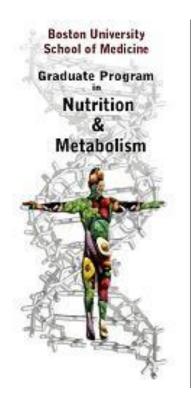
GUIDE FOR DOCTORAL STUDENTS

GRADUATE PROGRAM

in

NUTRITION AND METABOLISM

Boston University School of Medicine Division of Graduate Medical Sciences



Revised July 2014

Division of Graduate Medical Sciences, Boston University School of Medicine

GRADUATE PROGRAM IN NUTRITION AND METABOLISM

GUIDE FOR DOCTORAL STUDENTS

Welcome to the Graduate Program in Nutrition and Metabolism (N&M). This guide summarizes the requirements for doctoral-level graduate study in N&M and provides other helpful information as well. Additional documents regarding academic policies and procedures, course registration and the like are available through the Division of Graduate Medical Sciences (DGMS) website (see Section XI). *This Guide is subject to ongoing review and change with the approval of the Program Directors and Executive Committee.*

Please note that students are responsible for checking the GSM website for all academic deadlines (add, drop, etc) and due dates for forms (e.g. full time certification, graduation forms, dissertation submission requirements).

I. PROGRAM CONTACTS AND COMMITTEES

Program Director & Co-Director

Susan K. Fried, PhD, Professor, Dept Medicine, Section of Endocrinology, Diabetes and Nutrition, is the Program Director, and can be contacted at <u>skfried@bu.edu</u> or at 617 638-7110. Her office is in Building X, Room-815.

Lynn L. Moore, PhD, Associate Professor, Dept of Medicine, Section of Preventative Medicine and Epidemiology, is the Co-Director. She can be contacted at <u>Ilmoore@bu.edu</u> or by phone at (617) 638-8088. Her office is in the Crosstown Building at 801 Massachusetts Ave., Suite 470.

Administrators

Di (Eddy) Gao (<u>dgao@bu.edu</u>) Coordinates Admissions and Student Records. His office is in the Crosstown Building at 801 Massachusetts Ave., Suite 470.

Admissions Committee

All admissions are through the PiBS portal.

Curriculum Committee

This Committee oversees the first and second year curricula of the N&M students, including approving credits and requests for exemptions from requirements because of prior course work. This committee routinely reviews the curriculum and may identify areas requiring modification or improvement, current topics to be added to the curriculum. They report to bi-yearly faculty meetings, and make recommendations for curriculum changes.

This Committee also monitors the progress of each student during the completion of the qualifying exam process. The Committee may assign a Program Advisor for each student from N&M faculty with interests similar to the student's interests. The Committee evaluates each student's progress annually, or more frequently if needed. The Committee may make specific recommendations regarding student programs and progress. The Committee may also

recommend dismissing a student from the program if academic performance or research progress is unsatisfactory

This Committee (or a subcommittee thereof) reviews procedures for the qualifying examinations and will schedule and administer these examinations.

II. ADVISORS

Program Advisor: Upon entry into the program, each student is assigned an appropriate advisor (according to identified interests). This advisor will be responsible for assisting the student with course selection, how program requirements can be met, identifying rotation laboratories, and any academic or related issues that may arise.

Dissertation Advisors: After rotations are completed (see below), the student will choose a dissertation advisor and committee, with the guidance of his/her Program Advisor. This generally occurs after about 1.5 years of study.

III. COURSE OF STUDY

Overview of Degree Requirements for the PhD:

Credits Required.

Those entering with <u>Bachelor's degree</u> must take a total of 64 credits, usually including 32 course credits, with the remaining credits coming from research credits (NU 901 or 902).

Those entering the PhD program with a <u>Master's or MD degree</u> are required to complete at least 32 credits, including a minimum of 16 course credits (including Core courses if no equivalent course has been previously taken), with the remaining credits coming from research credits (NU 901 or 902). All PhD students are required to complete the FiBS curriculum.

Students must review their previous coursework and discuss their course requirements with the Program Directors.

Students may petition the Curriculum Committee to be exempted from taking certain core courses based on the comparability of the previous course material, grades received, the college/university granting the credits, and time since the completion of the previous course. To apply for exemption from a course requirement, the student should submit a short letter, note their grade (must be at least B) and a syllabus of the course they took to the Curriculum Committee.

Research credits are normally accumulated (2-10 cr/semester for fall and spring and both summer terms) as students carry out their dissertation research.

Research Rotations.

Three research rotations usually 8 weeks in length will be completed during the first year of the program. These rotations are designed to provide a breadth of research experience and allow students to choose a research group and area. There are no credits given for rotations (please see section VII for more information).

Qualifying Examinations.

Students are required to satisfactorily complete the two-part qualifying examination as described in Section VIII.

Doctoral Dissertation Committee.

All students are required to assemble a Dissertation Committee. A preliminary committee should be assembled after part I of the comprehensive exam is passed. This committee participates in part II of the comprehensive exam ('mock thesis proposal' – see section VIII). The committee provides guidance and monitors student progress. This committee meets at least once per year, but usually every ~6 months.

Upon completion of their dissertation, the student shall presents a public seminar of dissertation results, and defend the dissertation through an oral presentation to and examination by the committee and outside readers (details in subsequent section of this document).

Time to degree.

For those entering with a Bachelor's degree, coursework is generally completed within 2 years, and the dissertation in a total of 5 years. For those entering with a Master's degree, the PhD may be completed in as little as 4 years.

Core Coursework (Required Courses)

The core courses provide a broad background in nutritional sciences, taking an integrative approach that addresses basic science as well as clinical, epidemiological and public health aspects. Small group discussion classes hone critical thinking skills through readings of primary literature. The focus of the program is an interdisciplinary approach to nutrition research; required and elective coursework is designed to meet that goal. The student's Advisors or the subcommittee of the Curriculum Committee will guide students in the selection of coursework and monitor student performance.

Required core courses will differ somewhat for those whose area of focus is in the basic sciences vs. those whose focus is clinical, translational or epidemiologic research. The section below describes the core requirements.

The **Foundation in Biomedical Sciences Curriculum (FiBS)** is required of all first year Nutrition and Metabolism PhD students. This course covers biochemistry, cell biology, and genetics and genomics. Please note that the FiBS curriculum has a slightly different calendar so pay attention to class schedules:

http://www.bumc.bu.edu/gms/gateway/prospective/phd-programs/fibs-foundations-inbiomedical-sciences/foundations-in-biomedical-sciences/

NUTRITION CORE COURSES:

GMS NU 755 Molecular, Biochemical and Physiologic Bases of Nutrition I: Energy Balance and Micronutrients (Prerequisite: at least one semester each of biochemistry and physiology, or equivalent, and permission of the instructor)

This is the first semester of a 2 semester sequence (that can be taken in either order) that focuses on the Physiological, Biochemical and Molecular Bases of Nutrition. This semester will cover concepts of essential nutrients and methods for determining their requirements (DRIs), body composition, nutrition and growth, energy expenditure, regulation of energy intake,

vitamins and macro-mineral metabolism(Ca, P) and micronutrients. Functions and roles of micronutrients in signaling from gene to whole organism will be discussed. Implications for nutrient requirements through the lifecycle and in health and disease will be addressed. A discussion session will teach students to critically evaluate cutting-edge and seminal papers addressing each topic, and introduce students to state of the art research approaches and methodologies – basic (cell and molecular), clinical and epidemiological. Weekly writing assignments on the papers will provide experience and hone skills with scientific writing. (*Fried, 4 cr, Fall*)

GMS NU 756 Molecular, Biochemical and Physiologic Bases of Nutrition: Macronutrients (*Prerequisite: at least one semester each of Biochemistry and Physiology and permission of the instructor*) Regulation of lipid, carbohydrate, and protein digestion, absorption, transport, tissue and cellular metabolism. Integration of macronutrient metabolism in response to alteration in nutritional status (e.g. starvation, obesity) on a whole body and tissue-specific basis. Mechanism regulating macronutrient metabolism in response to stresses such as exercise and aging and disease. A discussion session will teach students to critically evaluate research papers, provide knowledge of seminal papers in the field, and introduce students to research approaches and state of the art methods (e.g. assessment of metabolic flux using stable isotopes, euglycemic clamps, metabolomics). (*Fried, 4 cr, Spring*).

This course focuses on macronutrient (carbohydrate, lipids, protein and amino acid) metabolism from an integrated perspective. Mechanisms underlying adaptations in whole body, tissue- and cell-specific nutrient metabolism with alterations in nutritional states (starvation, re-feeding, over- and under-nutrition) and disease states (obesity, diabetes, osteoporosis, cancer) will be discussed. Students will be required to critically read primary research papers and gain familiarity with state-of-the-art research techniques in nutrition and metabolism. Prerequisite: Biochemistry and permission of instructor. (note: NU 755 is not a prerequisite).

GMS NU 700 Nutrition & Metabolism Seminar: Students develop and present a research seminar. (*Fried and Moore 2 cr, Spring*).

GMS NU 620 Clinical Nutrition Research (*Prereq: Human Physiology or equivalent, consent of instructor. Prereq or Coreq NU 755 or 756*). The course will focus on disease states related to nutrition and diet, with a major focus on clinical nutrition research. The course goals are as follows: (1) acquaint students with current concepts and methods in clinical nutrition-related questions in their specific fields to answer questions related to disease states, (3) evaluate the role of nutrition as it relates to development, prevention and therapy of major diseases, including cardiovascular disease, diabetes, gastrointestinal disorders, osteoporosis, obesity, and cancer. (Moore, 3 cr, Spring).

At least , ADVANCED TOPICS COURSES subject to the approval of the students advisor.

REQUIRED Foundations in Biomedical Sciences (FiBS)Courses . (<u>http://www.bumc.bu.edu/gms/global-pages/fibs-foundations-in-biomedical-sciences/</u>) FiBS course are offered consecutively through the first semester and first few weeks of the 2nd semester

GMS FC 701 Foundations in Biomedical Sciences I: Protein Structure, Catalysis and Interaction The first module of the Foundations in Biomedical Science course "Protein structure, catalysis and interactions" will provide students with a quantitative understanding of protein structure, function, posttranslational modification and the turnover of proteins in the cell. In addition, students will gain facility with thermodynamics, catalysis, kinetics and binding equilibria as they apply to proteins and also to other molecules in biological systems (e.g. nucleic acids, lipids, vitamins, etc.). This course is part of a series of four core integrated courses and additional elective courses aimed towards first year Ph.D. students in the Division of Graduate Medical Sciences. The four cores will be integrated in content and structure, and therefore are intended to be taken as a complete, progressive sequence. *(Course Managers: McKnight, Nugent. 2 cr, Fall sem).*

GMS FC 702 Foundations in Biomedical Sciences II: Structure and Function of the Genome The second module of the Foundations in Biomedical Sciences course will focus on

the mechanisms of biological processes that influence the inheritance, regulation, and utilization of genes. Genetic and genomic, molecular, cell biological, and biochemical experimental approaches to understanding these processes will be explored. In addition, we will discuss the possibilities of utilizing these technologies in medical treatments. This course I part of a series of four core integrated courses and additional elective courses aimed towards first year Ph.D. students in the Division of Graduate Medical Sciences. The four cores will be integrated in content and structure, and therefore are intended to be taken as a complete, progressive sequence. (*Course Managers: Dasgupta, Viglianti. 2 cr, Fall sem*).

GMS FC 703 Foundations in Biomedical Sciences III: Architecture & Dynamics of the Cell The third module of the Foundations in Biomedical Sciences course will focus on the movement of proteins and membranes with the cell, the secretory process, the cytoskeletal framework of the cell and the resulting cell-cell interaction and communication with the matrix. Molecular, cell biological, and biochemical experimental approaches to understanding these processes will be explored. In addition, we will discuss the possibilities of utilizing these technologies in medical treatments. This course is part of a series of four core integrated courses and additional elective courses aimed towards first year Ph.D. students in the Division of Graduate Medical Science. The four cores will be integrated in content and structure, and therefore are intended to be taken

as a complete, progressive sequence. (Course Managers: Trinkaus-Randall, Zoeller. 2 cr, Fall sem).

GMS FC 704 Foundations in Biomedical Sciences IV: Mechanisms of Cell Communication

The fourth module of the Foundations in Biomedical Sciences course will focus on the mechanisms of cell communication. This module will begin by discussing overarching concepts before examining the specific types of molecules that initiate and transduce signals. Examples of cell signaling and subsequent cellular responses will then be considered in different contexts to provide a framework on which future learning can be applied. As the module progresses, the complexity of the systems explored will increase from individual cells to multicellular environments such as tissues, organs, and organisms. In addition, normal processes as well as the dysregulation of cell-cell communication is disease will be studied. This course is part of a series of four core integrated courses and additional elective courses aimed towards first year Ph.D. students in the Division of Graduate Medical Sciences. The four cores will be integrated in

content and structure, and therefore are intended to be taken as a complete progressive sequence. (*Course Managers: Symes, Hsu. 2 cr, Spring sem*).

GMS FC706 Molecular Metabolism (Prerequisites FC 701-704 or equivalent with permission of the instructors) This module of the Foundations in Biomedical Sciences curriculum focuses on the biochemical, cellular and molecular mechanisms that regulate cell and tissue-specific fuel metabolism. The course will present an integrated view of biochemistry and the control of cellular and organismal functions with regard to nutrient utilization. Classes include small group discussions of key papers. Mechanisms that allow cells to survive variations in nutrient supply (starvation, feeding, nutrient stress) and metabolic derangements that contribute to disease pathogenesis (e.g. diabetes, obesity, cancer) will be discussed. *(Course Managers: Fried, Pilch, 2 cr Spring)*

OPTIONAL FiBS Courses

GMS FC 705: Translational Genetics and Genomics

This course will explore the process by which insights from basic science research ultimately lead to new strategies for patient care with a focus on examples from genetics and more recent genome-wide experimental approaches. The course will cover examples of translational research using genetic, epigenomic, transcriptomic, proteomic, approaches in human and/or model systems. Research that leads to new approaches for establishing disease diagnosis, prognosis, therapy, and personalized medicine will be discussed. The ethical and societal implications of these developments will also be considered. *(Myers, Lenburg. 2cr, Spring sem)*. Prereq: consent of instructor.

GMS FC 707: Physiology of Specialized Cells

This course is one of the elective course modules (Module V) of the Foundations in Biomedical Sciences curriculum. Knowledge of cellular and molecular physiology is critical to understanding the higher order of functioning of tissues, organs, and organs systems. The objective of the course is to discuss the specialized adaptations of cells that help them to function in their respective tissues and organs. This course will also provide a framework to bridge the gap between the biochemistry and the molecular and cellular biology that students have acquired in the core modules (I through IV) and organ physiology and pharmacology that will be addressed in the second year. Pathogenesis (e.g. diabetes, obesity, cancer) will be discussed. Moore, *(Gabel. 2cr, Spring sem)*. Prereq: consent of instructor.

GMS FC 762: Critical Thinking in Biomedical Research

The primary goal of this course is to use the framework of the scientific literature to develop Critical Thinking Skills to generate novel hypotheses with a focus on establishing novel biological mechanisms and pathways. Critical Thinking skills will be used to examine research findings and theories to uncover inconsistencies, bias, or faulty logic. The student will be expected to build on their careful evaluation and analysis of the papers to create a novel hypothesis each week and design a single experiment to address their question. The weekly course discussion will be student led and this will facilitate the development of teaching skills. Generally the papers to be discussed will be an older, classic paper, which established an important new concept and a newer paper that builds on that theme. Grading is based on weekly participation in class discussions, presentations, and a concise final written assignment. Layne. 2cr, Spring sem. Prereq: consent of instructor.

GMS FC 764: Professional Presentation Skills

The course is designed for first year graduate students. The goal of this course is to teach students how to present their research in written and oral form. Students will give multiple short oral presentations and be critiques. They will also give 1 longer presentation. Students will learn to give presentations with and without slides. Students will also begin to acquire written skills in preparation for the Proposal writing course in the second year. The course will meet weekly and will be 2 credits.

STATISTIC COURSE:

GMS NU xxx Topics in Research Design and Statistical Methods

This course covers the following topics: developing study objectives, aims, and hypotheses; experimental vs. observational study design; bias and confounding; differential and nondifferential (random) error; fundamentals of data analysis including use of parametric and nonparametric tests; estimation of effects and statistical testing; independent vs. correlated data; and data presentation and interpretation. *(Moore, 3 cr, Spring sem)*

ELECTIVE STATISTICS COURSE

GMS CI 670 Biostatistics with Computer

Prereq: consent of instructor. This course is designed for students with no prior experience with sta-tistics who want to utilize computer software in performing statistical analysis. Topics include the col-lection, classification, and presentation of descriptive data; the rationale of hypothesis testing; t-tests and chi-square tests; correlation and regression analysis; sample size calculations, and analysis of contingency tables. Computer Laboratory course. (*Travison. 4 cr, Fall sem*).

NOTE:

Students conducting clinical nutrition or nutritional epidemiology studies are <u>required</u> to take *at least* 3 additional credits of <u>advanced statistics or research methods</u> in consultation with their advisor. For these students, competence with SAS programming is required so at least one statistics course with a computing lab must be taken unless mastery can be demonstrated.

ELECTIVE EPIDEMIOLOGY COURSES :

SPH EP 758 Nutritional Epidemiology (4 cr, Fall)

The purpose of this course is to introduce students to the discipline of nutritional epidemiology. In the class, we will focus on methodological issues relating to design, dietary assessment, and data analysis of studies on diet and disease. We will also review some of the literature relating nutrition to certain disease states, including coronary heart disease and cancer, in which we highlight methodological issues and interpretation of findings in nutritional epidemiologic research. Students completing this course will understand the basic principles of nutritional epidemiology and will be able to apply them in reading the literature and participating in nutrition research projects. This is a small, intermediate-level epidemiology class, which combines lectures with in-class discussion of classic and cutting-edge research articles. In addition, one-one meetings are set up with students throughout the semester to provide focused attention and facilitate mastery of the material (*consult BUSPH schedule*)

SAR HS 776 Nutritional Epidemiology (4 cr, Fall)

NOTE: This course includes an introduction to epidemiology followed by a focus on nutritional epidemiology. It is taught at the Sargent School on the main campus of BU. This course examines epidemiologic methods for investigating the role of diet in long-term health. Students learn to critically review the epidemiologic evidence relating diet, anthropometry, and physical activity to heart disease, cancer, and other chronic health conditions including obesity and diabetes. The methodological issues covered include epidemiologic study design; dietary and nutritional status assessment; issues of bias, confounding, effect modification and measurement error; and interpretation of research findings including an understanding of statistical modeling. Students participate weekly in critical reviews of published research. Students completing this course will understand the principles of epidemiology and will be able to apply them as they read the scientific literature and participate in nutrition-related research. 4 credits, 2nd semester

(Quatromoni, 4 cr, Sargent College, room 220, WF 2:30 pm-4:00 pm)

ELECTIVES.

Typical electives during the first and second year for students focusing on <u>basic</u> <u>nutrition research</u>:

GMS MM 701 Genetics & Epidemiology of Disease (2 cr, Fall)

Gain an appreciation for the human genetics field including the diverse areas of endeavor, genetic epidemiology in particular. Learn a variety of concepts in genetics and epidemiology which would allow a student to read and evaluate literature in most medical journals which report on this type of science. Be able to perform a variety of numerical solving problems related to the human genetics field without advanced training in math or statistics. Discover the relevance of genetics to virtually all areas of biomedical research and clinical endeavor, and perhaps utilize the knowledge in one's chosen discipline.

GMS MM 703 Cancer Biology & Genetics (2

The course will begin with an historical perspective; review the major mechanistic pathways relating to oncogenes, anti-oncogenes, cell cycle control, genome instability, repair, and apoptosis; discuss standard and experimental genomic principles of cancer treatment and diagnosis; and conclude with a discussion of cancer epidemiology and health policy issues that affect all basic translational cancer research.

GMS MM 707 Organ System Diseases

This course will address current topics in the molecular basis of non-malignant and nonimmunologic diseases of man in the fields of Cardiovascular Disease; Hemostasis; Metabolic and endocrine diseases; Genetics of renal disease; Pulmonary Disease; Gastrointestinal Disease and Dermal Diseases. Examples of topics that will be covered include the molecular basis of atherosclerotic heart disease and cardiomyopathy; molecular basis of pre-thrombotic disorders (such as Factor V Leyden); leptins and obesity; chloride channels and cystic fibrosis

Typical electives during the first and second year for students focusing on <u>epidemiologic</u>, <u>clinical/translational and applied nutrition research include</u>:

Typical courses for students focusing on epidemiological or clinical research

(2 cr, Fall)

(2 cr, Fall)

SPH BS 723 Introduction to Statistical Computing

Graduate Prerequisites: Successful completion of the biostatistics MPH core requirement or equivalent or consent of instructor.

This course introduces students to statistical computing with focus on the SAS package. Emphasis is on manipulating data sets and basic statistical procedures such as t-tests, chisquare tests, correlation and regression. Conditions underlying the appropriate use of these statistical procedures are reviewed. Upon completion of this course, the student will be able to use SAS to: read raw data files and SAS data sets, subset data, create SAS variables, recode data values, analyze data and summarize the results using the statistical methods enumerated above. This course includes hands-on exercises and projects designed to facilitate understanding of all the topics covered in the course. Students use equipment and software available through the Boston University Medical Center. This course is a prerequisite for BS805, BS820, BS821, BS851, BS852, BS853 and BS858.

SPH EP 751 Cardiovascular Epidemiology (*Prerequisite : The epidemiology MPH core requirement*). (4 cr)

The goal of this course is to enable students to understand major aspects of cardiovascular epidemiology and current strategies for primary and secondary prevention of major cardiovascular diseases (i.e. stroke, heart attack, heart failure or hypertension). The course concentrates on physiologic mechanisms leading to atherosclerosis; traditional and novel CHD risk factors; prediction models for CVD; and the role of lifestyle, dietary, and genetic factors on the development of CVD. In addition, relevant historical breakthrough and current controversies in CVD are discussed using the latest publication from lay press and peer-reviewed journals. A fair amount of time is devoted to acquiring skills in scientific writing and data interpretation. These latter skills are used by the students to design and complete a CVD epidemiology project on a topic of their choosing. Each student (group of students) then presents his/her completed project in class during the last 2 sessions of the course. The course is taught by the course Director and other senior investigators who are experts in different areas of cardiovascular disease.

SPH EP 752 Cancer Epidemiology (4 cr)

(Prerequisite : The epidemiology MPH core requirement.) This course provides an overview of the important concepts fundamental to the understanding, design, and conduct of cancer epidemiology studies. The course commences with the descriptive epidemiology of cancer, including time trends in incidence and mortality, and geographic and demographic variation in cancer rates. An overview of the biology of cancer, and a review of the major epidemiologic concepts critical to cancer epidemiology is covered. The descriptive and analytic epidemiology of major cancer sites, including breast, lung, colon, prostate, cervix and melanoma, is discussed, as well as major risk factors for cancer, including tobacco, nutrition, infections, and environmental exposures. The course format consists of a series of lectures by faculty and guests, discussion sessions, and directed readings from the current literature. Students are required to pursue a cancer-related topic of their choosing in depth, developing a proposal for an epidemiologic study that will further current knowledge based on their literature review of the topic.

SPH SB 721 Social and Behavioral Sciences for Public Health (3 cr)

(Prerequisite: Students who take SPH IH720 may not take SB721 for MPH degree credit.SB concentrators must take this course regardless of citizenship status). This survey course introduces MPH students to social and behavioral sciences within the context of public health scholarship, research, and practice. The basic aim of the course is to

teach students the social and behavioral science fundamentals (principles, theories, research, and techniques) that can and should be used to inform the identification, definition, assessment, and resolution of public health problems. The course focuses on providing a framework for considering the important questions in a thoughtful and evidence-based manner such that students will be able to critically analyze public health problems and determine the appropriate social and behavioral sciences principles, theories, and research that will be most effective and useful in intervening to address that particular public health problem. The course considers alternative paradigms for understanding and intervening to resolve public health problems in a critical way, drawing heavily upon the public health literature in which these various perspectives have been vigorously debated and discussed.

SPH SB 733 Mass communication and Public Health (4cr)

(Prerequisite : SPH SB721.) This course explores the use of mass communication as a tool for health promotion. It begins by examining the structure and function of the mass media and the role of mass media in shaping the social and cultural environment regarding health issues and behaviors. The course then presents the theory and basic elements of the range of mass media approaches available to the public health practitioner (public service announcements, public communication campaigns, integration of mass media into community-based health promotion strategies, advertising, entertainment programming, social marketing, and media advocacy). Students discuss the strengths and limitations of each approach and gain experience in applying principles to specific public health problems. Students also develop basic skills necessary to be able to collaborate with health communication and media specialists in public health organizations and agencies. Students work in groups on a final project in which they develop and present a proposal for a plan for a health promotion initiative that uses mass media.

SPH SB 821 Intervention Strategies for Health Promotion (4 cr)

(Prerequisite: SB721 and assessment selective; latter is recommended. For MCH concentrators only, MC725). This course focuses on strategic planning for public health practice. Social science and maternal and child health approaches are included. Working through a sequence of written assignments, students develop a strategic plan for a program intervention designed to change health behavior or a health outcome. Work in class and during individual consultations is designed to give students practice with elements of the strategic planning process, ideas for their project, and interim feedback on their written assignments.

GMS CI 675 Designing Clinical Research Studies (4 cr)

(*Prereq*: GMS CI 675 Designing Clinical Research Studies and Conduct and Consent of Instructor). This course is an integrative learning experience, combining a comprehensive review of the good clinical practice core principles with explanation and analysis of selected portions of the Code of Federal Regulations (CFR), applicable to clinical research during the new drug development process. The case study approach is used in this course since the drug development industry translates these regulations into both written and unwritten standards, practices, and guidelines.

Each session will use activities to expand the interpretation of the regulations, further integrating real-life issues into the classroom. In order to ensure that classroom learning is linked with the students' work experiences, there will be an outside project required which will incorporate the course work with the on-the-job situations, and a final presentation to share the learning with the entire class.

GMS CI 640 Regulatory & Compliance Issues (4 cr)

(Prereq: Premedical course requirements and Consent of Instructor). Course explains the regulatory requirements for healthcare products, that is, drugs, biologics, diagnostics, and devices. Intended for those interested in regulatory affairs or in the clinical evaluation, development, manufacture, testing and/or commercialization of these products. Provided is an in-depth review of the pertinent FDA regulations and guidelines and links these to the scientific and logistical activities involved in taking a product from research to market. Content and preparation of regulatory submissions, including an Investigational New Drug Application (IND), an Investigational Device Exemption (IDE), a New Drug Application (NDA), a Biologic License Application (BLA), a Pre-Market Approval Application (PMA), and a 510K Premarket Notification are described. International requirements for health care products are also reviewed.

Waiving requirements: Students may petition the curriculum committee to waive requirements if they have had equivalent previous coursework. Waiver of a course requirement does not reduce the number of credits required to complete the PhD degree.

Add and Drop dates: It is your responsibility to remain aware of these deadlines. They are posted on the GMS website.

Helpful Course Links.

Full listing of GMS courses can be found on the student link and basic information about registration, etc. is found on the GMS web site: Go to: <u>http://www.bumc.bu.edu/gms</u>

Current GMS Students: http://www.bumc.bu.edu/gms/gateway/students/

Current Course Offerings: <u>www.bumc.bu.edu/gms/gateway/students/gms-course-offerings/</u> Click on <u>"Student link"</u> and work your way through the class schedule

GMS Course Registration (via the Web).

Students may register by going to the Student Link page and clicking on the tab for "Academics":

http://www.bu.edu/link/bin/uiscgi_studentlink.pl/uismpl/?ModuleName=menu.pl&NewMenu=Ho me

For School of Public Health (SPH) Course Registration.

You may take classes at the SPH but you need to discuss this in advance with the program directors (Drs. Fried or Moore). For information on registering, go to the SPH registrar's web page: <u>http://www.bu.edu/sph/students/resources/forms/</u>

To register for a class, you will need to complete that "add/drop form" that is available on that page. If a course is full, you can get a Waitlist form here as well.

Fax the Form to the SPH Registrar's office at 617-638-5060

IV. STUDENT PERFORMANCE

Annually, students will submit a progress report (signed by their Advisor) to the Program Directors and to their committee, once it has been formed. The progress report shall include the following components: coursework completed (or underway), rotations, seminars attended or given. The student's progress in these areas as well as general academic and professional conduct will be evaluated first student's Advisor and then by the Dissertation Committee (if already convened) and then by the N&M Curriculum Committee. A written report will be provided to the student and advisor. If a student fails to meet the standards for a satisfactory performance, the matter will be referred to the Executive Committee for appropriate action, within the guidelines of the Division of Graduate Medical Sciences. Such action could include the revocation of financial aid or dismissal from the program and the graduate school.

If students do not perform satisfactorily on either Part 1 or 2 of the Qualifying Exam, They will be provided with an opportunity to re-take all or part of it in an oral or written format, at the discretion of the Qualifying Exam subcommittee. This subcommittee is responsible for identifying any areas of weakness and suggesting remediation (e.g. a course or tutorial) prior to a second attempt. Failure on a second attempt usually means dismissal from the PhD program with the option to complete a Master's degree upon approval of the Curriculum committee and the Directors.

V. SEMINARS

Seminars are an important component of training at all stages of a scientific career and all students are expected to attend all Nutrition and Metabolism Seminars and annual Evans Days events. For Evans Day, advanced students will be expected to present a poster on their research. Students will also participate in a weekly N&M seminar (that may include journal article reviews).. Students who have passed their Qualifying examination will be expected to present an annual research seminar to their colleagues and the program faculty in this time slot.

Students are also expected to regularly attend research seminars in the Department of Medicine or the basic science or other department in which they are carrying out their dissertation research.

Upon completion of the written dissertation and prior to the official dissertation defense, the student is required to present a seminar of their dissertation work. It is the responsibility of the student and advisor to schedule this seminar at a time that ensures maximum attendance by members of the Department and the Medical School community.

VI. BU RESEARCH REQUIREMENTS

As a student you must complete the following training:

Lab Safety Certification (course required yearly for ALL students) (new: <u>http://www.bu.edu/orctraining/ehs/research-safety-training/</u>)

All graduate students are required to attend the lecture series on the Responsible Conduct of Research presented approximately quarterly by the Division of Graduate Medical Sciences.

Responsible Conduct in Research (RCR) (required for ALL students http://www.bu.edu/orctraining/rcr/core-grad/

Radiation Safety Certification (course required yearly if working with radiation) (new: <u>http://www.bu.edu/orctraining/</u>)

Animal Handling Training and Certification (required for students working with animals): <u>http://www.bu.edu/orctraining/animal/</u>

Human Subject Research Training and Certification (required if working with human subjects, tissues or cells): http://www.bumc.bu.edu/ocr/certification/

VII. RESEARCH / LABORATORY ROTATIONS

PiBS students are required to complete 3 laboratory/research group rotations of 12 weeks in length during their first 12 months in the program. Students will generally begin their first rotation during the first semester of the first year. Research rotations provide the student with the opportunity to learn a variety of techniques, experience different research environments, and choose a laboratory or research setting for their dissertation research.

Note that the research laboratories and programs of the Department of Medicine are varied and widely dispersed. Research rotations should be selected to obtain a wide range of research experiences to aid in the selection of a focus area for dissertation research. Students who interested in clinical research or epidemiology should complete at least one rotation in a related setting.

The student's Program Advisor (assigned by PiBS for the first year) can assist with choosing laboratories (and many senior students can provide advice as well). The process is defined by the PiBS Executive Committee – please see their guidance documents.

Social Contract between Mentor and Mentee: The Student-Advisor relationship is an important one. It is guided by the official GMS policy on "Fair expectations for graduate students": <u>http://www.bumc.bu.edu/gms/gateway/students/phd/fair-expectations-for-graduate-students/</u>

Should you have any questions about this policy or your relationship with your Research or Program Advisor, you should bring them to the attention of the Program Director or Co-Director.

VIII. QUALIFYING EXAMINATIONS

Prior to sitting for the Qualifying Examination

Candidates for the PhD in Nutrition and Metabolism al will be held to a high standard of performance. A minimum of a B (3.0) average is required to take the qualifying examination. Students entering at the post-master's level will sit for the Qualifying Examination after completing 1.5 years in the program (but no later than the end of the second year). Students entering at the post-bachelor's level sit for the Qualifying Examination at the end of their second year of study (no later than 2.0 continuous years into the program unless otherwise approved by Program Directors).

Qualifying Examination

Successful completion of the qualifying examination is required to proceed with dissertation research. The qualifying exam consists of two parts: a written examination and a mock dissertation proposal. Part 1 of the exam must be successfully completed before moving on to Part 2.

Part 1: The first part of the Exam will be offered up to twice yearly, depending on the numbers of students prepared to take the exam at any time. Students are urged to collaborate in the scheduling of and preparation for the Exam. The exact date(s) will be determined in consultation

with the Program Directors. Students who wish to sit for Part 1 of the Exam should notify the Program Director 10-12 weeks in advance of the preferred time period. The following timeline will be used in preparation for the Exam:

- (a) Notify Program Director of intent to sit for exam (10-12 weeks in advance)
- (b) Exam date selected by mutual agreement (8 weeks before Exam)
- (c) Two possible exam topics and readings given to students (8 weeks before Exam)
- (d) Student selects one of two topics for study focus (7 weeks before Exam)
- (e) Study period (6-7 weeks before Exam)
- (f) Two related manuscripts (that will serve as basis for examination) will be given to students (1 basic, 1 clinical/epi) (2 weeks before Exam)
- (g) Exam, Part 1. Students will be provided with a computer (personal laptops not allowed) without an internet connection. No papers, notes or hand-held devices may be brought to the examination

Part 1 of the Qualifying Exam is written and involves answering specific questions about two research papers (one basic, one clinical/epidemiologic) on the same topic. Students are expected to prepare for the exam by studying a broad range of background material background material and other evidence on the topic. In their responses to the Exam questions, students must demonstrate broad knowledge of the field of nutrition as well as critical thinking skills as demonstrated by the ability to write a clear and concise analyses and critiques of the rationale, design, methods, and interpretation of the two studies including a discussion of the implications of the work and the importance for relevant fields. The specific qualifying exam questions related to these manuscripts will be distributed at the exam itself; clean copies of the original papers will be provided as well. No written materials may be brought to the Exam. The Exam will be designed to be completed in about 3-4 hours but additional time will be allowed.

This exam is graded by a subcommittee of the Curriculum on a scale of 0-10. If one or more scores under 8 are received, follow-up written or oral questions will be designed by the Curriculum Committee. If the average grade is below 7, then the exam must be retaken.

Part 1 must be passed before proceeding to Part 2.

Part 2: Mock Thesis Proposal: Usually 6 months after passing Part 1, but not more than 1 year, each candidate will prepare a Mock Thesis Proposal consisting of a 5 page proposal (not including references) that follows the format below. The topic should generally be the same as or related to the anticipated topic for the student's doctoral dissertation research and will be selected in consultation with the Dissertation Advisor and Program Director and approved before proceeding.

Once the Mock Thesis Proposal topic has been approved, the candidate is required to hand in the proposal within 2 weeks. No later than 1 week following submission, the applicant must orally defend the proposal in front of the Qualifying Exam subcommittee of the Curriculum Committee. The student will be expected to answer questions about all aspects of the proposal, including the background, rationale for the approach, and relevant methods. The subcommittee will be chaired by a faculty member who is not the dissertation advisor.

The student is allowed to discuss the proposal with colleagues, as long as he/she writes the complete proposal and makes any colleagues aware that the proposal is being written as the second part of the Qualifying Examination. *The proposal should represent the candidate's own ideas and should not replicate the mentor's grant proposal (or any other existing proposal).*

After successful completion of both Part 1 and 2 of the qualifying exam, the student becomes official 'PhD' Candidate.

Guide to Writing the Qualifying Exam Proposal

The "Mock" Thesis Proposal should be written in current NIH format and is limited to 5 singlespaced pages (11 pt type, at least 0.5 inch margins) in length, not including references or figures. Like a grant application, the goal of the proposal is to establish the specific aims (addressing the research questions) of the proposal, with at least one testable hypothesis for each specific aim, and to describe the approach and methods/experiments to be used to address each specific aim. Writing should be clear, concise, and to the point; here, as in an NIH grant application, quantity over quality is not of value. The following format should be used:

1. Specific Aims. After stating the broad, overall goal of the research, state each of the specific aims and at least one associated hypothesis to be tested. Since the doctoral dissertation should comprise three publishable manuscripts, the proposal should include at least three specific aims (but no more than 4). Provide sufficient detail to describe the basic methods to be used. (up to 1 page)

2. Research Strategy.

- a. Significance. This section of the proposal should begin by stating the larger research question to be addressed and its importance. Review the essential literature, providing background evidence to identify what is known in the field, where the gaps in knowledge exist. Explain the rationale for the proposed studies (experiments/analyses). The summary of existing evidence in the literature should be written for a knowledgeable but not necessarily expert reader. (1 page)
- b. Innovation. This section is designed to convince the reviewer of the innovative nature of your proposed study. Include a brief statement of what you will do and then explain how your study has the potential to impact such things as existing knowledge, theories, clinical practice, clinical or research methods, and so on. Your study may develop or test new methods or refine existing ones in some innovative way. (1/2 page)
- **c. Approach.** Provide an overview of the overall design of your experiments/studies and how these will address each of your specific aims. Include appropriate preliminary data (or analyses) to support the feasibility of the approach as well as your experience that will assist you in carrying out the proposed studies. Preliminary data may also provide the basis for power analyses. Explain your methods precisely, including how you will collect, manage and analyze the data. For clinical and epidemiologic studies that are based on existing data, describe the original study design as well as the data collection methods, and variables to be used. Explain what variables will be explored as potential confounder or effect modifiers as well as the rationale for doing so. The approaches to the analysis should be described as well. In general, treat each aim individually and describe the laboratory, clinical or analytic approaches to be used. The level of detail should be sufficient to convince the reader of the validity of the methods to be used. Finally, discuss any potential experimental difficulties or analytic complexities as well as alternative strategies should such problems arise. (2 3 pages)
- **d. References.** Provide references at the end of the Research Strategy. Each citation must be complete, and include the names of all authors, title of the article, journal or book, volume, page numbers, and year of publication. The reference list is not included in the 5 page limit of the proposal.

- 3. Protection of Human Subjects (if applicable see NIH guidance)
- 4. Vertebrate Animals (if applicable see NIH guidance)

IX. DOCTORAL DISSERTATION

Dissertation Committee

The student's PhD dissertation committee must have five members: (a) committee chair, (b) student's advisor (first reader), (c) second reader, (d) third reader, and (e) external member. The guidelines and roles of the various members are given below:

- 1. Committee Chair. The committee chair is responsible for moderating all meetings of the committee, and will assist the student with organizing and scheduling the meetings. The chair keeps written records of committee recommendations and decisions and tracks follow up on those decisions as the student moves through the completion of the dissertation. The written report of the meeting must be provided to the Directors and the Curriculum and a copy will be given to the Program's Curriculum Committee (within 3 business days). The committee chair must be a member of the regular GMS nutrition faculty and may not serve as the student's dissertation advisor. The committee chair is responsible for scheduling the student's proposal defense as well as the defense of the dissertation itself, including completion of the paperwork from the GMS office. The chair should ensure that the requisite 5 committee members are in attendance at the student's final dissertation defense.
- 2. Dissertation Advisor. The dissertation advisor also serves as the first reader of the dissertation. The Advisor should have thorough scientific knowledge of the student's research topic and the methods required to complete the dissertation work. The dissertation advisor oversees the scientific conduct of the study. The dissertation advisor must be a member of the regular GMS nutrition faculty.
- **3. Second Reader.** The second reader of the dissertation committee provides backup to the dissertation advisor and can help guide the student through any problems and suggest alternative approaches, etc.
- **4.** Third and fourth readers: The third reader brings additional expertise and perspective (e.g. clinical to a basic project or vice versa) that can provide breath and balance on the committee.
- 5. External member: This may be someone with subject area expertise who is not a part of the Nutrition and Metabolism Graduate Program faculty, and can be from outside BU/BUSM. A Special Appointment form may be needed (from GMS office).

N&M students should assemble a Dissertation Committee as soon as feasible, generally at the time that Part 2 of the comprehensive exam is taken (except for the outside member, which can be added later). The committee comprises at least five members including the Chair (who must be a member of the N&M faculty), the primary dissertation Advisor, one faculty member from outside of N&M (and preferably outside of BUSM), and two additional GMS faculty members. Committee members from BU who are not GMS faculty members may receive a special appointment to serve. Committee members should be qualified to assist the student with his/her dissertation and examine him/her at its completion. Faculty from other institutions who are particularly qualified to review the dissertation research can serve on a dissertation Committee, but must apply to the Division of Graduate Medical Studies for a special service faculty appointment. The Committee roster should be submitted to the N&M office for approval on the proper form.

The <u>student</u> will convene the Dissertation Committee (subject to approval of the Directors) and schedule the meetings of the committee. The committee should meet for the first time within 6

months of successfully completing the qualifying examination. The Dissertation Committee will determine the frequency of meetings for the full committee but it shall meet at least annually. At critical junctures in a student's work, mote frequent meetings may be advised. A written summary of the progress is required at all committee meetings.

Dissertation Proposal.

No less than one week prior to the first meeting (within 6 months of passing part 1 of the comps), the student must provide the Committee with a revised dissertation proposal that includes a modified research plan incorporating changes resulting from the feedback at the 'mock thesis proposal' component of the qualifying exam. The document should also include a report of progress to date.

The dissertation proposal should follow a standard grant format with an abstract, specific aims, background, preliminary results, research design and methods, and proposed experiments or analyses. A discussion of the feasibility and rationale should be included. For the first meeting of the Dissertation Committee, the dissertation proposal may be incomplete; it is subject to change incorporating the feedback and advice of committee members. The proposal should, however, be sufficiently complete and WELL-WRITTEN to all for a careful and accurate assessment of the proposed research. At each subsequent meeting, the student should provide a written update (no less than one week prior to each committee meeting) that highlights any modifications made to the specific aims or research plan and summarizes (with tables, figures and/or text) any important data and results obtained since the previous meeting.

The student with the assistance of the primary advisor and the Dissertation Committee will form an outline of what constitutes an adequate body of original research that is suitable for a written dissertation. The Dissertation Committee shall determine when the student's proposal is ready for the "defense" of the proposal. The defense shall take the form of a 30-minute student seminar presentation at a N&M seminar. The seminar presentation will be followed by 30-60 minutes of discussion/questions. At the conclusion of the meeting, the Committee will meet in the students' absence for a discussion of the proposal, progress to date and concerns.

The student should provide a brief written report on progress at each meeting of their dissertation committee. The format may be determined by the committee, but it is recommended that it include the following:

- Re-statement of original Specific Aims
- Statement of any revisions to the Aims and rationale for any changes
- Progress on each Aim
- Plans for the next 6-12 months
- A time line for completion

After each committee meeting, it is the responsibility of the committee chair to prepare a short written report summarizing the committee's evaluation of the student's research direction and progress, and stating the timeframe for the next committee meeting. This summary is to be sent to the N&M office which will forward it to the other Committee members and to the student.

Dissertation requirements.

The dissertation should consist of three published or publishable papers (manuscripts to be submitted) with a general introduction and general discussion. When the written dissertation is approved by the student's Dissertation Committee, the student will notify the N&M office to schedule a formal dissertation defense. The defense will take the form of a formal departmental

seminar followed by an oral defense of the dissertation. The written dissertation should be delivered to the committee members at least two weeks before the scheduled date of the oral defense.

The complete, written dissertation should be provided to the committee two weeks prior to the scheduled defense.

The student is responsible for checking GMS website for deadlines for submission of forms for graduation and the general rules for the dissertation format (e.g. fonts, margins, etc).

Each student is required to provide the Department with a final copy of his/her dissertation before the Department will sign off on the necessary paperwork in order for the student to complete his/her degree requirements. The Department will have the dissertation reproduced and bound and provide copies for the student, the advisor, and the Departmental library.

X. GRADUATION

PhD degrees are awarded three times a year, January, May and October. It is the student's responsibility to consult the Graduation Calendar available in the Division of Graduate Medical School for the timelines for submitting various documents, including the scheduling of final Dissertation defense in sufficient time to meet graduation deadlines. The department shall not be responsible for the student missing any graduation-related deadlines if the student fails to allow sufficient time to meet all program requirements.

XI. USEFUL LINKS

GMS: http://www.bumc.bu.edu/gms/ Nutrition & Metabolism Website: http://www.bumc.bu.edu/gms/nutrition-metabolism/ BU GMS forms: http://www.bumc.bu.edu/gms/gateway/students/phd-mdphd/forms/ Graduate Medical Sciences Student Organization (GMSSO): Department of Medicine: http://www.bumc.bu.edu/medicine/ Boston University Medical Campus: http://www.bumc.bu.edu/ BU Main Site: http://www.bu.edu/ BU Student Link: https://www.bu.edu/link/bin/uiscgi_studentlink.pl/1389729333?applpath=menu.pl &NewMenu=Home GMS Student Organization: http://www.bumc.bu.edu/gms/student-life/gmsso/ Pub Med: http://www.ncbi.nlm.nih.gov/sites/entrez/ Core Facilities and other Research Resources: http://www.bumc.bu.edu/ResearchIndex.html

E-mail

Students will sign up for an e-mail account in the Computer Lab on the 12th floor of the L-Building (in the Medical Library). A student ID is required to sign up for an email account.

Computers

The Medical School Computer Lab is located in the library on L12. Research groups are expected to provide students with computers and space for their day to day activities.

Fitness

Students may use the Recreation Center on the Charles River Campus (http://fitrec.bu.edu/) or purchase a membership to the South End Fitness Center (http://www.southendfitness.org/) located near the Medical Campus

Healthcare

Students are enrolled in BU's Aetna Medical Insurance. More information can be found at Student Health Services (<u>http://www.bu.edu/shs</u>)

Housing

A housing resources website available for students looking for housing opportunities and receive help in finding a place to live in Boston.

(http://www.bumc.bu.edu/gms/gateway/welcome-accepted-students/accepted-student-housinginformation/)