

# GRADUATE TRAINING PROGRAMS IN CLINICAL INVESTIGATION, PHD

The PhD degree is our flagship program for sub-specialty physicians, leading to both clinical board eligibility in a medical discipline and the PhD.

Candidates take one year of full-time didactic instruction after an initial training year in a medical or surgical subspecialty. This provides the scientific grounding for subsequent original research. GTPCI faculty and a preceptor from the fellow's SOM home division or department jointly mentor thesis research. Fellows already enrolled in a clinical fellowship program at Johns Hopkins usually apply during their first year of clinical training.

PhD candidates must complete 90 credit hours of instruction, including one full year of full-time coursework, with additional specialized coursework during the following two years, during which thesis research is conducted. A comprehensive exam is given at the end of the didactic year.

Candidates must satisfy all University requirements for the PhD, including preliminary oral examinations and thesis preparation and defense.

## Program Requirements

Course location and modality is found on the JHSPH website (<https://www.jhspth.edu/courses/>).

## Requirements for the PhD Degree:

- satisfactory completion of 90 credit hours of course work (including thesis research credits)
- 5 additional advanced elective courses to be taken AFTER the 1<sup>st</sup> year in the 2<sup>nd</sup> or 3<sup>rd</sup> years; to include PH.140.642 Design of Clinical Experiments – these courses must be at least 3 credits each and taken for grade. They should be advanced methodically and analytically, and are to build on the knowledge/curriculum learned in the 1<sup>st</sup> year. Elective courses taken prior to enrolling in GTPCI or in the 1<sup>st</sup> year do not qualify as one of the 5 advanced electives
- must earn a B or better in all required courses
- continuous registration for the PH.390.855 Research Forum and registration for thesis research each term during the following years
- comprehensive examination at the end of the didactic year
- satisfaction of all university requirements for the PhD, including preliminary oral examination, thesis preparation, and final defense

## PhD Residency Requirement

The JHSPH requires all PhD students to register full-time for a minimum of 16 credits for 4 consecutive terms. This does not necessarily have to be the first 4 terms of enrollment, but the full-time residency requirement must be fulfilled sometime during the PhD program PRIOR to taking the preliminary oral examination.

## Annual Review Requirement – Individual Development Plan (IDP)

The University Doctoral Board requires that each PhD student receive an annual review during every year in their program. This review is expected

to have 3 components: 1. Student self-assessment and Individual Development Plan (IDP form), 2. Monitoring of progress in the program, and 3. Written feedback to the student

## Comprehensive Examination

Taken after successfully completing the core coursework. It is a take-home exam distributed at the end of 4<sup>th</sup> term, in which students have 7 consecutive days for completion. One re-take of the exam is allowable with 3 days/72 hours for completion. If the exam is not passed on the second attempt, the student will be removed from the program.

## Preliminary Oral Examination

All PhD students must complete the PH.550.600 Living Science Ethics - Responsible Conduct of Research course prior to taking the preliminary oral exam.

The preliminary oral examination should ordinarily take place no later than December following the completion of the didactic year and comprehensive written examination. It is a 2-hour exam that serves to determine whether the student has both the ability and the knowledge to undertake significant research in his/her general area of interest. Specifically, the exam committee will be concerned with the student's: 1. capacity for logical thinking, 2. breadth of knowledge in relevant areas, and 3. ability to develop and conduct research leading to a completed thesis.

Students will provide a 10-15 min. presentation of their research topic, and discussion of this research topic may serve as a vehicle for determining the student's general knowledge, methodological approaches, and research capacity. This examination is not intended to be a defense of a specific research proposal.

When the student's thesis 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 thesis committee agree by unanimous vote that the student "passes" his/her oral thesis defense, they will then recommend to the Graduate Board of the University, the awarding of the PhD degree.

## Documentation of Thesis Progress

In addition to the JHSPH annual review requirement, GTPCI requires documentation of each thesis degree student's interaction with their thesis committee, as it pertains to their thesis progress. The policy is as follows:

1. Students must convene with their thesis committee within 6 months after completion of the preliminary oral exam and then every 12 months thereafter. A minimum of 3 members must be present for the meeting. Thesis committee members may participate by teleconferencing if necessary to achieve a quorum.
2. It is the student's responsibility to organize the required meeting of the thesis committee.
3. It is the student's responsibility to present the report form at the meeting, obtain committee member signatures, and return the form to the GTPCI Program office.
4. The Program will notify each student and Academic Advisor via e-mail one month prior to the due date.

## Documentation Form

1. The form will be distributed for completion to students during the December and May monthly GTPCI Research Forum.

2. Students who are absent from the Research Forum will be notified via e-mail to complete the form and return it to the GTPCI Program Office.

### PhD Continuing Course Requirements:

After all required coursework is completed, PhD students must continuously be registered for a minimum of 3 credits per term until graduation.

PhD students are required to register for and attend the monthly PH.390.855 Research Forum every year after the 1<sup>st</sup> didactic year, until all degree requirements are met or they leave the institution.

Students are expected to attend at least six of the eight 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. The purpose is to provide students with an opportunity to present interim research results and obtain constructive criticisms from their peers and faculty.

The format of the meetings is a brief presentation by the investigator (10-15 minutes) of problems presented by work in progress. Another PhD student 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.

### Final Oral Examination (Thesis Defense)

The structure of the defense includes two parts: an initial public presentation of the thesis work, followed by a closed critical examination by the student's thesis committee.

The public seminar should include a 30 minute presentation by the student, followed by a question period of 15 minutes. Public announcement and invitations should be initiated by the student.

Afterward, the thesis committee and 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, after which they will announce their decision to the student.

Students should schedule a two-hour time block with their thesis committee, and reserve suitable space for both parts of the defense.

The Appointment of Thesis Reader and Final Exam form is DUE ONE MONTH PRIOR TO EXAM DATE.

#### Exam Committee Members - who can serve for GTPCI

ADKINSON, F.	GTPCI or DOM Clinical Immunology
AMBINDER, R.	GTPCI or SOM Oncology
BANDEEN-ROCHE, K.	GTPCI or SPH Biostatistics
BIENVENU, O	GTPCI or SOM Psychiatry
CELENTANO, D.	GTPCI or Epidemiology
DIENER-WEST, M.	GTPCI or SPH Biostatistics
DODSON, J.	GTPCI or SOM Urology
FLEXNER, C.	GTPCI or DOM Clinical Pharmacology

GARONZIK-WANG, J.	GTPCI or SOM Surgery
GELBER, A.	GTPCI or SOM Rheumatology
GHANEM, K.	GTPCI or SOM Infectious Disease
GOTTESMAN, R.	GTPCI or Neurology
GRIFFIN, D.	GTPCI or SPH MMI
HAUT, E.	GTPCI or SOM Surgery
HENDRIX, C.	GTPCI or DOM Clinical Pharmacology
KLAG, M.	GTPCI or DOM GIM
LEVINE, D.	GTPCI or SOM GIM
LIN, F.	GTPCI or SOM Otolaryngology
LUCAS, G.	GTPCI or SOM Infectious Disease
MILLER, P.	GTPCI or SOM Epidemiology
NEEDHAM, D.	GTPCI or SOM Pulmonary
NEWMAN-TOKER, D.	GTPCI or SOM Neurology
PUNJABI, N.	GTPCI or SOM Pulmonary
ROTHMAN, R.	GTPCI or SOM Emergency Medicine
SEGEV, D.	GTPCI or SOM Surgery

### Required Coursework

Completion of Introduction to Online Learning (<https://courseplus.jhsph.edu/core/index.cfm/go/course.home/cid/90/>) is required prior to beginning 1st term.

According to the requirements of the Council on Education for Public Health (CEPH) (<http://e-catalog.jhu.edu/public-health/ceph-requirements/>), all JHSPH degree students must be grounded in foundational public health knowledge. The courses below meet these requirements: 552.601, 552.603, 552.607, 552.608, 552.609, 552.610, 552.611, 552.612.

Code	Title	Credits
PH.390.750	Introduction to Clinical Research (Optional in Summer prior to matriculation)	2
PH.552.601	Foundational Principles of Public Health	0.5
PH.552.603	The Role of Qualitative Methods and Science in Describing and Assessing a Population's Health	0.5
PH.552.607	Essentials of Environmental Health	0.5
PH.552.608	Biologic, Genetic and Infectious Bases of Human Disease	0.5
PH.552.609	Psychological and Behavioral Factors That Affect A Population's Health	0.5
PH.552.610	The Social Determinants of Health	0.5
PH.552.611	Globalization and Population Health	0.5
PH.552.612	Essentials of One Health	0.5
PH.550.600	Living Science Ethics - Responsible Conduct of Research	1
PH.550.860	Academic & Research Ethics at JHSPH	

PH.390.673	Ethical and Regulatory Issues in Clinical Research (or 306.665)	3
PH.390.631	Principles of Drug Development	2
PH.390.751	Seminars in Clinical Investigation	2
PH.390.801	Professional Goals and Objectives	1
PH.390.710	Biomedical Writing I	2
PH.390.711	Biomedical Writing II	2
PH.390.721	Principles of Grant Writing I	2
PH.390.722	Principles of Grant Writing II	4
PH.390.703	Presentation Skills	1
PH.140.621	Statistical Methods in Public Health I (or 140.651)	4
PH.140.622	Statistical Methods in Public Health II (or 140.652)	4
PH.140.623	Statistical Methods in Public Health III (or 140.653)	4
PH.140.624	Statistical Methods in Public Health IV (or 140.654)	4
PH.340.606	Methods for Conducting Systematic Reviews and Meta-Analyses	4
PH.340.751	Epidemiologic Methods 1	5
PH.340.752	Epidemiologic Methods 2	5
PH.340.753	Epidemiologic Methods 3	5
In place of 340.754, choose electives: 5 or more total credits, taken for grade		
16 credits per/term required for 1st-4th terms: choose electives in terms with less than 16		
In 2nd year - must take 5 advanced electives; 3 credits each; taken for grade (including 140.642)		
PH.140.642	Design of Clinical Experiments (1 of 5 advanced electives in 2nd year)	3
PH.390.855	Research Forum (taken each year beginning 2nd year until graduation)	1

**In addition to the Schoolwide policies (<http://e-catalog.jhu.edu/public-health/policies/>), these are the following GTPCI PhD program policies:**

### Academic Adviser

1. An academic adviser will be appointed during the 1<sup>st</sup> term from among the Advisory Council (<https://www.jhsph.edu/academics/graduate-training-programs-in-clinical-investigation/advisory-council/>). Assignments are determined on the basis of perceived mutual interests, availability, and sometimes professional background. Students and their assigned advisers work together with mutual consent. The academic adviser assigned will not be the same person as the research mentor.
2. Each student and assigned adviser are expected to have a face-to-face introductory meeting by the end of 2nd term in the didactic year. This provides an opportunity for at least one detailed discussion regarding career objectives, mentoring arrangements, and thesis development.
3. The academic adviser's responsibility is to: advise student on course work selection and monitor academic performance, provide general mentoring and support for academic issues, and to serve on the student's thesis committee. Students are required to have an introductory meeting no later than the end of 2nd term in the didactic year. Then students are required to contact their academic adviser in June and December in each succeeding research year until a degree is awarded. Each academic

adviser will provide brief, written documentation of these contacts to the Program Office.

4. The academic adviser does not function as the student's advocate which is the role of the research mentor. (Note: JHSPH graduate degree documents frequently use the term "adviser" by which is meant the student's GTPCI academic adviser. Both the academic adviser and research mentor must be present during the preliminary oral exam and participate on the thesis committee/final oral examination).

### Thesis Research Mentors

The principal research mentor is a faculty member in the student's home division or department. Unlike the academic adviser, the research mentor 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 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 mentors may also need to be involved in assisting and directing the student's thesis research. *The GTPCI Program continually emphasizes the importance of establishing a successful mentoring relationship with the research mentor, and with other key faculty who are important for research training or professional development.*

### Thesis Committee

A thesis committee must be established within 3 months of completing the 1<sup>st</sup> didactic year, and each PhD student will use this committee for research oversight through completion of the thesis. PhD students are required to have 5 member committees, who will also serve for the preliminary oral exam AND the final oral examination.

The Academic adviser, Research Mentor, a second GTPCI representative, a JHSPH representative, and another representative outside GTPCI (this can be a SOM person) will serve on the thesis committee. **The sponsoring department is GTPCI** (these are JHSPH forms & guidelines, not SOM). Any faculty listed on the Advisory Council (<https://www.jhsph.edu/academics/graduate-training-programs-in-clinical-investigation/advisory-council/>) or GTPCI Standing Committees can represent GTPCI (the home department). Anyone on the GTPCI committees who has a PRIMARY appointment in JHSPH may also represent "outside department JHSPH". You may check JHSPH faculty appointment status (<https://www.jhsph.edu/faculty/directory/list/>). Questions regarding thesis committee composition should be directed to the GTPCI Program Coordinator.

JHSPH thesis committee forms are available on the JHSPH Portal ([https://my.jhsph.edu/\\_login/PS.JHSPH.Login.aspx?ReturnUrl=%2f\\_layouts%2f15%2fAuthenticate.aspx%3fSource%3d%252FPages%252FDefault%252Easpx&Source=%2FPages%2FDefault%2Easpx](https://my.jhsph.edu/_login/PS.JHSPH.Login.aspx?ReturnUrl=%2f_layouts%2f15%2fAuthenticate.aspx%3fSource%3d%252FPages%252FDefault%252Easpx&Source=%2FPages%2FDefault%2Easpx)). You will need your JHSPH e-mail address and password to log in for access to the forms.

### Acceptable Doctoral Thesis

During the 2<sup>nd</sup> term PH.390.801 Professional Goals and Objectives students will initiate the structured process of considering and choosing among a variety of research topics for career development and thesis requirements.

A PhD 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. It must also include primary data collection which is defined as assimilation

of new information directly from first-hand sources such as surveys, prospective observations, and/or experimentation. It is compiling data from new or original research that (a) have not been previously published and (b) can be subjected to statistical analyses to address a predefined objective or research question. It can also include hypothesis-driven new laboratory assessments of existing samples from a defined population. 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. 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 PhD 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 in evaluating a thesis are: the originality and publication potential of the research, the student's understanding of the details of the methodological and analytic work, the magnitude of the student'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 JHSPH. 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."

## IRB Approval for Thesis Projects

Candidates for thesis-requiring degrees must document IRB approval or exemption for their thesis project(s). If the project is exempt, a brief application process to JHMI 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 committee. Failure to get prospective IRB approval or exemption will result in the thesis being administratively disapproved.

## Important Links

### JHSPH Thesis Guidelines

### JHU Graduate Board Guidelines Applicable to PhD Dissertations

PhD Mentoring (<https://provost.jhu.edu/education/graduate-and-professional-education/phd-mentoring-policies-and-resources/>)

## ScM Degree (only available to those who can not complete the PhD)

The ScM is a thesis-requiring degree which can be awarded to PhD students who cannot fulfill the full set of requirements for a PhD because of curtailed time available, unanticipated research difficulties, or late shifts in thesis projects. Requirements include:

- 70 credit 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 students 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.

Students who transfer to, or remain in the ScM track, must establish a thesis committee within 3 months of completing the 1<sup>st</sup> didactic year. Each ScM student will use this committee for research oversight through completion of the thesis. ScM students are required to have 2 members on their thesis committees.

PhD students who are advised or elect for valid reasons to transfer to the ScM program must receive approval from their thesis committee. From the term the ScM transfer is effective, the program provides students with tuition for up to 4 additional non-summer terms to complete the ScM requirements, after which students will be responsible for their own tuition costs. However, the maximum duration of student enrollment may not exceed 4 years from original matriculation into the PhD/ScM program.

However, an automatic transfer to the ScM candidacy will occur if a PhD student does not form a thesis committee and complete the preliminary oral examination by the end of their 3<sup>rd</sup> academic year. Students matriculating into a thesis-requiring degree program will not be allowed to transfer into the MHS degree program.

## Upon successful completion of the Doctor of Philosophy, students will have mastered the following competencies:

- Maintain an understanding and perspective on the importance of excellent and rigorous clinical research in public health and the practice of medicine
- Take a scholarly, comprehensive, and objective approach to the selection and formulation of a clinical research question
- Identify, interpret, and critique relevant clinical literature
- Effectively communicate scientific information to professionals and the lay public
- Demonstrate proficiency in the clinical skills needed to conduct clinical research and manage study subjects
- Provide advice on clinical research methods to professionals within and outside of the academic medical environment

- Identify analytical laboratory techniques and methodologies appropriate to answer a specific research question for a proposed study
- Prepare a scientific proposal
- Develop and write a study protocol using systematic protocol documentation
- Effectively manage a clinical study team
- Develop and implement an ongoing system for data intake and management
- Recruit study participants in an ethical manner
- Monitor study progress
- Analyze data
- Interpret statistical analysis
- Adhere to regulatory requirements