obtained from the Registrar's office. If the student is not pre-registered for the term, it is not a withdrawal.

A student who does not enroll for three consecutive semesters is administratively withdrawn from the university by the Registrar. An individual who was withdrawn must receive approval from the Associate Dean to re-enroll in a graduate program. Re-enrollment is not automatic. The Associate Dean will review the student's academic performance and progress toward the degree and request recommendations from the student's Advisory Committee. Additional coursework and examinations may be required. If the student's time-to-degree limit has been exceeded, he/she may have to meet additional requirements recommended by the CTS Program Director and Major Advisor and approved by the Associate Dean or apply to the program as a new student and meet all program requirements.

HIPAA Requirements

All trainees having clinical access to patient information (verbal, printed, and/or electronic format) must be trained annually and tested to ensure compliance with the federal privacy law known as the Health Insurance Portability and Accountability Act (HIPAA).

HIPAA training is provided online through MCG. Each lesson will take approximately 15 minutes to complete. Since the Office of Institutional Audit and Compliance must audit

all HIPAA training records to ensure 100% compliance, trainees should complete these lessons within 30 days from when they become available.

For details about how to sign-on or information about who to contact for questions, visit the following website for HIPAA training information: http://www.mcg.edu/success/bannermatters/Tutorials/HIPAAtrainingInfo.pdf.

Checklist and Forms Required by the School of Graduate Studies

CHECKLIST FOR MASTER'S REQUIREMENTS

It is the responsibility of the trainee to keep this form up to date and to meet all requirements in a timely fashion.

DATE	PROCEDURE
_____	Program Entry Date (Semester, Year)
_____	Major Advisor Selected
_____	Advisory Committee Selected, Approved by Chair and Submitted to School of Graduate Studies
_____	Coursework Proposal Approved and Submitted to School of Graduate Studies
_____	Research Proposal Approved and Submitted to School of Graduate Studies
_____	Research Tool Requirement Fulfilled
_____	Comprehensive Examination Passed
_____	Admission to Candidacy
_____	Obtain Thesis/Dissertation Instruction Booklet from School of Graduate Studies
_____	Advisor Approved Draft of Thesis Submitted to Members of Advisory Committee (5 weeks before Final Oral Examination)
_____	Signed Thesis Approval Form Submitted to School of Graduate Studies (3 weeks before Final Oral Examination)
_____	Date of Final Oral Examination Scheduled with School of Graduate Studies and Advisory Committee
_____	Corrected Draft Copy of Thesis to School of Graduate Studies (2 weeks before Final Oral Examination)
_____	Faculty Agreement Form – Date and Time of Final Oral Examination Submitted to the School of Graduate Studies
_____	Final Oral Examination Announcement Mailed
_____	Final Oral Examination Passed
_____	Three Final Copies of Thesis/Project on Crane's Thesis Paper delivered to School of Graduate Studies (1 week prior to graduation)
_____	Completed Library Binding Form Submitted to School of Graduate Studies
_____	Application for Graduation Submitted to School of Graduate Studies

School of Graduate Studies Forms

All forms required by the School of Graduate Studies can be found in the MCG Graduate Student Guide for Masters Degree Programs (http://www.mcg.edu/gradstudies/pdf/esmaster.pdf).

Additional Forms Required by the CTS Program

Plan of Study
Transfer of Courses Approval Form
Tuition Assistance Program (TAP) Application

Department of Biostatistics, Medical College of Georgia
Clinical & Translational Science Plan of Study

Trainee Name: _____ **ID #:** _____ **Primary Mentor:** _____

Admission Date: _____ **Anticipated Graduation Date:** _____ **Biostatistics Mentor:** _____

Core Courses (24 Credit Hours)			**Summer 20__**		**Fall 20__**		**Spring 20__**		**Summer 20__**		**Fall 20__**		**Spring 20__**		**Acad. Advisor Initials and Date**
CRN	**Number**	**Name (Hours)**	**Reg.**	**Grade**	**Reg.**	**Grade**	**Reg.**	**Grade**	**Reg.**	**Grade**	**Reg.**	**Grade**	**Reg.**	**Grade**	
	STAT 7040*	Biomedical Statistics													
	STAT 8130*	Intro to Epidemiology													
	STAT 8240*	Intro to Clinical Trials													
	STAT 8260*	Design & Anal Observ													
	STAT 8360	Systematic Reviews													
	STAT 8390*	Seminar in CTS													
	STAT 8400*	Mentored Research													
	SGSS 8011*	Resp Con of Research													
	SGSS 8012*	Scientific Com.													
	SGSS 8130*	Sci. Grant Writing													
Elective Courses (Minimum 6 Credit Hours)															
	GNMD 8050	Com. Meth. Genomics													
	GNMD 8051	Trans. Gen. & Prot													
	GNMD 8052	Func. Gen. Pro. AM													
	IMPH 8001	Public Health Inform.													
	IMPH 8100	HC Info Req & Stand.													
	IMPH 8400	HD Mang. & Knowl.													
	IMPH 8600	Fund. Health Promo.													
	IMPH 8700	Intro to Enviro Health													
	IMPH 8800	Health Dec. Sup Sys													
	NURS 8650	Qual. Design & Anal													
	NURS 8860	Critical Anal HBT Res													
	NURS 8870	Theory & Res in H Dis													
	NURS 8880	Clinic. Out. Research													
	SGSS 8092	Fund. Gen. Medicine													
	STAT 8270	Categorical Data													
	STAT 8350	Epidemic Modeling													

Primary Mentor Signature: _____ **Date:** _____

Biostatistics Mentor Signature: _____ **Date:** _____ **Date Transcript Audited:** _____

Transferred Graduate Courses: Courses transferred must be approved by the Major Advisor and the Director of the CTS Program. Courses transferred do not reduce the number of credit hours a student must take for the CTS certificate or degree to be conferred and an approved replacement course must be taken. A maximum of 2 courses (6 credit hours) can be transferred. Transfer credits must be approved by the completion of the second semester at MCG.

MCG Course Number	MCG Course Description	Transferred Course Number	Transferred Course Description	Institution of Transferred Course	Signatures of Major Advisor & CTS Program Director	Date Approved

Additional Notes:

Any changes in the Plan of Study must be approved by the Major Advisor and the Director of the CTS Program.

University System of Georgia
Employee Application for Tuition Assistance Program (TAP)

Complete this application with all required approval signatures and submit by the required deadline to the TAP Coordinator at the Home Institution. This application is subject to final approval by the TAP Coordinator of the Teaching Institution.
Tuition Assistance waives tuition and applicable student fees for credit courses at a USG institution.

SECTION BELOW TO BE COMPLETED BY EMPLOYEE (PLEASE PRINT)

LAST NAME | FIRST NAME | STUDENT ID / SSN | PHONE

HOME INSTITUTION | JOB TITLE | EMAIL ADDRESS

TEACHING INSTITUTION | ACADEMIC TERM / YEAR

SECTION BELOW TO BE COMPLETED BY EMPLOYEE

Enrollment Status: Are you pursuing a degree? Yes **[ ]** No **[ ]**

If yes, please indicate your degree program (e.g., associate, bachelor, etc.) ***and*** area of discipline (e.g., math, psychology, etc.)

Additional Tuition Assistance: Are you eligible for a Hope Scholarship, Hope Grant, or Pell Grant? Yes **[ ]** No **[ ]**

List Requested Course(s): The number of semester credit hours (maximum of eight) must be consistent with one's institutional work commitment.

Course	Course Title (e.g., Elementary Statistics)	Course Name / # (e.g., Math 1104)	Credit Hours	Class Days & Times (e.g., T & Th 1:30 – 2:45 pm)
1				
2				
3				

Employee Certification: My signature below certifies that the information provided is accurate and truthful. I understand that I must register for courses only during the employee registration period of the Teaching Institution I wish to attend. I also understand that I must receive a grade of "C" or better and provide a copy of my grade report to the TAP Coordinator of the Home Institution upon completion of the course(s). Finally, I certify that I have read and agree to abide by the policies and procedures of the TAP Program.

EMPLOYEE SIGNATURE_____ **DATE** _____

IMMEDIATE SUPERVISOR'S APPROVAL

[ ] **I approve** this request and certify that the employee's participation will not adversely affect departmental services nor cause undo hardship for other employees. If I am allowing the employee to attend classes during the workday, attached is the alternate work arrangement.

[ ] **I cannot approve** or certify the employee's request to attend classes because

_____

_____

SUPERVISOR SIGNATURE _____ **DATE** _____

TAP COORDINATOR APPROVALS

HOME INSTITUTION TAP COORDINATOR APPROVAL: Yes [ ] No [ ] If no, reason _____

_____

SIGNATURE _____ **DATE** _____

(After approval by the Home Institution Tap Coordinator, this application must be forwarded to the Teaching Institution TAP Coordinator within 10 business days following the TAP application deadline).

TEACHING INSTITUTION TAP COORDINATOR APPROVAL: Yes [ ] No [ ] If no, reason _____

_____

SIGNATURE _____ **DATE** _____

Course Descriptions for CTS Program

Required Courses
(Note: All courses except STAT 8360 Systematic Reviews are required for the Certificate Program.)

STAT 7040 Biomedical Statistics (3 Credit Hours)

This course offers an introduction to the majority of statistical techniques used to analyze and interpret data in the biomedical sciences and related fields. Emphasis is on applications of these methods, with the following topics covered: graphical methods, probability, discrete and continuous distributions, inferential statistics (estimation and hypothesis testing for the one and two-sample case) for numeric and categorical data, non-parametric methods, one-way ANOVA, simple linear regression, correlation, factorial ANOVA (fixed and random effects), multiple linear regression and correlation, ANCOVA, logistic regression, longitudinal data analysis, and survival analysis.

STAT 8130 Introduction to Epidemiology (3 Credit Hours)

This course serves as an introduction to epidemiology. Topics include basic concepts, types of studies, description and analysis of epidemiologic data, and epidemiology in disease control.

STAT 8240 Introduction to Clinical Trials (3 Credit Hours)

This introductory course will address basic statistical techniques used in clinical trials. Material presented will include the principles underlying the planning, management and implementation of clinical trials, the application of basic statistical methods used in the analysis of data from clinical trials, and the interpretation of results.

STAT 8260 Design and Analysis of Observational Studies (3 Credit Hours)

Advantages and disadvantages of prospective and retrospective study designs; design and analysis issues in both cohort and case-control studies, including proper selection of study subjects, data quality, sources and types of bias, controlling for confounding, maximizing participation and minimizing loss to follow-up in prospective studies, power and sample size; statistical methods including chi-square, log-linear models, logistic regression, Cox regression; use of statistical packages such as SAS and StatXact for analysis. Review and discussion of current representative studies.

STAT 8360 Systematic Reviews (3 Credit Hours)

This course covers systematic reviews of the literature for controlled clinical trails and observational studies. Statistical methods and computer software are reviewed and how to use systematic reviews in practice is detailed. Topics to be covered are Introduction to systematic reviews and meta analysis, systematic reviews of controlled clinical trails, investigating variability between studies, systematic reviews of observational studies,

statistical methods and computer software, using systematic reviews in practice, the Cochrane collaboration, an other evidence-based medicine topics.

STAT 8390 Seminar in Clinical and Translational Science (1 Credit Hour)

This course consists of clinical and translational research seminars by MCG faculty members and visiting researchers. Students will have an opportunity to talk to each speaker informally and to serve as hosts to visiting scientists.

STAT 8400 Mentored Research in Clinical and Translational Science (1 - 12 Credit Hours)

The student works closely with his/her faculty mentors and Advisory Committee on an in-depth study of a research question of interest to both student and mentors. The course may be repeated as necessary until the student completes the research.

SGSS 8011 Responsible Conduct of Research (1 Credit Hour)

This course will provide an overview, via lecture and discussion, of critical issues related to the responsible conduct of research. In addition, it will fulfill the requirements established by the Office of Research Integrity and the Public Health Service for ensuring that PHS-supported researchers are provided adequate instruction in conducting responsible research and ensuring integrity of the research record.

SGSS 8012 Scientific Communication (1 Credit Hour)

This course focuses on writing and presentation skills needed for a career in biomedical sciences. It provides basic instruction in writing abstracts, curriculum vitae, and grant applications as well as how to organize and give oral scientific presentations. Also covered are basic aspects related to teaching skills needed in the biomedical classroom and laboratory.

SGSS 8130 Scientific Grant Writing (1 Credit Hour)

Practical course on grant writing. Specific steps in writing a grant Application, from the hypothesis and Specific steps in writing a grant Application, from the hypothesis and Specific Aims through the final product, are presented and discussed as the student writes an application that will be submitted to a granting agency.

Elective Courses
(Note: Only trainees in the Masters Program are required to take Elective Courses.)

GNMD 8050 Computational Methods in Genomics and Genetics (4 Credit Hours)

This course covers computational methods applied to genomics and genetics. The course will cover Bayesian statistics, nonparametric inference, phylogenetic trees, sequence analysis, microarray analysis, networks, multivariate methods, linkage analysis, and association genetics. The focus of the course will be to understand the basic concepts underlying the various analyses used in modern genomic and genetic research, and to understand how to use software that is available for basic analyses. A large component of the course will be to provide students with hands-on experience with analysis of datasets.

GNMD 8051 Translational Genomics and Proteomics (3 Credit Hours)

The purpose of this course is to 'translate' basic scientific discoveries directly into useful clinical tools and information for physicians, genetic counselors, clinical researchers and ultimately, patients. The course will cover high throughput SNP discovery and genotyping, biomarker discovery for disease prediction and prognosis, tissue microarray, RNA1 microarray and drug discovery (pharmacogenomics).

GNMD 8052 Functional Genomics and Proteomics using Animal Models (3 Credit Hours)

The purpose of this course is to show how animal models of human diseases can be analyzed using genomic and proteomic technologies. The course will overview high throughput methods of generating disease models in mouse and describe ongoing efforts in this field. The focus of the course will be on mouse models of diseases affecting immune, cardiovascular and nervous system. Attempts to identify molecular mechanisms of the disease will be presented with particular emphasis on drug target discovery.

IMPH 8001 Public Health Informatics (3 Credit Hours)

An overview of the field of public health informatics, integrating themes from information sciences, public health, computer science and medical science. Topics include: utilization of health information services, organization and management of online collections, automation of information technology, and public health professional knowledge as a component of evidence-based practice.

IMPH 8100 Healthcare Information Requirements and Standards (3 Credit Hours)

Healthcare information standards are addressed with emphasis on current healthcare regulations and standards. The effective use of networks to share health care data is

explored; emphasis is placed on developing the expertise to apply standards effectively in a health care facility to achieve full integration of organizational health information systems.

IMPH 8400 Health Data Management and Knowledge Discovery (3 Credit Hours)

This course focuses on the acquisition and use of patient level data to support population, administrative and clinical decision-making in health care organizations. Course emphasis is in data mining and knowledge discovery techniques including the advanced treatment of statistical analysis and methods of communicating the outcomes of health interventions.

IMPH 8600 Fundamentals of Health Promotion (3 Credit Hours)

An overview of theories and principles of social and behavior determinants of health, the social-ecological approach to public health, an overview of health promotion and disease prevention models of success, and the challenges of Healthy People 2010 objectives and health promotion informatics.

IMPH 8700 Introduction to Environmental Health (3 Credit Hours)

Major environmental health problems, including water quality, wastewater, and occupational health, trace elements in the environment, municipal, hazardous, and medical waste, food protection, vector control, and air quality are discussed. Introduction to the concept of environmental health informatics.

IMPH 8800 Health Decision Support Systems (3 Credit Hours)

This course presents an overview of automated decision systems used in clinical care, health administration and public health. The intensive format of the course allows for topic discussion, on-site observation of clinical, managerial, and population-based decision support systems.

NURS 8650 Qualitative Design and Analysis (3 Credit Hours)

This course will focus on a critical analysis of the epistemological basis of the qualitative paradigms. Emphasis includes research design, data collection, analysis, interpretation and evaluation.

NURS 8860 Critical Analysis of Health Behavior Theories for Research (3 Credit Hrs)

This course will focus on critically analyzing behavioral theories for their application in conducting research. The analysis will include examining the historical development, underlaying assumptions, concepts, and relational statements as they have been applied in research in a variety of scientific domains. Health behavior theories will be examined

to determine their internal consistency and external application to a variety of health and health care areas. Specific areas of research that were based on the theoretical perspectives will be examined and critiqued.

NURS 8870 Theory and Research in Health Disparities (3 Credit Hours)

Disparities in health and quality of life between those who do and those who do not have access to resources have become more pronounced in their effect over time. These long-term effects pose challenge to health scientists to conduct research on health disparities in their local, national, and global communities. Such community-driven research requires researchers to understand the history, attribution of cause, and theoretical approaches to the study of health disparities. Such research also requires modification of philosophical and methodological approaches used in more traditional research. In this course, the student will learn philosophical, conceptual and methodological approaches to health disparities and will design a research proposal that has the potential for describing and/or intervening in an aspect of a health problem in a selected vulnerable population.

NURS 8880 Clinical Outcomes Research (3 Credit Hours)

This doctoral course provides an opportunity for concentrated study of clinical outcomes research in nursing and related disciplines with an emphasis on clinical trial design in the testing of theory-driven interventions. The use of conceptual models in models in intervention research to guide the formulation of interventions and selection of appropriate clinical outcomes is addressed. Major topics in the course include the selection and evaluation of various clinical outcome measures, and analysis of outcome data. Feasibility issues related to the conduct of clinical research in formal clinical settings and informal community settings will be analyzed. Alternatives to traditional clinical trial design for clinical research will also be considered.

SGSS 8092 Fundamentals of Genomic Medicine (4 Credit Hours)

Course will provide a theoretical framework for understanding the fundamental concepts of mammalian genetics, functional genomics and bioinformatics as well as advanced technical and biological tools used in today's biomedical research environment. The course will provide lectures on a wide range of classical and modern topics such as classical genetics, linkage analysis, genetic mapping, positional cloning, genomics, proteomics and bioinformatics. The focus of the course will be to understand the experimental identification of genes responsible for disease and modern applications of genomics and proteomics to understanding biological processes as well as their impact on modern medicine.

STAT 8270 Categorical Data Analysis (3 Credit Hours)

This course focuses on statistical methods for analyzing categorical data; topics include inference for a single proportion; inference for two-way contingency tables; models for categorical response variables, including logistic and loglinear models; analysis of

matched-pairs data; power and sample size considerations. Emphasis will be placed on methods and models most useful in health-related research.

STAT 8350 Epidemic Modeling (3 Credit Hours)

This course serves as an introduction to types of epidemiological studies and covers modeling of various types of epidemics.