Graduate Training Programs in Clinical Investigation

A Joint Educational Enterprise of The Johns Hopkins Schools of Medicine and Public Health

Policy and Procedures Manual 2006-2007

The Graduate Training Program in Clinical Investigation and the University of necessity reserve the freedom to change without notice at any time the programs, policies, requirements, or regulations published in this manual. This manual is not to be regarded as a contract.
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Please visit our website at www.jhBSPH.edu/gtpci

Overview of The Johns Hopkins University Graduate Training Programs in Clinical Investigation

BACKGROUND

In 1989, a Task Force on Clinical Research in the Department of Medicine reported results of a survey, in which 1/3 of our clinical post-doctoral fellows indicated their desire to pursue "full-time clinical research" as a career objective. In the same survey a large majority of post-doctoral fellows felt they were inadequately trained in clinical trial design (70%), data management (70%), the ethics of human experimentation (69%), and biostatistics (83%). At that time, almost half of the responding post-doctoral fellows expressed an interest in a structured training program in clinical investigation. Discussions on ways to meet this need ensued at the department and School of Medicine levels, and eventually enlarged to include The Johns Hopkins School of BSPH & Public Health. At the same time, voices began to be heard at the national level about adverse trends for clinical investigation, and concerns about the inadequate supply of qualified clinical investigators. Johns Hopkins' response to these local and national needs has been the creation of a Graduate Training Program in Clinical Investigation jointly sponsored by the Schools of Medicine and Public Health. This program was inaugurated in 1992 and admitted its first students in 1993.

CONCEPT

The program is targeted toward internal physician post-doctoral fellows in clinical departments of the School of Medicine. It involves one year of full-time academic classroom work, followed by at least two years of mentored training in clinical research. After fulfilling all requirements for an advanced degree, a Master of Science in Clinical Investigation is awarded by the School of Public Health. In 1996, the University approved expansion of the program to include a Ph.D. degree in Clinical Investigation which is now being offered to students in this program. Normally, an interested fellow applies for admission into the program during his or her first year of clinical post-doctoral training, or for longer training programs, after completion of more than 80% of required subspecialty training. The first GTPCI year is devoted entirely to a full-time academic curriculum (see below). Thereafter, the student returns to the sponsoring department or division to undertake mentored clinical research and to complete any other requirements for clinical certification. In 1997 an MHS degree option was added for those who seek access to the didactic curriculum without the requirement for a thesis project.

CURRICULUM FOR THE DIDATIC YEAR

The didactic year begins with a short course on Clinical Research Methods taught during the summer. A Seminar Series begins during the summer to explore career objectives and inculcate a broad understanding of clinical investigation. During the four terms of the academic year, students take required courses in each of three tracks: Biostatistics, Epidemiology, and Clinical Investigation. For the Biostatistics and Epidemiology cores, a standard series of courses is drawn from the existing School of Public Health Graduate Curriculum. Courses in the Clinical Investigation core are specifically designed for students in the GTPCI program and largely taught by School of Medicine faculty. An effort is made to involve as many appropriate role models of

successful clinical investigators as possible. This core includes courses on biomedical writing, grant writing and thesis preparation, topics in clinical investigation, ethical and regulatory issues, drug development, analytical methodology, outcomes effectiveness research and a seminar series in clinical investigation. In 2005-2006, restructuring of the core curriculum occurred with two new courses called “Methods in Clinical Research I and II” replacing and expanding the previous courses in topics in clinical investigation and analytical methods. A course listing and course descriptions are included in the Course Sequence and Descriptions section elsewhere.

All thesis-degree students enter into an intensive grant writing-thesis development course during the third and fourth terms of their didactic year, out of which comes a thesis research proposal. All degree candidates are required to successfully complete a written comprehensive examination at the end of the didactic year. Thereafter, research progress is monitored by a Thesis Advisory Committee according to the rules of the University, with further requirements dependent on whether the student pursues a masters or doctoral degree.

PROGRAM ADMINISTRATION

An Advisory Council appointed from faculties of the School of Medicine and the Bloomberg School of Public Health establishes policy for the program and oversees students’ progress. Appointments are for rotating terms of three years, with the possibility of reappointment. Functional sub-committees have been created for Curriculum, Admission, Research Review, and Visiting Scholars; these committees also contain faculty not on the Advisory Council.

FUNDING

For admission to the program, the nominating department or division must guaranty three years of stipend support as well as identify a source for the tuition costs for the didactic year. For many trainees, existing NIH training grants are used to pay stipend and tuition. A limited number of institutional tuition grants are provided by the program. From July 1999, an NIH Curriculum Development Award (K30) provides for administrative, development and enrichment costs of the GTPCI program. The Program also sponsors two NIH K12 grants which select applicants competitively each year to be NIH Clinical Research Scholars. These Scholars who may be post-doctoral fellows or junior faculty receive stipends/salary, full tuition and some research support for at least three years.

EXPERIENCE TO DATE

As of July 2006, 159 students have entered the program: 113 in thesis-degree tracks and 46 in the MHS track. Eighteen new trainees matriculated for the 2006-2007 academic year.

Disciplines represented include:

Anesthesiology	5
Cardiology	9
Clinical Immunology	2
Clinical Pharmacology	11
Dentistry	2
Dermatology	2
Emergency	1
Endocrinology	6
Gastroenterology	9
General Pediatric	2
General Surgery	8
Geriatrics	3
Geriatric Oncology	1
Infectious Disease	12
Medical Genetics	1
Neonatology	1
Neurology	5
Oncology	20
Ophthalmology	2
Otolaryngology	2
Outside	1
Pathology	1
Pediatric Critical Care	2
Pediatric Cardiology	3
Pediatric Hematology	2
Pediatric Infectious Disease	2
Pediatric Nephrology	1
Pediatric Neurology	1
Pediatric Oncology	9
Pediatric Pulmonary	3
Physical Medicine & Rehabilitation	1
Psychiatry	2
Pulmonary and Critical Care	13
Renal	1
Radiology	1
Rheumatology	9
Urology	2
Total	159

Departments of Origin:

Anesthesiology and Critical Care Medicine	5
Emergency Medicine	1
Dentistry (NIH & Howard University)	2
General Surgery	7
Institute of Genetic Medicine	1
Kennedy Krieger Institute	2
Medicine	81
Neurology	5
Oncology	30
Ophthalmology	2
Otolaryngology	2
Outside	1
Pediatrics	15
Psychiatry	2
Radiology	1
Urology	2
Total	159

As of July 2006, 76 students have completed their degree requirements, 15 have withdrawn from the program before completion, and 68 are currently in residence or completing their thesis requirements elsewhere.

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Charges to the Standing Committees of the GTPCI

The Admissions Committee shall (a) review and recommend to the Advisory Council written criteria for admission to the various tracks of the GTPCI Program; (b) review and approve admission applications for all Program tracks, referring to the Advisory Council difficult or unusual cases; (c) establish criteria for evaluation of requests for early admission; and (d) conduct inquiries or interviews as necessary to reach admission decisions.

> Current Procedures. The Committee is composed of a Chair and 3-4 members of the Advisory Council. As required it circulates admission materials and deliberates by phone or e-mail. Personal interviews are conducted in special cases.

The Research Review Committee shall (a) recommend to the Advisory Council an appropriate advisory system to monitor academic and research performance of GTPCI students; (b) instruct students, advisors, and research preceptors and mentors on the Program's expectations for their roles; (c) monitor thesis research progress by each student after satisfactory completion of the comprehensive examination at the end of the didactic year; (d) periodically review written reports of academic advisors, and alert the Program Director/Associate Director and the Advisory Council when problems are identified; and (e) devise and implement a set of procedures for monitoring the student's research progress.

> Current Procedures include assignment of program academic advisors to all incoming students no later than September of the didactic year, monitoring reports of academic advisors on each GTPCI student (especially regarding research progress) and communicating to advisors and research preceptors the Program's expectations of their roles in the graduate training process.

The Curriculum and Academic Standards Committee shall: (a) continually review and refine as necessary the curriculum requirements for all tracks of the GTPCI Program; (b) to obtain and review student evaluations of the curriculum components; (c) to compose and administer a comprehensive written examination to all GTPCI students at the conclusion of their didactic year; and (d) to review annually academic performance and comprehensive exam results in order to recommend to the Advisory Council the awarding of the MHS degree, or the advancement of thesis degree candidates to the Ph.D. or ScM tracks.

> Current Procedures: This Committee is chaired by the Associate Program Director and has 3-4 members, at least one of whom does not currently sit on the Advisory Council. It constructs and grades a written examination to be taken in early June of each year. When results are known, the Committee meets to review individually each first-year student's academic performance, and to recommend to the Advisory Council advancement to the Ph.D. or ScM track.

The Visiting Scholars Committee shall: (a) receive and evaluate suggestions for enrichment opportunities for GTPCI programs at JHMI; these may include lectureships, visiting professorships, short topical programs, internal forums, or other creative ventures which could promote the cause of clinical investigation within JHMI or enrich the training experience of GTPCI students; (b) organize and implement several such enrichment programs each academic year; (c) recommend to the Advisory Council programs which may build bridges and promote cooperation between JHMI elements concerned with training and nurturing clinical investigation in its broadest definition; this would include the GCRCs, Clinical Trials program, Welch Center programs, Health Services research groups, and others. *9/1/01*

Information for GTPCI Advisors and Advisees

1. All GTPCI degree students (Ph.D., ScM, and MHS) are assigned an academic advisor from among the Program's faculty. Assignments are generally made by the Program Director or Associate Director not later than September of the academic year in which graduate coursework begins. Pairings are made on the basis of perceived mutual interests, availability, and sometimes professional background. Advisors are not chosen because of presumed expertise in the student's intended research interests. Students and their assigned advisors work together with mutual consent, and either may request reassignment if the relationship is not satisfactory.

2. Each student and his/her assigned advisor are expected to have a face-to-face introductory meeting not later than mid-November of the didactic year. A required course (*Professional Goals and Objectives*; course #390.801) will provide each student with an opportunity for at least one detailed discussion with his/her advisor regarding career objectives, mentoring arrangements, and thesis development.

3. For Ph.D. and ScM candidates, the faculty advisor's responsibility is to: (a) advise the student on coursework selection and monitor academic performance during the didactic year; (b) provide general mentoring and support for academic issues and the selection of a thesis research topic; (c) to review and approve the preliminary thesis proposal at the end of the didactic year; and (d) to serve on the student's thesis committee(s). In this latter role the advisor represents the Program's faculty, and as such has the responsibility to strive for application of uniform academic standards across the program. The academic advisor therefore usually does not function as the candidate's advocate which is the role of the research mentor. *(Note: BSPH graduate degree documents frequently use the term "advisor" by which is meant the student's GTPCI academic advisor. BSPH requires that the advisor be present during the preliminary oral exam and participate on the thesis committee/final oral examination. GTPCI requires that the research mentor be present at these exams as well).* For MHS candidates the advisor's role is complete once the student has passed the comprehensive examination at the end of the didactic year, and hence satisfied the degree requirements.

4. For Ph.D. and ScM tracks, student are required to contact their faculty advisor by phone or in person at least once per academic term during the didactic year and by July 1 and again by December 1 each succeeding research year until a degree is awarded. Each faculty advisor will provide a brief, written documentation of these contacts to the Program office for monitoring by the Research Review Committee. After the didactic year, the content of these semi-annual exchanges will focus on the candidate's research progress, relationship with mentor(s), and general academic and professional well being. If problems are identified, the advisor should help structure a list of viable alternative solutions for the student to consider. Rarely communication with research preceptors and mentors may be advisable and helpful. The Program's Research Review Committee or the Program Director or Associate Director should be informed when situations that could prevent successful completion of the program arise.

5. By June 1 of the didactic year, each thesis-degree candidate will submit to his/her academic advisor and to any research mentors the equivalent of a 3- to 5-page single-spaced research thesis proposal which outlines the background and rationale for the proposed thesis research, describes the proposed study design and methods, discusses major methodologies and practical challenges, and indicates how ethical concerns will be addressed. When acceptable to the academic advisor and research mentors, each Ph.D. candidate will initiate the formation of a committee for the preliminary oral examination, using procedures described elsewhere.

6. When the Ph.D. candidate's academic advisor and the GTPCI Research Review Committee agree that a written draft of the dissertation work is acceptable, the student may proceed to schedule the "oral defense" of his/her thesis. A similar committee of Thesis Readers is appointed to review and approve the thesis of ScM candidates. Ordinarily the academic advisor will serve on the thesis committees of his/her advisees, again representing the GTPCI Program. *9/1/01*

Information for GTPCI Thesis Research Preceptors and Their Students

1. Each thesis-degree candidate in the GTPCI has an assigned academic advisor who advises the student on coursework selection and monitors academic performance during the academic year, provides general mentoring and support for academic issues and the selection of a thesis research topic, and serves on the student's thesis committee(s). The students are required to contact their academic advisor by phone or in person by July 1 and again by December 1 of each succeeding year after completion of didactic work until a degree is awarded. The student's academic advisor is not chosen because of requisite expertise in the area of student's research. The assigned advisor monitors student progress on behalf of the GTPCI Program, and represents the Program on any academic committees reviewing the student's research. In addition, the student's advisor must review and approve the proposed thesis project before the preliminary oral examination can be scheduled (Ph.D. candidates only). Otherwise, the academic advisor is not involved in the direct supervision or review of research results, or in resolving research problems which may arise. Nevertheless communication between the student's advisor and research preceptor (and other mentors) may be usefully undertaken when it is in the student's best interest to do so.

2. For GTPCI students, the principal research preceptor usually is a faculty member in the candidate's home division or department. Unlike the academic advisor, the research preceptor knows the scientific and medical disciplines involved in the research and therefore can supervise and critically evaluate the student's research progress. The same individual quite commonly serves as a mentor for the student's professional and career development. In some thesis projects, especially when new methodology is involved, other research preceptors and mentors may also need to be involved in assisting and directing the student's thesis research. *The GTPCI Program continually emphasizes to its students the importance of establishing a successful mentoring relationship with the research preceptor, and with other key faculty who are important for research training or professional development.*

3. Occasionally the research preceptor may be contacted by the student's academic advisor, the GTPCI Program Director, or a member of the Research Review Committee to discuss the student's research progress. Likewise the GTPCI Program Director or Associate Program Director, or the student's academic advisor, are always available and willing to hear from research preceptors who are concerned about their student's research progress or other aspects of academic or professional performance. Similarly, the Program may contact research preceptors to initiate inquires or dialogues if it has concerns about the student's ability to successfully complete the program.

4. *Under rules of the Graduate Board of the University, a Ph.D. candidate's thesis committee must contain his/her advisor. Under rules of the GTPCI Advisory Council, a Ph.D. candidate's thesis committee must also contain his/her research preceptor.* Therefore faculty who are precepting GTPCI students will be called upon to participate in evaluating the student's oral defense of his thesis, even though the preceptor may have little working knowledge of the GTPCI Program or the operation of such committees. This is not infrequently the case since most research preceptors are from the faculty of clinical departments which ordinarily do not have graduate students. If the need arises, the Program Director or Associate Director will be pleased to provide written instructions on the process and personal advice if requested. The student receives instructions and advice on these procedural matters from the Program so that the research preceptor need not be concerned with advising the student about these academic procedures.

5. The GTPCI Advisory Council welcomes the interest and active participation of all clinical investigators who may serve as research preceptors for GTPCI students. Please feel free to call the Program Director or Associate Program Director at any time to discuss an interest in more active participation in the Program through its committees and Advisory Council functions.

9/1/01

I. Doctor of Philosophy in Clinical Investigation

Policy

All candidates for the mentored GTPCI curriculum will normally be admitted to the Ph.D. program. By written request to the Program director, Ph.D. candidates may request transfer to ScM candidacy if for valid reasons they are unable to complete the residential or research requirements for the Ph.D. program. Alternatively, students may be advised to request transfer to ScM candidacy if in the opinion of their faculty advisor or the GTPCI Advisory Council, research achievements are not of sufficient scope or depth to satisfy the Ph.D. requirements but do completely fulfill the expectations for a Master's degree. Students matriculating into a thesis-requiring degree program will not be allowed to transfer into the MHS degree program.

Prerequisites for this degree include: satisfactory completion of 90 credit hours of course work (including thesis research credits), including one year of full-time in-residency course work, five additional courses to be taken the second year, continuous registration for the Research Forum and registration for thesis preparation each term during the following years; comprehensive examination at the end of the didactic year; satisfaction of all university requirements for the Ph.D., including oral preliminary examination, thesis preparation and defense. This is the flagship program to which all subspecialty residency trainees should aspire, and into which all accepted candidates are routinely matriculated.

Procedures

After a candidate is accepted into the program, a faulty advisor will be appointed by the Research Review Committee. The faculty advisor will normally be a member of the Advisory Council or a GTPCI Committee, or an active GTPCI faculty member. The faculty advisor's responsibility is to: advise the student on course work selection and monitor academic performance, provide general mentoring and support for academic issues and the selection of a thesis research topic, and to serve on the student's thesis committee, if requested. Students are required to contact their faculty advisor by phone or in person at least once per academic term during the didactic year, and by July 1, and again December 1 in each succeeding research year until a degree is awarded. Each faculty advisor will provide brief, written documentation of these contacts to the Program Office for monitoring by the Research Review Committee.

During the second term of the didactic year, a required course (*Professional Goals and Objectives;* course number 390.801) will provide each student with an opportunity for at least one detailed discussion with his/her advisor regarding career objectives, mentoring arrangements and thesis development. In addition, this course will initiate the structured process of considering and choosing among a variety of research topics for career development and thesis requirements.

By June 1 of the didactic year, each Ph.D. student will submit to his/her faculty advisor (and to any research mentors) the equivalent of a 3 to 5 page single-spaced research thesis proposal which outlines the background and rationale for the proposed Ph.D. research effort, describes the proposed study design and methods, discusses major methodologies and practical challenges, and indicates how any ethical concerns will be addressed. When acceptable to the faculty advisor and research mentors, each Ph.D. student will initiate the formation of his/her thesis committee. A thesis committee must be established within 3 months of completing the first didactic year, and each Ph.D. student will use this committee for research oversight through completion of the thesis. Ph.D. students are required to have 5 member committees. Ph.D. students are strongly encouraged to have all 5 members of their committee serve for the preliminary oral exam. While BSPH only requires a 4 member committee on the final oral examination, GTPCI strongly encourages all 5 members of the thesis committee to attend.

The preliminary doctoral oral examination should ordinarily take place no later than September following the completion of the didactic year and comprehensive written examination. The research proposal should be presented in writing in a detailed format (equivalent to 15-25 single spaced pages) to members of the Thesis Committee at least three weeks before the oral examination. The purpose of this examination is to determine whether the student has both the ability and knowledge to undertake significant research in his/her general area of interest. Discussion of the specific research proposal may serve as a vehicle for determining the student's general knowledge and research capacity, but this examination is not intended to be a defense of a specific research proposal.

When the student's faculty advisor and the GTPCI Research Review Committee agree that a written draft of the dissertation work is acceptable, the student may proceed to schedule the "oral defense" of his/her thesis. If the Committee of Thesis Readers agree by unanimous vote that the candidate "passes" his/her oral thesis defense, the Committee will then recommend to the GTPCI Advisory Board and the Graduate Board of the University, the awarding of the degree of Doctor of Philosophy. Alternatively the Committee may recommend a ScM degree in Clinical Investigation if the scope and depth of the research accomplishments are insufficient for the doctoral degree and the candidate is unable or unwilling to extend his/her thesis work in an effort to qualify for a doctoral degree, and the completed work fulfills requirements for the ScM degree.

<u>Characteristics of an Acceptable Ph.D. Doctoral Dissertation</u>
A doctoral student is expected to undertake a dissertation project which will represent a novel and substantial contribution to the chosen field of endeavor. The project must be of the student's own design, and the student must be largely responsible for its completion. Ideally, the thesis project will focus on a single, important research issue. In unusual circumstances, the thesis project may consist of a series of smaller related studies designed to address a particular clinical or methodological problem.

A doctoral dissertation must adhere to the published University guidelines for such a document. As a general guide, the completed doctoral dissertation

should consist of two or more units which would be publishable in peer-reviewed journals. For example, the Introduction chapter could be publishable as a rigorous and comprehensive review of the research problem, and individual chapters describing research results should be published as original papers in scientific journals. For dissertations which are more methods-oriented, chapters describing new research methodologies or data collection instruments might also be considered as publishable units. Acceptance of the thesis in partial fulfillment of the requirements for the Ph.D. does not require that manuscripts be submitted or accepted for publication. However, in the opinion of the Thesis Committee, at least two parts of the thesis must be suitable for publication if submitted to peer-reviewed journals, and prior acceptance or publication will be taken as substantial evidence in favor of this requirement.

The criteria to be applied by the Committee of Thesis Readers in evaluating a thesis are: the originality and publication potential of the research, the candidates' understanding of the details of the methodological and analytic work, the magnitude of the candidate's contribution to his/her chosen field of research, and the final quality of the written thesis document.

All thesis submissions MUST adhere to the formatting guidelines outlined by the Bloomberg School of Public Health. University policy stipulates that "previously published material must be incorporated into a larger argument that unites the whole work. A common thread linking the various parts must be identified and made explicit as the papers are joined into a coherent unit. Introductory, transitional, and concluding sections, as well as a bibliography must be included. Proper credit must be given to co-authors and to the publisher. Written evidence that permission has been granted by the publisher must accompany the dissertation. Discrete, unlinked papers are not acceptable."

II. Master of Science in Clinical Investigation

Policy Paragraph on ScM students matriculating prior to 1996 deleted

The ScM is a thesis-requiring degree which can be awarded to Ph.D. candidate who cannot fulfill the full set of requirements for a Ph.D. because of curtailed time available, unanticipated research difficulties, or late shifts in thesis projects. Requirements include: 70 hours of course work including a year of full-time coursework; comprehensive examination; continuous registration for the Research Forum following the didactic year; evidence of original research productivity as evidenced by submission of an acceptable Master's thesis. The written thesis must be based on original research, worthy of publication, and acceptable to the program's Advisory Council and a Committee of Thesis Readers. The document may consist of one or more original manuscripts derived from the student's research and submitted to peer-review journals, or a traditional thesis document with sections on background and introduction, literature review, methods, results, discussion and a copy of all study-related instruments. GTPCI candidates are not ordinarily accepted for this track initially, but may transfer into it by mutual agreement after matriculation. Students matriculating into the ScM degree program may not transfer into the MHS degree program.

Procedures

Students admitted to, or remaining in the ScM track, must establish a thesis committee within 3 months of completing the first didactic year. Each ScM student will use this committee for research oversight through completion of the thesis. ScM students are required to have 4 member thesis committees. If a 5 person thesis committee was previously appointed while the student was a PhD candidate, all 5 members should be asked to continue to serve as a programmatic thesis committee for the ScM degree, and all should be appointed as "thesis readers" as required by the BSPH, even though school policy requires only four.

ScM students can choose one of two formulas for submission of their thesis results. The first will consist of one or more thesis-related manuscripts derived from the student's research which have been submitted to peer-reviewed journals, supplemented by an expanded description of study methods and results as well as a copy of all study-related instruments. Review articles alone do not fulfill this requirement. The second option will be the submission of a "traditional" thesis document with sections on background and introduction, literature review, study methods, results, discussion, and a copy of all study-related instruments. Within four weeks of receiving the student's thesis, the Committee of Readers will confer determine whether the student's research meets the thesis requirement for the award of the ScM in Clinical Investigation.

All thesis submissions MUST adhere to the formatting guidelines outlined by the Bloomberg School of Public Health. University policy stipulates that "previously published material must be incorporated into a larger argument that unites the whole work. A common thread linking the various parts must be identified and made explicit as the papers are joined into a coherent unit. Introductory, transitional, and concluding sections, as well as a bibliography must be included. Proper credit must be given to co-authors and to the publisher. Written evidence that permission has been granted by the publisher must accompany the dissertation. Discrete, unlinked papers are not acceptable."

Ph.D. students who are advised or elect for valid reasons to transfer to the ScM program must have the approval of their thesis committee and the Program Director.

III. Master of Health Science Degree

Policy

The MHS degree in Clinical Investigation is a non-research requiring degree which is awarded to GTPCI candidates who specifically apply for this non research track, fulfill the requirements of 70 credit hours of course work, MHS capstone experience beginning in 2006 and pass the comprehensive exam. These students will take the GTPCI didactic curriculum (exclusive of thesis preparation courses 390.701/702, for which electives must be substituted).

The GTPCI Advisory Council strongly advises all MHS candidates to complete coursework as rapidly as possible so that the benefits can begin to accrue in clinical research activities. Full time pursuit of the MHS degree is preferred and students are expected to successfully complete all required coursework and the comprehensive exam within one academic year. In some extenuating circumstances exceptions may be considered; therefore, MHS applicants who do not intend to devote full time to the curriculum must submit a detailed plan to complete 90% of the required coursework over a two year period (which can include summer terms.) The plan must be approved by the GTPCI Admissions Committee and Advisory Council prior to admission. After matriculation, part time MHS students are expected to abide by the approved course plan. Any changes in the initial course plan must be approved by the GTPCI program directors and academic advisor. Unapproved deviations in course plans may result in withdraw from the MHS program.

MHS candidates are assigned a faculty advisor whose role is to provide general academic and career advice and monitor the student's academic performance.

GTPCI thesis-degree students may not transfer into the MHS track, nor receive an MHS degree even though they may have satisfied the nominal requirements.

GTPCI MHS students who have successfully completed a minimum of 16 credits consecutively, 1st through 4th term, may formally request a transfer into the PhD track with the approval of their academic advisor. Requests should be made to the GTPCI Program Director or Associate Director, who will either grant the transfer or determine that the application must be reviewed and approved by the GTPCI Curriculum and Academic Standards Committee.

Procedures

When the coursework requirements are completed satisfactorily and the comprehensive exam has been passed, the Program Director will recommend for Advisory Council approval of the award of the MHS degree.

BSPH Policy and Procedure Memoranda for the above programs can be found at
http://www.jhBSPH.edu/schoolpolicies/ppms.html
[Academic Programs #14,15, and 16]

RESEARCH FORUM

Registration, attendance and participation at the monthly GTPCI Research Forum is a required activity for all PhD & ScM trainees who have taken their Comprehensive exams. Trainees are expected to attend at least 6 of the 8 sessions; if this requirement is not met, completion of a remedial assignment will be required. The Research Forum requirement ceases after passing the final oral thesis defense and/or completion of a ScM thesis.

The purpose of the Research Forum is to provide GTPCI trainees with an opportunity to present interim research results and obtain constructive criticisms from their peers and GTPCI faculty. The experience is designed to provide an informal colloquium for the entire GTPCI community.

MHS CAPSTONE EXPERIENCE

The course “Planning and Funding Clinical Research” was designed to serve as the MHS Capstone project. MHS students will consider the principles of successful clinical research strategies and the requirements of funding agencies. Each student will identify a defined research project, together with a suitable team of mentors and collaborators. With mutual review and criticism, each student will develop a written research proposal in the format of a grant application which will integrate the scientific principles of the GTPCI curriculum. MHS students must satisfactorily complete this class prior to graduation.

The format of the meetings is a brief presentation by the investigator (10-15 minutes) of problems presented by work in progress. Another PhD candidate will be assigned as a discussant for each presentation, and will comment for 5 minutes after the presentation. This will be followed by questions, answers and comments (10-15 minutes). The format is NOT intended to be a platform for formal presentation of research results. Instead, its intent is to facilitate critical discussion, and even disagreement that will be helpful to the presenter and other students in attendance as well. Whenever possible, dates will be assigned so that both the presenter's research preceptor and GTPCI advisor cab be present.

RELEASE OF AND REQUESTS FOR STUDENT INFORMATION

The GTPCI may provide JHMI Departments and/or Divisions academic updates of their sponsored trainee's performance from time to time. These updates may include copies of transcripts or any official GTPCI correspondence to trainees. The Program may also request updates from sponsoring departments or divisions about fellowship or faculty status, funding sources, visa status, or academic plans for GTPCI trainees.

INTERNATIONAL STUDENT POLICY

The GTPCI program may sponsor a student visa (F-1 or J-1) for one year of full time study to complete the MHS program. Visa sponsorship for applicants to the PhD program will be determined on a case by case basis and will likely be sponsored through the student's fellowship. Visa sponsorship may change throughout the course of the PhD program.

Regardless of visa status or sponsorship, all international students are obligated to notify the GTPCI Office immediately of any changes in academic appointment, employment, funding, or payroll. Students must also notify the GTPCI Office of any plans to travel or work outside of the U.S.

It is the sole responsibility of the student to ensure that all visa requirements are being met and valid status maintained. International students are expected to consult the Office of International Services regarding ANY changes in the situation under which they were issued their visa status. They must also notify the OIS of any plans to travel well in advance. The International Services Office website is http://www.hopkinsmedicine.org/intlsvcs/ The U.S. Department of State should be consulted prior to any travel outside of the U.S. to determine adequate visa processing times or travel advisories.

ECFMG certification is generally required of all applicants for thesis-requiring degrees, since clinical credentials are usually needed to undertake clinical investigation; some exceptions may be justified, and will be considered on a case by case basis. If an international student is admitted without having obtained ECFMG certification, they maybe required to obtain it during their GTPCI studies. It is the responsibility of the international student to determine if ECFMG is required through a formal request to the program directors.

TUITION FEES AND BILLING GUIDELINES

All trainees or faculty accepted into the GTPCI program must identify adequate funding to support their studies prior to matriculation. Students must provide complete support information to the GTPCI Office and are expected to arrange all payment for tuition, course materials fees, matriculation fees, books and supplies.

The Financial Aid Office is responsible for posting all payments to the student accounts. Students will receive on-line statements every month on the 16th from Student Accounts and Business Services. These statements will reflect all funding that has been applied by the Financial Aid Office and any outstanding financial responsibilities. The student is ultimately responsible to ensure all bills are paid.

Continuing Ph.D. students, after the first year of full-time coursework, **must maintain continuous registration** for part-time classes or thesis research until completion of the degree. If tuition support is available from grant or other sources, the student is expected to arrange for that payment source to be utilized. If no additional funding exists scholarship support for continuing students will be provided for up to 4 credits per term. All additional coursework to be supported by scholarship MUST be submitted to the GTPCI office in July for the upcoming academic year and must be approved prior to registration.

If students register, withdraw, or audit classes without arranging funding, they will be held personally responsible for payment. Students are personally responsible for late fees.

Faculty are expected to use tuition remission benefits and may be held personally responsible for payment if tuition remission is applicable and not utilized. Tuition remission updates and information can be found on the GTPCI website.

GTPCI THESIS COMMITTEE GUIDELINES

ALL ScM AND PhD STUDENTS ARE REQURIED TO FORM A THESIS COMMITTEE.

PhD students are required to have 5 member committees. All 5 members of the thesis committee must serve on the committee for the preliminary oral exam AND the final oral examination. While BSPH only requires a 4 member committee on the final oral examination, GTPCI strongly encourages all 5 members of the thesis committee to attend.

ScM students are normally required to have only 4 member thesis committees. However, if a 5 member committee has been previously appointed while the student was a PhD candidate, all five members should be asked to continue on the ScM Thesis Committee.

To meet University and GTPCI criteria, the thesis committee must include:
The GTPCI Academic Advisor, a second GTPCI division representative, a representative outside of GTPCI but within BSPH, another representative outside GTPCI (this can be a SOM person, and should be the student's project mentor if not already on the committee), and another outside person. The composition of each student's committee requires review and approval by the GTPCI Research Review Committee.

BSPH thesis committee forms can be found on
http://www.jhsph.edu/student_affairs/registrar/studentforms
which also enunciates the School's general requirement for composition of the thesis committees. Keep in mind that the sponsoring department is GTPCI (these are BSPH forms & guidelines not SOM). Any faculty listed on the GTPCI Advisory Council or GTPCI Standing Committees can represent GTPCI (the home department). Anyone on the GTPCI committees who has a PRIMARY appointment in BSPH may also represent "outside department BSPH". You may check BSPH faculty appointment status at http://faculty.jhBSPH.edu/appointments.cfm.

Questions regarding thesis committee composition should be directed to the GTPCI Program Coordinator. Students must put together a committee and have it approved by the advisor no later than August 1st following the didactic year.

GTPCI Thesis Guidelines

Refer to previous section: "Characteristics of an Acceptable Ph.D. Doctoral Dissertation"

BSPH Thesis Guidelines

Can be found at
http://www.jhsph.edu/student_affairs/registrar/DocScmThesisGuide.html

JHU Graduate Board Guidelines Applicable to PhD Dissertations

can be found at http://www.library.jhu.edu/services/cbo/guidelines.html

GTPCI COMMITTEE MEMBERS

Advisory Council and GTPCI Committee members are all eligible to represent the BSPH "department" of GTPCI. Below is a list of the capacities in which each member may serve on a thesis committee:

ADKINSON	GTPCI or DOM/Clinical Immunology
FLEXNER	GTPCI or DOM/Clinical Pharmacology
LAWRENCE	GTPCI or HPM
LIETMAN	GTPCI or DOM
YAGER	GTPCI or EHS
RUFF	GTPCI or IH
PIANTADOSI	GTPCI or Oncology
SAMET	GTPCI or EPI
ZEGER	GTPCI or BIOSTATS
POWE	GTPCI or EPI
KLAG	GTPCI or DOM/GIM
PRONOVOST	GTPCI or DOM/Anesthesiology & Critical Care
KRAG	GTPCI or BMB
FURTH	GTPCI or Pediatrics
AMBINDER	GTPCI or Oncology
HENDRIX	GTPCI or DOM/Clinical Pharmacology
GRIFFIN	GTPCI or MMI
BRANCATI	GTPCI or DOM/Internal Medicine
GOODMAN	GTPCI or SOM/Oncology
ZEITLIN	GTPCI or SOM/Pediatrics or Pulmonary
GELBER	GTPCI or SOM/ Rheumatology
PUNJABI	GTPCI or SOM/Pulmonary

IRB APPROVAL FOR THESIS PROJECTS

Candidates for thesis-requiring degrees (ScM and PhD) must document IRB approval or exemption for their thesis project(s). If the project is exempt, a brief application process to JHM IRBs will generate a document stating the project is exempt. Either this document, or an approval letter(s) from the IRB must be submitted to the GTPCI office no later than the submission of the thesis for review by the thesis advisor. Failure to get prospective IRB approval or exemption will result in the thesis being administratively disapproved.

COMPREHENSIVE EXAM

All GTPCI degree students are required to take a written comprehensive exam after successfully completing the 70 credits of core coursework. The exam is a take home exam comprised of 4 questions. The exam is distributed at the end of 4th term each year and students have one week to complete the exam. (Seven days including the day it is picked up and the day it is returned.) The Program Coordinator is responsible for the scheduling and distribution of comprehensive exams.

Because the GTPCI comprehensive exams are not offered until the end of May (after the BSPH deadline for graduation) MHS students are not able to participate in graduation at the end of their didactic year. Although MHS students will not technically graduate until the following May, transcripts will indicate the completion all of all degree requirements and maybe cited as a completed degree on a Curriculum Vitae.

Exam Forms & BSPH Timelines

All forms and graduation instructions/timelines can be found at
http://www.jhsph.edu/student_affairs/registrar/

PRELIMINARY ORAL EXAM

The preliminary doctoral oral examination should be scheduled no later than September 1st following the completion of the didactic year and comprehensive written examination. The research proposal should be presented in writing in a detailed format (equivalent to 15-25 single spaced pages) to members of the Thesis Committee at least one month before the prelim oral examination. The purpose of this examination is to determine whether the student has both the ability and knowledge to undertake significant research in his/her general area of interest. Discussion of the specific research proposal may serve as a vehicle for determining the student's general knowledge and research capacity, but this examination is not intended to be a defense of a specific research proposal.

If students have not taken and passed the preliminary oral exam by the end of the second year, BSPH may take disciplinary action. If for some reason the exam cannot be taken within this timeframe, a formal request for an extension, approved by the academic advisor, must be submitted to the Program Coordinator who will then submit to BSPH for approval. Students should reserve suitable space for both parts of the defense by communicating with schedule@jhBSPH.edu at least 30 - 45 days prior to the exam.

FINAL ORAL EXAM (Thesis Defense)

The structure of the Final Thesis Defense for all GTPCI doctoral candidates includes two parts: an initial public presentation of the thesis work, followed by a closed critical examination by the candidate's thesis committee.

The public seminar should include a 30 minute presentation by the candidate, followed by a question period of 15 minutes. Public announcement and invitations should be initiated by the candidate and his/her advisor. Afterward, the examination committee

and the student will meet privately to continue a critical evaluation of the thesis as needed. Thereafter the thesis committee will convene in private for voting and discussion as specified in procedures for the doctoral degree, after which they will announce their decision to the student.

Candidates should schedule a two hour time block for their thesis defense with their examining committee. Ideally the final defense will take place in late afternoon when more students and faculty can attend. Students should reserve suitable space for both parts of the defense by communicating with schedule@jhsph.edu at least 30 - 45 days prior to the exam.

REQUIRED MHS COURSEWORK SEQUENCE 2006-07

Course Number	Credit	Course Title
SUMMER TERM	***July-August***	***OPTIONAL OPTIONAL OPTIONAL OPTIONAL***
340.655	6	Methods in Clinical Research *(Suggested not required)*
N/A	0	GTPCI Summer Seminars Series
FIRST TERM	***September-October***	***Total 17***
340.751	5	Epidemiologic Methods I M W F 8:30-9:50 Lab section 2 hrs.
140.621/651	4	Biostatistics Series (621 or 651) T Th 10:30-11:50 Labs 2hrs.
390.631	2	Principles of Drug Development W 1:30- 2:50
390.710.02	2	Biomedical Writing I (for MHS students) M 3:30-5:20
390.673	3	Ethical & Regulatory Issues in Clinical Research T 5:30-8:30
550.865	1	Public Health Perspectives F 1:30-2:50
SECOND TERM	***October-December***	***Total 16***
340.752	5	Epidemiologic Methods II M W F 8:30-9:50 Lab M W F 10-11:50
140.622/652	4	Biostatistics Series (622 or 652) T Th 10:30-11:50 2hr. Labs
390.751	2	Seminars in Clinical Investigation W 1:30-2:50
390.711.02	2	Biomedical Writing II T 3:30-5:00
390.801	1	Professional Goals and Objectives T 9-9:50
550.860	1	Research Ethics W 4:00 - 5:20
550.865	1	Public Health Perspectives F 1:30-2:50
THIRD TERM	***January-March***	***Total 15 (Electives must be selected by December 22)***
340.753	5	Epidemiologic Methods III M W F 8:30-9:50 Lab section 2 hrs.
140.623/653	4	Biostatistics Series (623 or 653) T Th 10:30-11:50 2hr. Labs
340.606	4	Systemic Reviews and Meta-Analysis M F 3:30-5:20
390.721	2	Planning and Funding Clinical Research *(Capstone)* F 8:30-10:20
FOURTH TERM	***March-May***	***Total 15 (Electives must be selected by December 22)***
550.710	6	Clinical Research Methods TBA Lab TBA (once a week)
140.624-654	4	Biostatistics Series (624 or 654) T Th 10:30-11:50 2hr. Labs
390.675**	3	Outcomes and Effectiveness Research T 5:30-8:30 (may change)
390.722	2	Planning and Funding Clinical Research *(Capstone)* M 3:30-5:20

The Bloomberg School of Public Health requires that full time students register for 16 credits per term; therefore, electives MUST be identified for 3rd and 4th terms.

It is each student's responsibility to ensure they complete 70 credits of coursework!

****** *These courses may be substituted with a suitable elective if approved prior to registration by the academic advisor and chair of the Curriculum Review Committee.*

Part time MHS students who are present for a second academic year are expected to take 390.612 (140.642) DESIGN & ANALYSIS OF CLINICAL TRIALS *1st term as a more advanced substitute for this course.*

Revised 8/01/06

GTPCI REQUIRED PhD/ScM COURSEWORK SEQUENCE 2006-07

Course Number	Credit	Course Title
SUMMER TERM	***July-August OPTIONAL OPTIONAL OPTIONAL OPTIONAL***	
340.655	6	Methods in Clinical Research *(Suggested not required)*
N/A	0	GTPCI Summer Seminars Series
FIRST TERM	***September-October Total 17***	
340.751	5	Epidemiologic Methods I M W F 8:30-9:50 Lab section 2 hrs.
140.621/651	4	Biostatistics Series (621 or 651) T Th 10:30-11:50 Labs 2hrs.
390.631	2	Principles of Drug Development W 1:30- 2:50
390.710.01	2	Biomedical Writing I T 3:30-5:20
390.673	3	Ethical & Regulatory Issues in Clinical Research T 5:30-8:30
550.865	1	Public Health Perspectives F 1:30-2:50
SECOND TERM	***October-December Total 16***	
340.752	5	Epidemiologic Methods II M W F 8:30-9:50 Lab M W F 10-11:50
140.622/652	4	Biostatistics Series (622 or 652) T Th 10:30-11:50 2hr. Labs
390.751	2	Seminars in Clinical Investigation W 1:30-2:50
390.711.01	2	Biomedical Writing II Th 9 – 10:20
390.801	1	Professional Goals and Objectives T 9-9:50
550.860	1	Research Ethics W 4:00 - 5:20
550.865	1	Public Health Perspectives F 1:30-2:50
THIRD TERM	***January-March Total 15 (Electives must be selected by December 22)***	
340.753	5	Epidemiologic Methods III M W F 8:30-9:50 Lab section 2 hrs.
140.623/653	4	Biostatistics Series (623 or 653) T Th 10:30-11:50 2hr. Labs
340.606	4	Systemic Reviews and Meta-Analysis M F 3:30-5:20
390.701	2	Thesis Preparation (Grant Writing) T 3:00-5:00
FOURTH TERM	***March-May Total 18***	
550.710	6	Clinical Research Methods TBA Lab TBA (once a week)
140.624-654	4	Biostatistics Series (624 or 654) T Th 10:30-11:50 2hr. Labs
390.675**	3	Outcomes and Effectiveness Research T 5:30-8:30 (may change)
390.702	4	Thesis Preparation (Grant Writing) M 3-4:50 & W 8-9:50
390.703	1	Presentation Skills W 8-9:50

First year PhD students must be registered for a minimum of 16 credits 1st through 4th term; therefore, will have to choose elective coursework 3rd term. It is each student's responsibility to ensure they complete 70 credits of coursework in the first year.

** *These courses may be substituted with a suitable elective if approved prior to registration by the academic advisor and chair of the Curriculum Review Committee.*

second year students are required to take five additional courses to include

390.612 (140.642) DESIGN & ANALYSIS OF CLINICAL TRIALS first term *Revised 8/01/06*

COURSEWORK AND GRADING POLICIES

Core Course Substitution:

The Bloomberg School of Public Health does not accept transfer credit; however, elective coursework maybe substituted for required coursework if:

a) the student can prove that he/she has already received academic credit for equivalent material; and
b) appropriate electives are selected; and
c) approval is obtained by the Academic Advisor, followed by the GTPCI Director or Associate Director

MHS students are strongly encouraged to take Professional Goals and Objectives, but may opt out with permission from the GTPCI Program Director or Associate Director.

Grading Policies:

All core (required) courses (including the 5 required advanced courses taken in the second year for PhD candidates) MUST be taken for a letter grade. Electives may be taken for Pass/Fail with prior approval from the course instructor and academic advisor. But if the elective is taken in place of a required course, it must be taken for grade.

Any grade of D or F in a core (required) course will automatically require that the course be re-taken within one year to improve the grade to at least a B or better.

MHS & ScM students must maintain a cumulative GPA of 2.75 to remain in good standing. PhD students must maintain a cumulative GPA of 3.00 to remain in good standing.

The GTPCI Curriculum and Academic Standards Committee may at any time upon review require any student receiving a “C” grade or lower to retake the course if it is judged central to the student’s thesis, or pivotal for mastery of subsequent coursework. Too many courses with “C’s” may also be a valid reason for requiring retakes.

Students who are required to retake any course are expected to receive a "B" or higher. Students who are unable to obtain at least a "B" grade after one retake will be referred to the GTPCI Curriculum Committee to determine whether a change in degree program or academic probation is warranted.

PhD Continuing Course Requirements:

PhD students must satisfactory complete 90 credit hours of course work and thesis research. 70 credits are normally taken the first year of study and the remaining 20 credits are taken in subsequent years.

Five additional courses must be taken the second or third year of study which will count towards the 90 credit course requirement. Each course must be at least 3 credits each. Please see timeline on the next page.

PhD and ScM students are required to register for the Research Forum every year after the first didactic year, until all degree requirements are met or they leave the institution.

Requirement Time Line for PhD/ScM Students *updated 8/7/06*

Year	Date	Milestones
First Didactic Year	April 1	Deadline for program application
	Late June	Summer Registration. METHOD OF TUITION PAYMENT must be determined.
	July-August	Summer Term: Seminar Series, Clinical Research Methods Course Any additional suggested coursework. Fall Registration.
	September	First Quarter begins Check 1st term billing at the end of the month
	November	Second Quarter begins -- Professional Goals & Development Course ***-- Academic Advisors Assigned and required meetings are expected to begin*** -- Begin to explore research topics
	December	3rd and 4th Term registration
	January	Third Quarter begins -- Begin thesis development (grant writing) -- Quarterly contact with GTPCI advisor Check Billing for 3rd & 4th Term at the end of month
	March	Fourth Quarter begins -- Completion of thesis development (mid May) -- Quarterly contact with GTPCI advisor
	Late May	Comprehensive Exam
	Early July	Quarterly meeting with advisor to begin selecting a Thesis Committee & Additional Coursework Plan Due Begin Planning Preliminary Oral Exam
Second	August	Thesis Committee MUST be selected and a proposed date for the Preliminary Oral Exam MUST be scheduled & submitted Fall registration/Selection of Additional Coursework 5 classes for the second year have been selected and approved
	September-May	Additional courses as selected and approved. Deviation in the originally submitted plan may result in personal liability of tuition fees. Check Billing for each term. Additional courses as required/desired
	December	Contact with GTPCI Advisor 3rd and 4th Term registration (reg. for Research Forum in 4th term)
	March (latest)	ScM: Thesis Readers Submitted PhD: Prelim Oral Exam must be completed
	May	Commencement: Degree Awarded
	July	Contact with GTPCI Advisor
Third (and any subsequent years)	August	Fall registration Thesis Research
	September-May	Thesis Research and/or additional courses as approved. Deviation in the originally submitted plan may result in personal liability of tuition fees. Check Billing for each term
	December	Contact with GTPCI Advisor 3rd and 4th Term registration (reg. for Research Forum in 4th term)
	March (latest)	PhD: Thesis Readers Submitted & Final Oral Scheduled
	May	Commencement: Degree Awarded
	July	Contact with GTPCI Advisor
	Submission deadlines for graduation can be found at http://www.jhsph.edu/student_affairs/registrar	

Courses offered by the GTPCI Degree programs

390.612 DESIGN AND ANALYSIS OF CLINICAL TRIALS

(3 units) First term. Dr. Piantadosi. Enrollment minimum of 5. Jointly offered with the School of Medicine.
Emphasizes quantitative design of randomized comparative studies and considers ethics, early developmental (non-randomized) trial designs, and monitoring/interim analyses. Topics include principles of terminology and study design, theoretical and practical aspects of randomization, quantitative design parameters (e.g., sample size and power), monitoring and interim analysis, analysis and reporting, and special designs, such as factorial and cross-over trials. Student evaluation based on class participation, five or six homeworks, each of which consists of a two-page memo discussing some problem or aspect of clinical trials.

390.631 PRINCIPLES OF DRUG DEVELOPMENT
(2 units) First term. Dr. Flexner
Presents principles underlying preclinical and clinical development of new therapeutic drugs and procedures. Describes and evaluates specific examples, and discusses legal and ethical regulations that apply to drug development. Student evaluation based on an exam.
Prerequisite: Consent of instructor for non-GTPCI students.

390.701-702 THESIS PREPARATION (GRANT WRITING) I AND II
(2 units third term/4 units fourth term) Third and fourth terms. Drs. Adkinson and Levine
These courses must be taken in sequence.
Students consider the principles of research strategy, the requirements of funding agencies, and choosing a research area of interest together with a suitable mentor. With mutual review and criticism, each student develops a research plan in the format of an NIH K23 application, which forms the basis for clinical research activity in the subsequent two years. Student evaluation is based on written assignments and the final research plan.

390.703 PRESENTATION SKILLS
(1 unit) Fourth Term. Ms. Sanders. Jointly offered with the School of Medicine.
Prepares students to organize and deliver an effective scientific presentation. Focuses on designing a scientific talk, including preparing effective visual aids. Complements 390.701-702, at the end of which students are required to present their work. Student evaluation based on the presentation.
Prerequisites: Restricted to students in Graduate Training Program in Clinical Investigation enrolled in 290.701-702.

390.710-711 BIOMEDICAL WRITING I AND II
(2 units each for first and second term) First and second terms. Dr. Deborah McClellan
Introduces the process of writing peer -reviewed research paper and provides a brief overview of grant proposal writing. Emphasizes a logical organization, clear writing, and an understanding of readers and reviewers expectations. Students prepare selected sections of a first draft of a research paper based on their own research, and they receive feedback on their drafts through in-class discussion and written comments from the instructor. Evaluation based on homework assignments and class participation.
Prerequisite: Restricted to students in the Graduate Training Program in Clinical Investigation.

390.751 SEMINARS IN CLINICAL INVESTIGATION.
(2 units) Second term. Dr. Flexner
Presents issues in clinical research, exemplified by readings from classical papers and contemporary literature. Student evaluation is based on a presentation.
Prerequisite: Restricted to students in the Graduate Training Program in Clinical Investigation.

390.801 PROFESSIONAL GOALS AND OBJECTIVES
(1 unit) Second term. Drs. Flexner and Adkinson

Consists of didactic sessions focused on career development and mentoring, meetings between students and their academic advisors and/or potential research mentors, to identify a single area or research focus and discuss short- and long-term career goals. Student evaluation based on a precis of proposed research plans.
Prerequisite: Restricted to students in the Graduate Training Program in Clinical Investigation.

390.675 SOCI SERIES: OUTCOMES AND EFFECTIVENESS RESEARCH
(3 units) Fourth Term Evening Course. Drs. Neil Powe and Peter Provost
Students will explore the applications of methods for assessing patient outcomes of care in inpatient and managed care settings, and the methods used to assess the contributions of treatment, patient characteristics, access arrangements and other factors on disease outcomes. The range of outcomes to be examined includes clinical/disease outcomes, functional status, quality of life, satisfaction, and cost outcomes. The course will explore conceptual modeling of treatment/outcomes relationships including decision analysis, the range of data sources, data collection strategies, statistical modeling, and application of the information including the use of systematic reviews. The course will be graded based on class participation in discussions, a discussion on an article, and a final project where students will develop an outcomes or effectiveness proposal. Prerequisites include epidemiology and statistics from the science of clinical investigation.

390.673 SOCI SERIES: ETHICAL AND REGULATORY ISSUES IN CLINICAL RESEARCH
(3 units) First term. Evening course. Ds. Adkinson, Fost, Goodman and Briefel
Enrollment minimum of 10, maximum of 30. Jointly offered with the departments of Biostatistics and Epidemiology.
Explores ethical issues central to clinical research, reviews clinical investigation regulations and their application to common clinical research scenarios, examines the role of IRB's and the impact of good clinical practices for clinical trials. Student evaluations based on written assignments.

390.820 THESIS RESEARCH IN CLINICAL INVESTIGATION
After the didactic year is completed, GTPCI students must continually register each term.
Prerequisite: Restricted to students in the Graduate Training Program in Clinical Investigation.

390.855 RESEARCH FORUM IN CLINICAL INVESTIGATION
(1unit) Fourth term. Drs. Adkinson and Piantadosi
A monthly research forum, lasting 90 minutes, in which advanced fellows will present interim research findings and plans for discussion with colleagues and faculty. Pass/Fail based on attendance and presentation participation.

390.721-390.722 PLANNING AND FUNDING CLINICAL RESEARCH I AND II (MPH CAPSTONE)
(2 units each term) Third and Fourth terms. Dr. Flexner
Considers the principles of successful clinical research strategies and the requirements of funding agencies. Students identify a defined research project together with a suitable team of mentors and collaborators. With mutual review and criticism, each student develops a written research proposal in the format of a grant application which integrates the scientific principles of the GTPCI curriculum. Designed as a capstone project for GTPCI MHS candidates. Student evaluation is based on the final written grant application and associated materials.

550.710 CLINICAL RESEARCH METHODS
(6 units) Fourth term. Drs. Flexner, Goodman, and Louis
Presents fundamental concepts and methods used specifically in clinical research. The two-course sequence covers three overarching topics: Measurement, Design and Diagnosis/prediction. This first course covers measurement and design. The measurement module covers basic concepts of measurement, with specific application to measurement

technologies used in clinical research, from the lab to surveys. The design component covers commonly used designs in clinical research, such as early phase, crossover and factorial designs, as well as the issues of surrogate endpoints and problems of multiplicity. Student evaluation based on in class mid-term and take-home final.

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Required Courses offered by other School of Public Health Departments

340.655 METHODS IN CLINICAL RESEARCH
(6 units) Summer term. Drs. Klag, Guallar, Eliseo, and Goodman
Enrollment maximum of 30. Students must pre-register for this course. Provides an intensive two-week introduction to clinical research methods, emphasizing epidemiological, biostatistical, and computing methods. Hand-outs and homework exercises provided at each session. Student evaluation based on paired pre- and post-test of knowledge base. Prerequisites: Prior submission of an abstract for research project and consent of instructor.
Offered by the Department of Epidemiology

340.751 EPIDEMIOLOGIC METHODS I
(5 units) First term. Drs. Platz and Samet
First offering in the Epidemiologic Methods sequence. Introduces students to history, principles, and concepts of epidemiologic research. Covers epidemiologic reasoning and causal inference, models of disease causation and prevention, and the cohort framework for characterizing the health of populations. Presents measures of population health, measures of association, and screening. Provides experience through laboratory problems with epidemiologic methods and inference, calculation of population health measures, and literature interpretation. Students evaluation based on 20% Written assignment(s), 40% Midterm examination, 40% Final examination. Offered by the Department of Epidemiology

340.752 EPIDEMIOLOGIC METHODS II
(5 units) Second term. Drs. Guallar and Jacobson
Second offering in the Epidemiologic Methods sequence. Builds on the concepts of epidemiologic reasoning, causal inference, and cohort design taught in Epidemiologic Methods 1. Provides a detailed presentation of threats to validity (information, confounding and selection bias), precision, and study generalizability. Discusses a wide range of epidemiologic designs in detail, together with their advantages and limitations. Provides experience through laboratory exercises with epidemiologic methods and inference, issues in study design, calculation of measures of association, and literature interpretation. Student evaluation based on 20% Written assignment(s), 40% Midterm examination, 40% Final examination. Offered by the Department of Epidemiology.

340.753 EPIDEMIOLOGIC METHODS III
(5 units) Third term. Drs. Gange and Mehta
Third offering in the Epidemiologic Methods sequence. Expands on the presentation of modern epidemiologic inference emphasizing the theory and practice of epidemiologic data analysis. Covers, in detail, detection and analysis of confounding and effect modification using multivariable models in the context of the major epidemiological study designs. Develops an understanding of the underlying principles & assumptions, practical application, and correct interpretation of the epidemiologic results using appropriate multivariable models. Provides experience through laboratory exercises with applying epidemiologic analysis in both infectious and non-infectious disease settings. Student Evaluation based on 20% Written assignment(s), 40% Midterm examination, 40% Final examination. Offered by the Department of Epidemiology.

140.621 STATISTICAL METHODS IN PUBLIC HEALTH I
(4 units) First term. Dr. Diener-West
Introduces the basic concepts and methods of statistics as applied to diverse problems in public health and medicine. Demonstrates methods of exploring, organizing, and presenting data, and introduces fundamentals of probability, including probability distributions and conditional probability, with applications to 2x2 tables. Presents the foundations of statistical inference, including concepts of population, sample parameter, and estimate; and approaches to inferences using the likelihood function, confidence intervals, and hypothesis tests. Introduces

and employs the statistical computing package, STATA, to manipulate data and prepare students for remaining course work in this sequence. Student evaluation based on problem sets and exams. Prerequisite: Consent of instructor required for non-public health students. Offered by the Department of Biostatistics Special Comments: One 90-minute lab per week: M-F 1:30-3:00 or M, T, Th 3:30-5:00. As soon as you register, go to the website http://www.biostat.jhBSPH.edu/courses/bio621/ to sign up for ONE lab. You will receive confirmation by email. Course Materials Fee is $30.00.

140.622 STATISTICAL METHODS IN PUBLIC HEALTH II

(4 units) Second term. Dr. Diener-West

Presents use of likelihood functions, confidence intervals, and hypothesis tests to draw scientific inferences from public health data. Discusses null and alternative hypotheses, Type I and II errors, and power. Develops parametric and non-parametric statistical methods for comparing multiple groups (ANOVA). Also introduces measures of association and simple linear regression. Addresses methods for planning a study, including stratification, balance, sampling strategies, and sample size. Student evaluation based on problem sets and exams. Prerequisites: 140.621; consent of instructor required for non-public health students. Offered by the Department of Biostatistics. Special Comments: One 90-minute lab per week: M-F 1:30-3:00 or M, T, Th 3:30-5 Labs to be assigned at registration by Dept. Course materials fee is $30.00.

140.623 STATISTICAL METHODS IN PUBLIC HEALTH III

(4 units) Third term. Dr. Diener-West

Presents use of generalized linear models for quantitative analysis of data encountered in public health and medicine. Specific models include analysis of variance, analysis of covariance, multiple linear regression, logistic regression, and log-linear regression for incidence rates. Student evaluation based on problem sets, a data analysis project and exams. Offered by the Department of Biostatistics Prerequisites: 140.622; consent of instructor required for non-public health students.

Offered by the Department of Biostatistics

140.624 STATISTICAL METHODS IN PUBLIC HEALTH IV

(4 units) Fourth term. Dr. Tonascia

Expands students' abilities to conduct and report the results of a valid statistical analysis of quantitative public health information. Develops more advanced skills in multiple regression models, focusing on log-linear models and on techniques for the evaluation of survival and longitudinal data. Also presents methods for the measurement of agreement, validity, and reliability. Student evaluation based on problem sets, a data analysis project, and a final exam. Prerequisites: 140.623; consent of instructor required for non-public health students. Offered by the Department of Biostatistics

140.651- 652 METHODS IN BIOSTATISTICS I AND II

(4 units per term) First and second terms. Departmental faculty. Contact: Mary Joy Argo

Presents fundamental concepts in applied probability, exploratory data analysis, and statistical inference, focusing on probability and analysis of one and two samples. Topics include discrete and continuous probability models; expectation and variance; central limit theorem; inference, including hypothesis testing and confidence for means, proportions, and counts; maximum likelihood estimation; sample size determinations; elementary non-parametric methods; graphical displays; and data transformations. Student evaluation based on several problem sets and one exam each term. Prerequisite: Working knowledge of calculus and linear algebra. Offered by the Department of Biostatistics

140.653- 654 METHODS IN BIOSTATISTICS III AND IV

(4 units per term) Third and fourth terms. Dr. Zeger

Focuses on regression analysis for continuous and discrete data, and data analyses that integrate the methods learned in 140.651-652. Regression topics include simple linear regression; a matrix formulation of multiple linear regression; inference for coefficients, predicted values, and residuals; tests of hypotheses; graphical displays and regression diagnostics; specific models, including polynomial regression, splines, one- and two-way ANOVA; variable selection non-parametric regression; log-linear models for incidence rates and contingency tables; logistic regression; and generalized linear models. Student evaluation based on problem sets, a data analysis project, and one exam each term. Prerequisites: 140.651-652. Offered by the Department of Biostatistics

340.606 SYSTEMIC REVIEWS AND META-ANALYSIS

(4 units) Third term. Drs. Dickerson, Goodman, and Guallar

Presents basic methods in qualitative and quantitative meta-analysis, including formulating a hypothesis that can be addressed via meta-analysis, methods for searching the literature, abstracting information, and synthesizing the evidence. Quantitative methods include Bayesian and likelihood approaches to meta-analysis. Student evaluation based on problem sets and a meta-analysis project. Prerequisites: 340.601, and 140.621-622 or former 140.602

550.860.01 RESEARCH ETHICS

(1 units) Second term. Dr. Sharon Krag

Presents information concerning issues related to the responsible conduct of research, such as authorship, data management, data ownership, guidelines of professional conduct, research fraud or scientific misconduct, academic ethics, conflict of interest, federal and institutional guidelines related to research using human and animal subjects, ethical issues involving vulnerable subjects in research, confidentiality, the Institutional Review Board (IRB) and the Institutional Animal Care and Use Committee (IACUC). Uses case studies to stimulate discussion. Student evaluation based on a take-home essay exam.

550.865 PUBLIC HEALTH PERSPECTIVES I AND II

(1 unit each term). First and second terms. Dr. Krag

Introduces the substantive and methodologic basis for public health research presenting human health throughout the life span; the major causes of morbidity and mortality; and strategies for health interventions in each stage of life. Also provides examples of common public health methodology drawn from the quantitative, qualitative, biologic, social, and behavioral sciences. Highlights principles of high-quality research, including the value of a population perspective, interdisciplinary cooperation, the importance of new measurement techniques, and the interface between theory and practice. Gives students information about the interactions between the public and the researcher. Student evaluation based on a take-home exam and participation in group projects.

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340.645 INTRODUCTION TO CLINICAL TRIALS
(3 units) Second term. Drs. Martin and Holbrook
Introduces clinical trial design in the context of epidemiological concepts, covers various topics in the design and conduct of clinical trials, and profiles clinical trials that illustrate these issues. Topics include the definition and history of clinical trials; trial designs, including phase I-IV, cross-over, factorial, and large, simple designs; internal and external validity; controls, randomization, and masking; ethical issues; data analysis principles; monitoring of accumulating safety and efficacy data; and adverse event reporting. Student evaluation based on assignments and final exam. Note: this may not be taken as an advanced PhD elective; it is intended as a substitute for 390.612 for MHS students.

340.660 PRACTICAL SKILLS IN PLANNING, ORGANIZING, AND CONDUCTING CLINICAL RESEARCH IN EPIDEMIOLOGY
(3 units) First term. Drs. Jacobson and Fink
Emphasizes the practical aspects of conducting and organizing a clinical research project. Focuses on developing skills to conduct and manage a research protocol, monitor the data collection, manage the data, and disseminate results. Covers basic components of a clinical research team, the components of good clinical practice, the responsibilities, expertise and tasks that each member is expected to perform, and organizational, logistical and attitudinal issues that need to be addressed in producing an effective research group specifically translational research and the kinds of issues that arise in the multi-disciplinary teams brought together to conduct it. Student evaluation based on laboratory exercises, class participation.

309.714.01 PATIENT OUTCOMES AND QUALITY OF HEALTH CARE
(4 units) Fourth term. Dr. Neil Powe
Examines the role of patient outcomes studies (health status/quality of life, clinical status, satisfaction, and cost of care) in assessing quality of health care. Examines conceptual approaches to understanding the relationship of treatment, provider, and system characteristics to patient outcomes for acute and chronic conditions managed in outpatient or inpatient settings. Uses major outcomes studies to examine issues related to conceptualization, measurement, severity adjustment, statistical modeling, and interpretation. Focuses on the utility of patient outcomes results for improving the quality of health care services. Includes lab sessions. Student evaluation based on a final exam and presentations of group projects examining outcomes for specific diseases/health care delivery systems and proposing how to extend knowledge to contribute to better outcomes and improved quality of health care. Prerequisites: 309.712 and 311.615 preferred, at least one required.

313.630.01 COST-BENEFIT ANALYSIS: THEORY AND TECHNIQUES
(3 units) Third term. Dr. Kevin Frick
Reviews the basic theory of welfare economics underlying the techniques of cost-benefit, cost effectiveness, and cost-utility analysis. Covers opportunity cost, the valuation of time-streams of net benefits, and problems of valuation arising from the non-existence of markets. Also focuses on techniques for monetary valuation of health states (e.g., willingness to pay in contingent markets). Student evaluation based on a short paper, a midterm exam, and a final exam. Prerequisites: 313.640-641. Instructor consent required.

313.631.01 COST-EFFECTIVENSS, COST-UTILITY, AND THEIR APPLICATIONS
(3 units) Fourth term. Dr. Kevin Frick
Reviews techniques for cost-effectiveness and cost-utility analysis. Emphasizes framing the question, the perspective of the analysis, methods for valuing outcomes, such as the use of quality adjusted life years (QALYs), and presentation of the results. Students critique studies in the literature and present them in class. Student evaluation based on problem sets, a mini cost

effective analysis, and a final paper. Prerequisites: 313.630

312.633.01 HEALTH MANAGEMENT INFORMATION SYSTEMS

(3 units) Fourth term. Dr. Michael Minear

Course is tailored to the needs of health care administrators. Provides a global perspective on the use of information systems in heath care organizations, including provider institutions, insurers and physicians practices. Focuses on fundamental concepts of management information systems; systems planning and selection; current issues in health care informatics; clinical, financial and administrative applications; current and future role of the internet; overview of data confidentiality and security. Pertinent guest lectures will address topics and emerging trends in their environments. Student evaluation based on an evaluation of a systems initiative in a health care organization; project proposal (10%), midterm project evaluation (40%), and final project evaluation (50%). Prerequisites: 312.612 and 312.619

312.623.01 FINANCIAL MANAGEMENT IN HEALTH CARE I

(3 units) Third term. Dr. John Ellis

Case studies present an overview of financial theory and financial management principles and concepts in a health care setting. Topics include discounted cash flow analysis, long-term debt financing, equity financing, lease financing, capital budgeting, analysis, and forecasting. Student evaluation based on a team-written case analysis (60%) and its oral presentation (40%). Prerequisites: 312.617, 312.619

309.712.01 ASSESSING HEALTH STATUS AND PATIENT OUTCOMES

(3 units) Second term. Dr. Albert Wu

Provides an understanding of the conceptual basis for measures of health; some of the common measures, their properties, and strengths and weaknesses; and a framework for judging the appropriateness of a particular measure for students' own work.
Student evaluation based on two papers. Enrollment minimum 12.

309.615.01 INTRODUCTION TO METHODS FOR HEALTH SERVICES RESEARCH AND EVALUATION

(4 units) Second term. Dr. Anne Riley

Introduces basic methods for undertaking research and program evaluation within health services organizations and systems, and reviews major completed studies. Topics include the relationship between health services research (HSR) and health care policy and management; the multidisciplinary philosophy of HSR; research design, including experimental and quasi-experimental approaches; issues of reliability, validity, and measurement; survey research techniques; use of existing data systems; basic cost benefit and effectiveness analysis; and measurement of quality of care. Students critique published HSR studies and develop a design for a research or evaluation project. Intended for students who will be carrying out policy research, social science research, or program impact evaluation within health delivery systems; or applying the results of HSR done by others. Student evaluation based on mid-term and final exams.

300.651.01 INTRODUCTION TO THE U.S. HEALTHCARE SYSTEM

(4 units) Offered Various Terms. Health Policy and Management faculty

Describes and analyzes the way that health care is financed in the U.S. in both the public and private sectors and how this affects delivery of services and health outcomes. Explores how hospitals and physicians in the United States are paid and organized, and the major issues they face in the current environment. Presents conceptual for access to care, vulnerability, health insurance, primary care, cost containment, managed care, long term care, and quality of care. International comparisons of health care systems examine alternative methods of organizing and financing health services within the U.S. and other developed countries. Introduces the major policy issues concerning the organization, financing, and delivery of healthcare facing the nation. Student evaluation based on mid-term and final essays.

140.641.01 SURVIVAL ANALYSIS

(3 units) Third term. Dr. Mei-Cheng Wang

Discusses the basic concepts of survival analysis, including hazard functions, survival functions, types of censoring, Kaplan-Meier estimates, logrank tests, and the generalized Wilcoxin tests. Parametric inference includes the exponential and Weibull distribution. Discusses the proportional hazard models and extensions to time-dependent covariates. Clinical and epidemiological examples illustrate the various statistical procedures.

140.655.01 ANALYSIS OF LONGITUDINAL DATA

(4 units) Third term. Dr. Francesca Dominici

Covers statistical models for drawing scientific inferences from longitudinal data. Topics include longitudinal study design; exploring longitudinal data; linear and generalized linear regression models for correlated data, including marginal, random effects, and transition models; and handling missing data. Intended for doctoral students in quantitative sciences.

Additional Course Information can be found in the BSPH Catalogue and at http://commprojects.jhBSPH.edu/courses/

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