GRADUATE TRAINING PROGRAMS IN CLINICAL INVESTIGATION

About

The Graduate Training Programs in Clinical Investigation (https://www.jhsph.edu/academics/graduate-training-programs-in-clinical-investigation/) (GTPCI) are the first of their kind. A joint venture between the Johns Hopkins Bloomberg School of Public Health (BSPH) and the Johns Hopkins School of Medicine (SOM), GTPCI trains clinicians to be more effective clinical scientists. Participants gain the skills necessary to design and conduct clinical investigations of emerging medical treatments and technologies, and to apply new diagnostic techniques and approaches to the study of human pathophysiology. We train mostly faculty, postdoctoral fellows and other allied health professionals working with human subjects in clinical investigation. Our graduates pursue careers in academia, and as independent clinical investigators at pharmaceutical firms and federal regulatory agencies.

BACKGROUND

In 1989, a Task Force on Clinical Research in the Department of Medicine reported results of a survey in which one-third 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 SOM levels, and eventually enlarged to include the BSPH. At the same time, concerns about the adverse trends for clinical investigation and about the inadequate supply of qualified clinical investigators were being expressed at the national level. Johns Hopkins’ response to these local and national needs was the creation of GTPCI 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 SOM. It involves one year of full-time academic classroom work, followed by at least two years of mentored training in clinical research. In 1996, the University approved expansion of the program to include a PhD degree in Clinical Investigation. Normally, an interested fellow applies for admission during their 1st year of clinical post-doctoral training, or for longer training programs, after completion of more than 80% of required subspecialty training. The 1st 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, a MHS degree option was added for those who seek access to the didactic curriculum without the requirement for a thesis project.

CURRICULUM FOR THE DIDACTIC YEAR

The didactic year begins in the summer with a short course on clinical research methods and a seminar series 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: Biostatistics, Epidemiology, and Clinical Investigation. For the Biostatistics and Epidemiology cores, a standard series of courses is drawn from the existing BSPH Graduate Curriculum. Courses in the Clinical Investigation core are specifically designed for students in the GTPCI program and largely taught by SOM 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, ethical and regulatory issues, drug development, analytical methodology, outcomes effectiveness research and a seminar series in clinical investigation. A course listing can be found in the Requirements tab and course descriptions (https://e-catalogue.jhu.edu/course-descriptions/clinical_investigation/) are found here.

All degree students enter into an intensive grant writing/thesis development course during the 3rd and 4th terms of their didactic year, out of which comes a thesis research proposal. All degree students are required to successfully complete a written comprehensive examination at the end of the didactic year. Thereafter, research progress is monitored by a thesis committee according to the rules of the University.

FUNDING

For admission to the PhD degree program, the nominating department or division must guarantee three years of stipend support as well as identify a source for the tuition costs for the didactic year. For many students, existing NIH training grants (T32 or F32) 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 (CTSA) provides for administrative, development and enrichment costs of the program. Participation in the degree programs can also be funded by an NIH KL2 grant which select applicants competitively each year to be NIH Clinical Research Scholars. They are junior faculty, who receive stipends/salary, full tuition and some research support for at least 2 years. Applications are received each December for awards beginning the following July. Individual K23 (or other K awards) can also be used to fund participation in the program.

EXPERIENCE TO DATE

As of June 2021, 436 students have entered the program: 208 in thesis-degree tracks and 228 in the MHS track. Ten new students matriculated for the 2021-22 academic year. As of June 2021, 351 students have completed their degree requirements and 40 are currently in residence.

Programs

- Graduate Training Programs in Clinical Investigation, MHS (https://e-catalogue.jhu.edu/public-health/departments/graduate-training-clinical-investigation/graduate-training-clinical-investigation-mhs/)
- Graduate Training Programs in Clinical Investigation, PhD (https://e-catalogue.jhu.edu/public-health/departments/graduate-training-clinical-investigation/graduate-training-clinical-investigation-phd/)

GTPCI POLICIES AND IMPORTANT PROGRAM INFORMATION:

ADVISORY COUNCIL AND SUB-COMMITTEES:

An Advisory Council (https://www.jhsph.edu/academics/graduate-training-programs-in-clinical-investigation/advisory-council/) appointed from faculties of the SOM and the BSPH 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
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Review, and Visiting Scholars; these committees also contain faculty not on the Advisory Council.

**Admissions Committee:**
- Dale Needham, MD, PhD Chair
- Professor of Pulmonary & Critical Care

**Gregory Lucas, MD, PhD**
- Professor of Infectious Disease

**Richard F. Ambinder, MD**
- Professor of Oncology - Hematologic Malignancies

**Khalil Ghanem, MD, PhD**
- Professor of Infectious Disease

**Edgar (Pete) Miller, MD, PhD**
- Professor of Medicine & Epidemiology

**Research Review Committee:**
- Richard Rothman, MD, PhD
- Professor of Emergency Medicine

**Diane E. Griffin, MD, PhD**
- Professor of Microbiology, Medicine, & Infectious Disease

**Allan Gelber, MD, PhD, MPH**
- Professor of Rheumatology

**Craig Hendrix, MD**
- Professor of Clinical Pharmacology

**Curriculum & Academic Standards Committee:**
- Khalil Ghanem, MD, PhD
- Professor of Infectious Disease

**Charles W. Flexner, MD**
- Associate Director, GTPCI Program

**O. Joseph Bienvenu, MD, PhD**
- Associate Professor of Psychiatry

**Frank Lin, MD, PhD**
- Associate Professor of Otolaryngology

**Marie Diener-West, PhD**
- Professor of Biostatistics
- Chair of MPH Program

**Visiting Scholars Committee:**
- Dorry Segev, MD, PhD
- Professor of Surgery & Epidemiology

**Associate Vice Chair, Department of Surgery**

**N. Franklin Adkinson, Jr., MD**
- Director, GTPCI Program and AC Chair
- Professor of Allergy & Clinical Immunology

**Research Forum Delegate**

**David Levine, MD**
- Professor of General Internal Medicine

**Program Delegate to Committee on Academic Standards**

**Khalil Ghanem, MD, PhD**
- Professor of Infectious Disease

**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 PhD or MHS program; (b) review and approve admission applications for all degree programs, 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. The Committee is composed of a Chair and 3-4 members of the Advisory Council.

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; and (d) periodically review written reports of academic advisors, and alert the Program Director/Associate Director and the Advisory Council when problems are identified.

The **Curriculum and Academic Standards Committee** shall: (a) continually review and refine as necessary the curriculum requirements for the PhD and MHS programs; (b) to obtain and review student evaluations of the curriculum components; (c) to review annually academic performance. This Committee is chaired by the Associate Program Director and has 3-4 members.

The **Visiting Scholars Committee** shall: (a) receive and evaluate suggestions for enrichment opportunities for GTPCI programs - 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 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 programs, Welch Center programs, Health Services research groups and others.

**TUITION, FEES, AND BILLING GUIDELINES**

ALL FELLOWS 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 for tuition, course materials fees, matriculation fees, books and supplies.

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

Continuing PhD students, after the 1st 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 three 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.

Students are personally responsible for late fees.

Faculty are expected to use tuition remission benefits, via the university tuition remission form (https://hr.jhu.edu/wp-content/uploads/2019/03/trffacandstaff.pdf).

**COURSEWORK AND GRADING**

The BSPH does not accept transfer credits; however GTPCI will waive required courses if taken within the past five years at BSPH, or if the student can verify via exam or transcript that competencies for that course have been mastered. However, such waivers do not reduce the required number of academic credits for a degree; therefore all courses waived must be substituted with an elective course.

GTPCI will also give academic credit for up to 16 hours of required coursework, completed with an A or B, within the past three years at the BSPH if those credits did not apply to another degree earned. Credit is not given for previously taken elective courses, or coursework not taken for a grade.

**Grading Policies:**

All core (required) courses (including the five required advanced courses taken in the 2nd and/or 3rd year for PhD students) MUST be taken for a letter grade. Electives may be taken for Pass/Fail, unless the elective is taken in place of a required course, which must be taken for grade.

PhD students must maintain a cumulative GPA of 3.00 to remain in good standing, and must earn a B or better in all required courses. Any grade of C in a required course must be retaken for a B or better or GTPCI can recommend a suitable replacement course for a grade of B or better.

MHS students must maintain a cumulative GPA of 2.75 to remain in good standing. Any grade of D or F in a 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.

Courses taken for audit do not count toward the PhD and MHS registration requirements.

**SPECIAL STUDIES**

Special Studies (390.840) is an ad hoc course designed to provide educational experiences not available in the formal curriculum. It can involve directed reading or writing, original research, or clinical or administrative experience. It must be approved by your academic advisor and by either Dr. Adkinson or Dr. Flexner, and it must be supervised by GTPCI faculty or another approved mentor. Special Studies cannot generally be substituted for a required core or advanced course requirement in GTPCI. In order to register for Special Studies, you must have your advisor’s approval of a written course plan with a defined workproduct. Documentation of the activities completed must also be submitted to the person assigning the grade at the end of the term (e.g., a clinical protocol, draft manuscript, or other written report of activities). They will evaluate the work performed and assign a grade of pass or fail based on the quality of the work. One credit of Special Studies is considered the equivalent of three hours of personal work per week, either in or out of a classroom.

**LEAVE OF ABSENCE**

Students in need of a Leave of Absence (https://www.jhsphs.edu/offices-and-services/student-affairs/resources/student-policies/_documents/Academic_Leave_of_Absence.pdf) must submit a request to the GTPCI Advisory Council Committee, and if approved, the student must complete a LOA form which can be obtained from the Registrar’s Office.

**How will the didactic (1st) year be affected by missing a term(s)?**

Many required GTPCI courses are part of a series of courses or multi-term; therefore enrollment in subsequent terms is contingent upon completion of the preceding course/term. For example, if a student is on LOA in 2nd term and misses the second courses in the Epi and Biostat series, the student can not continue the course series in the 3rd and 4th terms, but must restart the series with the 2nd term in the following year. Other courses that may have Epi and Biostat as prerequisites may also be affected, so the impact on curriculum choices is major when there is a LOA in the didactic year of the GTPCI program.

**How will the PhD residency requirement be affected by missing a term(s)?**

PhD students are required to complete a minimum of four consecutive full-time terms of 16 credits to fulfill the degree; generally students meet this requirement at the end of the didactic year. If LOA is taken during this time, the student must register full-time (16 credits) upon returning from LOA, even if the term is during the 2nd year when GTPCI PhD students are normally only required to register part-time. Full-time registration must continue until four consecutive terms of 16 credits are completed.

**How will the completion of the MHS degree be affected by missing a term(s)?**

The inability to take required courses during the didactic year due to a LOA will not allow MHS students to complete the 70 credits of required coursework in one year. Therefore completion of the MHS degree must be extended to a 2nd year.

**PARENTAL LEAVE**

Students who take Parental Leave (https://hr.jhu.edu/benefits-worklife/time-off/leave-for-new-parents/) must complete a LOA form which can be obtained from the Registrar’s Office. Those who take Parental Leave during the didactic year can anticipate the delays in program completion that are detailed in the LOA policy.

**Will my KL2, T32, or F32 stipend be affected by taking parental leave?**

According to the National Institutes of Health regulations, trainees (KL2, T32, or F32 NRSA awardees) may continue to receive stipends up to 15 calendar days of sick leave per year. Sick leave may be used for the medical conditions related to pregnancy...
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and childbirth pursuant to the Pregnancy Discrimination Act (42 USC 2000 e(k)). Trainees may also receive stipends up to 30 calendar days of parental leave per year for the adoption or the birth of a child when those in comparable training positions at the grantee institution have access to paid leave for this purpose and the use of parental leave is approved by the program director.

INTERNATIONAL STUDENTS

The GTPCI program may sponsor a student visa for one year of full-time study to complete the MHS program. Ordinarily, visa sponsorship for PhD applicants will be the responsibility of the sponsoring home clinical department, but in unusual and appropriate situations the GTPCI may sponsor or co-sponsor a visa or visa extension for a PhD student. This would be determined on a case by case basis. Please consult the Office of International Services (https://ois.jhu.edu/) (OIS) for proof of funding and other requirements.

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 OIS 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 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.

Generally, ECFMG certification is 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 may be 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.

Foreign applicants are not entitled to U.S. Federal Aid. Therefore they must be sponsored financially by their home organization or government.