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 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 BSPH website (https://publichealth.jhu.edu/academics/course-directory/coursesection-numbers-explained/).

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 1st year in the 2nd or 3rd 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 1st year. Elective courses taken prior to enrolling in GTPCI or in the 1st 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 BSPH 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
3. Written feedback to the student

Comprehensive Examination

Taken after successfully completing the core coursework. It is a 4-hour, in-person, open-notes exam that is distributed at the end of 4th term. One re-take of the exam is allowable; 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 their 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
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 their thesis. If the thesis committee agree by unanimous vote that the student “passes” their 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 BSPH 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 Adviser 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 1st 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, Franklin - GTPCI or DOM Clinical Immunology
ALEXANDER, Caleb - GTPCI or BSPH Epidemiology
AMBINDER, Richard - GTPCI or SOM Oncology

BANDEEN-ROCHE, Karen - GTPCI or BSPH Biostatistics
BEMBEA, Melania - GTPCI or SOM Anesthesiology/Critical Care Medicine
BIENVENU, Joe - GTPCI or SOM Psychiatry
CELENTANO, David - GTPCI or BSPH Epidemiology
DIENER-WEST, Marie - GTPCI or BSPH Biostatistics
FLEXNER, Charles - GTPCI or DOM Clinical Pharmacology
GELBER, Allan - GTPCI or SOM Rheumatology
GHANEM, Khalil - GTPCI or SOM Infectious Disease
HAUT, Elliott - GTPCI or SOM Surgery
HENDRIX, Craig - GTPCI or DOM Clinical Pharmacology
HOOVER-FONG, J. - GTPCI or SOM Pediatric Genetics
JOHNSTON, Fabian - GTPCI or SOM Surgery and Oncology
KING, Elizabeth - GTPCI or SOM Transplant Surgery
KUDCHADKAR, Sapna - GTPCI or SOM Pediatrics and Anesthesiology/Critical Care Medicine
LEVINE, David - GTPCI or SOM General Internal Medicine
LIN, Frank - GTPCI or SOM Otolaryngology
LUCAS, Greg - GTPCI or SOM Infectious Disease
MILLER, Pete - GTPCI or SOM Medicine and Epidemiology
NEEDHAM, Dale - GTPCI or SOM Pulmonary
ROTHMAN, Richard - GTPCI or SOM Emergency Medicine
SEGEV, Dorry - 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) (https://e-catalogue.jhu.edu/public-health/ceph-requirements/), all BSPH 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.

<table>
<thead>
<tr>
<th>Code</th>
<th>Title</th>
<th>Credits</th>
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<tbody>
<tr>
<td>PH.390.750</td>
<td>Introduction to Clinical Research (Optional in Summer prior to matriculation)</td>
<td>2</td>
</tr>
<tr>
<td>PH.552.601</td>
<td>Foundational Principles of Public Health</td>
<td>0.5</td>
</tr>
<tr>
<td>PH.552.603</td>
<td>The Role of Qualitative Methods and Science in Describing and Assessing a Population’s Health</td>
<td>0.5</td>
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<tr>
<td>PH.552.607</td>
<td>Essentials of Environmental Health</td>
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<tr>
<td>PH.552.608</td>
<td>Biologic, Genetic and Infectious Bases of Human Disease</td>
<td>0.5</td>
</tr>
<tr>
<td>PH.552.609</td>
<td>Psychological and Behavioral Factors That Affect A Population’s Health</td>
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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: BSPH graduate degree documents frequently use the term "advise" 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 1st 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 BSPH 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 BSPH forms & guidelines, not SOM). Any faculty listed on the Academic Committee (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 BSPH may also represent "outside department BSPH". You may check BSPH faculty appointment status (https://www.jhsph.edu/faculty/directory/list/). Questions regarding thesis committee composition should be directed to the GTPCI Program Coordinator.

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

**Acceptable Doctoral Thesis**

During the 2nd 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 their 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 BSPH. 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**

**BSPH Thesis Guidelines**
• 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