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Award Number: W81XWH-13-1-0223

TITLE: Undergraduate Training in the Epidemiology of Prostate Cancer with Focus on Genetics of Disease Progression and Quality of Life

PRINCIPAL INVESTIGATOR: Emanuela Taioli, MD, PhD

CONTRACTING ORGANIZATION: Feinstein Institute for Medical Research
Manhasset, NY 11030-3816

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Fort Detrick, Maryland 21702-5012

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14. ABSTRACT The goal of the Department of Defense Undergraduate Training grant is to create a transdisciplinary summer internship training in prostate cancer research for 4 interns per summer in clinical and translational epidemiology and bio-behavioral science. We accomplished this in numerous areas outlined below from the original statement of work, and continue to improve our methodology and training options based on experiences learned throughout the first year of the grant program. Overall, the partnership between NSLIJ and HU project investigators has been a successful one in the fostering of greater carcinogenesis content in courses offered by HU, as well as developing new coursework specific to Epidemiology. Due to the health system resources, we were able to offer summer interns a wide breadth of experience in cancer research, and basic research in general, ranging from clinical interventions to population-based studies. Undergraduate trainees were introduced to all critical areas in research, such as literature review, presentation skills, and data management, among others. Through the HU Epidemiology course, we have introduced many more undergraduates to the concepts behind general epidemiology, as well as cancer research, which we believe will influence an increased involvement in the sciences.				
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I. Introduction

The goal of the Department of Defense Undergraduate Training grant is to create a transdisciplinary summer internship training in prostate cancer research for 4 interns per summer in clinical and translational epidemiology and bio-behavioral science. We accomplished this in numerous areas outlined below from the original statement of work, and continue to improve our methodology and training options based on experiences learned throughout the first year of the grant program.

II. Keywords

- Prostate cancer
- Epidemiology
- Genetics
- Undergraduate
- Training
- Health disparities
- Research
- Didactic program

III. Overall Project Summary

Program Content Overview

The study team at NSLIJ began IRB submission preparation in May 2013 for a chart review study on African American men diagnosed with prostate cancer within the North Shore-LIJ Health system, with the main goal of understanding factors associated to outcome and quality of life. The chart review would include recording numerous variables pertaining to demographic, lifestyle, family history and clinical factors. The initial IRB submission was approved on 06/04/13 (initial approval letter attached).

Prior to the start of the internship, all interns were given several modules to complete from the CITI training website hosted by the University of Miami, , to assure adequate understanding of human subject protection and research ethics. The modules completed by both sessions of summer interns included Conflict of Interest, Biomedical Research Introduction, and Responsible Conduct of Research. They also completed the required appropriate conflict of interest forms for internal processing. Once these steps were completed, modifications were submitted to our Institutional Review Board, to add the summer interns to our initial IRB-approved study and approved appropriately (modification approval letter attached).

When the interns were IRB-approved to proceed with research, and registered through the Visiting Scholar program at the Feinstein Institute for Research, the study team arranged initial presentations on Health Service Research, HIV/AIDS research, Prostate Cancer research, Health Disparities research, Cardiovascular Epidemiology research and other lecture series with NSLIJ faculty members. These faculty members included Dr. Emanuela Taioli, Dr. Renee Pekmezaris, Dr. Manish Vira, Dr. Alicia McDonald, Dr. Marlene Camacho, Dr. Bian Liu, and Dr. Rebecca Schwartz. Students also participated in the undergraduate course “Principles of Epidemiology” offered at Hofstra and completed all the course work

In order to give the interns an overview of the different regulatory steps behind human subjects research, they participated in numerous Feinstein Institute lectures on various topics pertaining to this area. They were also given an assignment to collectively develop a hypothesis for a research study, and to create the IRB documents, including protocol, consent forms, and questionnaires. After this was completed, the study team reviewed the documents with them, and performed a day-long workshop on the consent process, as well participant recruitment in research studies. They were also able to shadow the research team on another IRB-approved study (to which they were added) by preparing study documents and samples, and shadowing participant recruitment, in order to expose them to population-based research.

In development of different hypotheses on prostate cancer, and general translational research, the interns performed extensive literature searches on a broad range of research topics, in order to expose the interns to a breadth of current biobehavioral and epidemiological research. This also allowed them to develop a valuable skill in the field of research, which is necessary in order to perform high level translational research. They were also given Microsoft Excel and Microsoft Access training in terms of study data entry, another crucial skill in the field of research. They also learned how to perform standardized data entry, data coding and quality checks.

The interns were then given a chart-review project on African American men with a prostate cancer diagnosis to work on, which included review of both physical charts from the NSLIJ Cancer Center, as well as electronic medical records (EMR). Data from both sources were collected and quality controlled by the interns under the supervision of a division study coordinator. Interns were then asked to develop various hypotheses related to prostate cancer health disparities and outcome, using the collected variables, and to put together a final paper on their chosen interest topic.

To address the clinical side of prostate cancer research, and due to the fact that several interns were interested in entering the field of medicine, we arranged for Dr. Manish Vira, a Urologist and Co-Investigator on the grant project, to allow them to shadow him during several rotations at the Urology center. This also included a lecture series on prostate cancer, as well as observation of several prostatectomies and accompanying discussion.

First Internship Period (Summer 2013)

The original intention was to recruit from both the Pharmacology and Biology departments, led by Drs. Saulsbury and Andraos-Selim, respectively; however, the School of Pharmacy implemented a new rotation schedule (to accommodate new accreditation standards). As a result, the P3 Pharmacology students were unable to participate in research projects during the summer at the Feinstein Institute. As such, Drs. Heyliger and Saulsbury worked with the School of Pharmacy to create a more flexible rotation schedule which will allow the rising fourth-year (P4) students to participate in research experiences the following summer.

Based on these changes, Dr. Andraos-Selim, the Hampton University Principal Investigator, was able to recruit applicants solely from her department. Based on her advertisement, which included flyers and informational sessions, we were able to obtain 7? applicants to the Feinstein Institute summer internship. After review of application materials, applications were ranked according to a pre-established quantitative method that included GPA, a statement of interest, and recommendation letters, and several ranking discussions with HU and NSLIJ co-investigators, we accepted three qualified Biology Department summer interns, Tahirah Burford, a Sophomore Biology major, Kelly Mitchell, a Junior Biology major, and Jennifer Perry, a Junior Biology major, all of whom had Dr. Andraos-Selim as their Hampton University advisor. While our original intention was to have four students participate in the summer internship, we ultimately did not feel that unqualified candidates should be offered a place in the internship program, and thus only accepted the three applicants for whom the ranking score was above a pre-established cut off.

Due to timing of award, offering the originally planned 10 week internship was not possible due to Hampton student schedules and NSLIJ course schedules. We had to compress the internship to 8 weeks.

HU Continued Training Period (Fall 2013)

Pharmacy

After the completion of the Summer Internship, we continued to work with Hampton University in order to increase training in cancer epidemiology at their home institution. In order to expand student exposure to oncogenesis as well as to neoplastic disorders, Drs. Saulsbury and

Heyliger increased cancer content in the second year pharmacy course PHA 423 (Microbiology and Immunology) where lectures were added to discuss genes involved in cancer progression and promotion as well as diagnostic tests utilized to identify neoplastic disorders. In addition, students were introduced to topics on specific cancers which disproportionately impact minority populations such as breast cancer, prostate cancer, colon and melanoma. In addition, the elective formerly called analytical studies is currently being revised to focus primarily on pharmacogenetics with special emphasis on cancer medications.

, During the Fall of 2013, 2 pharmacy students (P3) students Danielle Brown and Brooklyn Cobb (out of 6 applicants) were chosen to enroll in an independent study course within the School of Pharmacy under the supervision of Dr. Marilyn Saulsbury to cancer epidemiology and cancer pharmacogenetics. During this course students examined the incidences and prevalence of prostate, breast and colon cancers in underserved populations as well as explored pharmacogenetic considerations surrounding the use of common chemotherapeutic regimens.

Students met bimonthly to discuss journal articles and recent development in cancer therapy. Students were also required to develop a term paper on pharmacogenetics of chemotherapeutic agents as a capstone project. Specifically students were required to develop a paper outlining how polymorphisms in key genes impact patients' response as well as adverse effects of chemotherapeutic agents. Ms. Danielle Brown's Paper entitled "Pharmacogenomics and Prostate Cancer" focused on the impact of cytochrome P450 genes such as CYP2C9, CYP 2D6, CYP 1A1 and CYP 2C19 pharmacological properties of chemotherapeutic agents used in the treatment of prostate cancer (Vinca Alkaloids, Anthracenediones and Podophyllotoxins). Ms. Cobb's paper focused on the pharmacogenetics of breast cancer and on the role of phase 1 and phase 2 hepatic enzymes on pharmacological efficacy and adverse effects.

Biology

A three-credit honor, BIO 408-HR, Cancer Epidemiology course was developed in Fall 2013. The course was developed and taught jointly by Dr. Andraos-Selim, Associate Professor of Biology at Hampton University, and several Feinstein Institute professionals via SKYPE (Syllabus attached). The class convened at Hampton University twice a week on Tuesdays and Thursdays for 1 hour and 15 minutes each. Eleven undergraduate biology students were enrolled in this newly developed course; 9 seniors; 1 junior and one exchange student. Student's grades were as follows: 2 As, 7 Bs and 2 Cs. The course was advertized via flyers posted in the DuPont Building, which houses the biology department and is visited frequently by chemistry students. In addition, the course was announced to the biology advisors to advertise it to their advisees. None of the enrolled students were able to apply to the 2014 summer internship, as almost all of them graduated in May 2014.

Topics discussed in the course included: Foundations of Epidemiology; Historic Developments in Epidemiology; General Health and Population Indicators; Descriptive Epidemiology; Analytical Epidemiology; Design Strategies and Statistical Methods in Epidemiology; Cancer Health Disparities; Ethics Approval Process (IRB); and Genetic Epidemiology. Students were also engaged in one final project studying the effect of different risk factors on prostate cancer. They worked in groups of 3-4 and they gave final oral presentations. In addition, students had to complete an assignment regarding the Genome Wide Association Study and different cancers.

Three Hampton students participated in cancer epidemiology research at Feinstein Institute in summer 2013. These students participated in the summer research before the cancer epidemiology course was offered. Upon their return to Hampton, two of the three students enrolled in BIO 408-Research Problems in fall 2013 and wrote a paper about their summer research topic. The summer internship was advertised to both School of Science and School of Pharmacy students via posted flyers and word of mouth.

Recruitment Period (Spring 2014)

Early in 2014, we began discussions with Hampton University co-investigators to begin planning for recruitment of the second cycle of summer interns. We were able to assist Pharmacy in creating recruitment materials, as they had successfully worked with their administration to allow Pharmacy interns the scheduling flexibility to participate in the NSLIJ internship. These flyers were posted on bulletin boards in main areas frequented by Pharmacy students, as well as disseminated via informational sessions by Drs. Saulsbury and Heyliger. The effort was made to advertise earlier in the Spring semester, hoping to attract a larger amount of eligible applicants. However, while we did increase the applicant pool, we did not identify more than two candidates whom we felt met our criteria, after reviewing applications and administering two rounds of telephone interviews.

At the end of this process, two candidates, Kaia Amoah, a Freshman Biology major, and Brittany Williams, a Sophomore Pharmacy major, were selected. Both offers of acceptance were confirmed by the students; however, after further consideration, Brittany Williams decided to decline the internship spot due to distance from home. By this point of declination, we did not have enough time prior to the internship start date to identify further candidates for participation.

Second Internship Period (Summer 2014-through July 5th)

Kaia Amoah, the HU intern for the second internship cycle, participated in the same training described in the First Internship Period section. The one main deviation was the lack of a course offering in introductory Epidemiology from Hofstra University. As a result, the study team developed an Epidemiology Fundamentals Discussion Group in order to guide the reading of the Fundamentals of Epidemiology 101 textbook used by the previous year's interns. In this discussion group, Kaia and a faculty member met once a week to review the topics covered in the textbook and to synthesize the material. Based on Kaia's interests, and review of publications, she developed the following research question: "Is the consumption of processed meats associated with prostatic inflammation (i.e., serum PSA)" with the following hypothesis "Men with a diet high in processed foods are more likely to have higher levels of prostatic inflammation (i.e., serum PSA) levels than men with no diet or a diet low in processed foods." In order to assess this research question, Kaia is at report date, working on a combined dataset of NHANES data from 2010 with Drs. McDonald and Camacho. Kaia is also working with Drs. Taioli and McDonald to develop a publication for submission based on the results of the analysis.

Annual Workshops for Final Projects

- Plans are in place for annual workshops where students will present their final projects.
- Presentations have been made to the Population Health and Hofstra-North Shore-LIJ faculty on their chosen topics.

Didactic Training

We aimed to have all summer interns participate in didactic training involving introductory epidemiology research methods, prostate cancer biology, prostate cancer epidemiology, dietary risk factors and prostate cancer and community-based research methods for prostate cancer early detection and control. We accomplished this aim in the following ways:

- The interns participated in periodic clinical seminars on prostate cancer biology, treatment and outcome, to become familiar with the topic.
- They acquired a solid background in Epidemiology through a formal training at Hofstra.
- They learned how to manage data sets and data entry.
- They learned the basics of statistical analysis through personalized tutoring by junior faculty at Hofstra.

Course Work

We addressed this critical component of the original scope of work in the following offerings:

- **Epidemiology I:** Summer 2013 Hampton University interns (Kelly Mitchell, Tahirah Burford and Jennifer Perry) participated in the Hofstra University's MPH program summer course "Introduction to Epidemiology". The three interns audited the class at Hofstra every Tuesday and Thursday for the duration of their internship. They completed course assignments, and completed the Robert Friis textbook, "Essentials in Epidemiology 101" by APHA Press during their coursework.
- **Microbiology and Immunology Course:** Described previously (Hampton University).
- **Pharmacology Independent Study Course:** Described previously (Hampton University).
- **Cancer Epidemiology Course:** Described previously (Hampton University).
- **Feinstein Institute Lecture Series:** Interns were able to view numerous on-line lecture series pertaining to different aspects of the research enterprise.
- **Translational Research Working Group Symposia** "Management of low-risk prostate cancer", presented by Drs. Cory Abate Shen, Sven Wenske and Saravanan (Van) Krishnamoorthy at the Columbia University Medical Center.
- **Epidemiology Fundamentals Discussion Group:** Due to the fact that Epidemiology I was not offered during the Summer 2014 internship period, we created an internal program in the Population Health Department consisting of three Epidemiology faculty members. The members met with intern Kaia Amoah weekly in order to discuss the concepts presented in the Robert Friis textbook, "Essentials in Epidemiology 101", which was also read by the prior year's students. As of this report, Kaia Amoah is half-way through her internship, and has completed half of the assigned textbook, as well as completed associated readings to accompany the book chapters.

Discussion with Hampton University regarding Fall 2015 course offerings, content and syllabi are underway as of date of report.

IV. Key Research Accomplishments (bulleted points)

- Designed and implemented a cross-disciplinary didactic research program for undergraduate students.
- Introduced students to a broad range of topics in prostate cancer that would prepare them for future involvement in research.
- Increased the carcinogenesis content in current Hampton University course offerings, allowing greater exposure of the student body to the current topics in cancer research.
- Collected data on over 400 prostate cancer cases diagnosed within the NSLIJ Health System for analysis.
- Fostered an increased interest in training in the epidemiology behind prostate cancer, with 2 of the 3 first cycle interns enrolling in the Epidemiology course co-taught by Hampton University and NSLIJ faculty.

V. Conclusion (summarize results to include importance/implications of the completed research and when necessary, recommend changes to future work to better address the problem.)

Overall, the partnership between NSLIJ and HU project investigators has been a successful one in the fostering of greater carcinogenesis content in courses offered by HU, as well as developing new coursework specific to Epidemiology. Due to the health system resources, we were able to offer summer interns a wide breadth of experience in cancer research, and basic research in general, ranging from clinical interventions to population-based studies. Undergraduate trainees were introduced to all critical areas in research, such as literature review, presentation skills, and data management, among others. Through the HU Epidemiology course, we have introduced many more undergraduates to the concepts behind general epidemiology, as well as cancer research, which we believe will influence an increased involvement in the sciences.

In the future, we would like to implement a more codified system for annual project presentation, and are in discussions with Hampton University faculty in order to arrange for a date that NSLIJ faculty can attend a presentation day for the completed projects that began during the summer internships. We are confident that this can be arranged in Year 2 of the current grant.

We are also working with Hampton University faculty to develop further advertisement for the Epidemiology course to be taught in Fall 2014. In addition, we are considering the addition of further topics in cancer epidemiology, such as health disparities in cancer treatment.

Due to the challenges encountered in identifying qualified candidates for the summer internship program, we will be requesting a no-cost extension in order to fulfill initial goal of a total of 8 undergraduate trainees under this grant project. In anticipation of this, we plan to recruit for the summer internship program still earlier so that we may be able to reach more qualified candidates within a longer time frame.

VI. Publications, Abstracts, and Presentations

Manuscripts/ Abstracts

- “Pharmacogenomics and Prostate Cancer”: Capstone project by Pharmacy student Danielle Brown (under the supervision of Dr. Marilyn Saulsbury).
- “Pharmacogenetics of breast cancer and on the role of phase 1 and phase 2 hepatic enzymes on pharmacological efficacy and adverse effects”. Capstone project by Brooklyn Cobb (under the supervision of Dr. Marilyn Saulsbury).
- “Processed Foods and Prostatic Inflammation: A Synthesis and Analysis Review”, paper in development by Kaia Amoah (under the supervision of Drs. Taioli and McDonald).

Presentations

- Summer Session 1 Internship presentation to the Department of Population Health.
- Upcoming Summer Session 2 Internship presentation to the Department of Population Health.
- Upcoming Internship presentation to Hampton University Department of Biology.

VII. Inventions, Patents and Licenses

Nothing to report.

VIII. Reportable Outcomes

Nothing to report.

IX. Other Achievements

Employment or research opportunities applied for and/or received based on training

- Summer Intern Jennifer Perry has plans to apply to medical school following graduation, and has asked for and received a letter of recommendation from Dr. Emanuela Taioli.

Degrees obtained supported by this work

- N/A as of report date.

Funding applied for based on work supported by this award

- Plans are in place for Dr. Emanuela Taioli to collaborate with HU faculty member, and Co-Investigator, Dr. Marilyn Saulsbury to apply for an R15 to continue research collaborations in training between the two institutions.

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XI. Appendices

To follow.



North Shore-Long Island Jewish Health System

To: Emanuela Taioli, MD, Ph.D.
Population Health
North Shore-LIJ Health System

From: Martin L Lesser, PhD
Chair, Institutional Review Board

Date: Tuesday, June 04, 2013

RE: **IRB #:** 13-225B
Protocol Title: Analysis of Prostate Cancer Registry Data
Expiration Date: 6/3/2014

Dear Dr. Taioli:

The above referenced project meets the criteria outlined in 45 CFR 46.110 and 21 CFR 56.110 for EXPEDITED REVIEW and has been approved. The following category(ies) apply(ies) to the project:

45 CFR 46.110 (5): **Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).**

Pre Meeting Action: Expedited Approval. Approval of this project includes:

1. Application Protocol (version 5/30/13)
2. This study has been granted a waiver of informed consent and HIPAA authorization

The Institutional Review Board - Committee will be notified of this action at its meeting on 6/20/2013. This study has not been approved for the inclusion of pregnant women, children, or prisoners. If you would like to include these populations, please notify the IRB for further instruction.

The IRB approval expiration date is listed above. As a courtesy, approximately 60 to 90 days prior to expiration of this approval, the Office of the IRB will send an e-mail reminding you to apply for continuing review. Failure to receive renewal notification does not relieve you of your responsibility to provide the Progress Report to the IRB in time for the request to be processed and approved prior to your expiration date. **It is your responsibility to apply for continuing review and receive continuing approval for the duration of the study.** Lapses in approval should be avoided to protect the safety and welfare of enrolled subjects.

Subject recruitment methods are appropriate, there is equitable selection of subjects, and there are provisions to protect and maintain the confidentiality of data and research participants.

Investigators are reminded that research must be conducted in accordance with all applicable Department of Health and Human Services regulations 45 CFR 46, Food and Drug Administration regulations 21CFR 50, 21CFR 56, 21 CFR 312, 21 CFR 812, and the Health Insurance Portability and Accountability Act (HIPAA).

All studies are subject to audits by the Office of Research Compliance and/or Institutional Review Board to confirm adherence to institutional, state, and federal regulations governing research. All research studies are expected to conform to Good Clinical Practice (GCP) guidelines.

NOTE: This approval is subject to recall if at any time the conditions and requirements as specified in the IRB Policies and Procedures are not followed (see next page and web site: <http://www.northshorelij.com/body.cfm?ID=2804>)

Internal #: 23175

The Office of the IRB no longer sends a hard copy of documents which have been electronically transmitted.
These are the only copies of the regulatory documents you will receive.

Revised: May 2013

NOTE: All IRB Policies and Procedures must be followed, including the following:

1. Using only IRB-approved consent forms, questionnaires, letters, advertisements, etc. in your research.
2. Submitting any modifications made to the study for IRB review prior to the initiation of changes except when necessary, to eliminate apparent, immediate hazards to the subject.
3. Reporting unanticipated problems involving risk to subjects or others..
4. Prior to implementation, any changes made to studies utilizing TAP must have COPP, as well as IRB approval.



North Shore-Long Island Jewish Health System

Institutional Review Board

FWA #00002505

Office of the Institutional Review Board
350 Community Drive, 4th Floor
Manhasset, New York 11030
Phone: 516-562-3101
Fax: 516-562-3105

To: Emanuela Taioli, MD, Ph.D.
Population Health
North Shore-LIJ Health System

From: Martin L. Lesser, PhD
Chair, Institutional Review Board

Date: Thursday, June 06, 2013

RE: **IRB #:** 13-225B
Protocol Title: Analysis of Prostate Cancer Registry Data
Modification Approval Date: 6/6/2013

Dear Dr. Taioli:

This is to advise you that the submission received 6/6/2013 for the above referenced study was reviewed by the Institutional Review Board and the following determination was made:

Expedited Approval for the following:

Modification:

1. Appropriate documentation to add Tahirah Burford, Kelly Mitchell, Jennifer Perry, and Cassandra Chan to this study.

This modification was reviewed in accordance with 45 CFR 46.110(b) and 21 CFR 56.110(b). All conditions of approval previously established by the IRB for this research project continue to apply. The Institutional Review Board - Committee will be notified of this action at its meeting on 6/20/2013.

All studies are subject to audits by the Office of Research Compliance and/or Institutional Review Board to confirm adherence to institutional, state, and federal regulations governing research. All research studies are expected to conform to Good Clinical Practice (GCP) guidelines.

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NOTE: All IRB Policies and Procedures must be followed, including the following:

1. Using only IRB-approved consent forms, questionnaires, letters, advertisements, etc. in your research.
2. Submitting any modifications made to the study for IRB review prior to the initiation of changes except when necessary, to eliminate apparent, immediate hazards to the subject.
1. Reporting unanticipated problems involving risk to subjects or others..
2. Renewing the study at the interval set by the Institutional Review Board. You should submit a progress report to the Institutional Review Board at least two months prior to expiration of the study. Failure to receive notification that it is time to renew does not relieve you of your responsibility to provide the IRB with the Progress Report in time for the request to be processed and approved prior to your expiration date.
3. Prior to implementation, any changes made to studies utilizing TAP must have COPP, as well as IRB approval.

IMPORTANT REMINDER: The International Committee of Medical Journal Editors (ICMJE) requires registration of clinical research studies meeting specific guidelines prior to publication. Please see ICMJE requirements for registration of clinical trials at <http://www.icmje.org>. Our organization account is in the name of the North Shore-Long Island Jewish Health System. To register your trial: <http://prsinfo.clinicaltrials.gov>



North Shore-Long Island Jewish Health System

Institutional Review Board

FWA #00002505

Office of the Human Research Protection Program
3333 New Hyde Park Road, Suite 317
New Hyde Park, NY 11042
Phone: 516-719-3100 or 516-321-2100
Fax: 516-321-2125

To: Emanuela Taioli, MD, Ph.D.
Population Health
175 Community Drive
Great Neck, NY 11021

From: Martin L. Lesser, PhD
Chair, Institutional Review Board

Date: Friday, June 20, 2014

RE: **IRB #:** 13-225B
Protocol Title: Analysis of Prostate Cancer Registry Data
Modification Approval Date: 6/20/2014

Dear Dr. Taioli:

This is to advise you that the submission received 6/10/2014 for the above referenced study was reviewed by the Institutional Review Board and the following determination was made:

Pre Meeting Action: Expedited Approval for the following:

Modification:

1. Appropriate documentation to add Kaia Amoah to this study. This investigator is not approved to obtain consent.

Please note: **If consent forms have been revised with this modification, please make sure to use the newly stamped consent forms going forward.**

This modification was reviewed in accordance with 45 CFR 46.110(b) and 21 CFR 56.110(b). All conditions of approval previously established by the IRB for this research project continue to apply. The Institutional Review Board - Committee will be notified of this action at its meeting on 7/1/2014.

All studies are subject to audits by the Office of Research Compliance and/or Institutional Review Board to confirm adherence to institutional, state, and federal regulations governing research.

NOTE: This approval is subject to recall if at any time the conditions and requirements as specified in the IRB Policies and Procedures are not followed (see next page and web site: <http://www.northshorelij.com/body.cfm?ID=2804>)

NOTE: All IRB Policies and Procedures must be followed, including the following:

1. Using only IRB-approved consent forms, questionnaires, letters, advertisements, etc. in your research.
2. Submitting any modifications made to the study for IRB review prior to the initiation of changes except when necessary, to eliminate apparent, immediate hazards to the subject.
1. Reporting unanticipated problems involving risk to subjects or others.
2. Renewing the study at the interval set by the Institutional Review Board. You should submit a progress report to the Institutional Review Board at least two months prior to expiration of the study. Failure to receive notification that it is time to renew does not relieve you of your responsibility to provide the IRB with the Progress Report in time for the request to be processed and approved prior to your expiration date.
3. Prior to implementation, any changes made to studies utilizing TAP must have COPP, as well as IRB approval.

IMPORTANT REMINDER: The International Committee of Medical Journal Editors (ICMJE) requires registration of clinical research studies meeting specific guidelines prior to publication. Please see ICMJE requirements for registration of clinical trials at <http://www.icmje.org>. Our organization account is in the name of the North Shore-Long Island Jewish Health System. To register your trial: <http://prsinfo.clinicaltrials.gov>

Hampton University
Department of Biological Sciences
BIO 408-HR
Cancer Epidemiology
Fall 2013

Instructor: Dr. Cecile Andraos-Selim
Office: Dupont Hall #117
Telephone Number: 727-5015
E-mail: cecile.andraos-selim@hamptonu.edu
Office Hours: TBA

Instructors (North Shore LIJ-Hofstra School of Medicine): Dr. Emanuela Taioli

Email: Etaioli@NSHS.edu

Course Description:

This is an elective course that surveys the basic concepts and principles of epidemiology. The course includes lectures, readings, homework assignments, and a practicum during which students will design and conduct an epidemiologic study of their choice. The course is team-taught comprising faculty from Hampton University and the North Shore LIJ-Hofstra School of Medicine, through SKYPE.

This course is supported in part by a grant from the Department of Defense.

Applied Course Description: This course will cover foundations of epidemiology, historic developments in epidemiology, practical disease concepts in epidemiology, descriptive epidemiology, general health and population indicators, cancer biology and statistics, and ethics approval process.

Required Textbook:

Merrill, Ray. Introduction to Epidemiology. Sixth Edition. 2013. Jones & Bartlett Learning , LLC.

DISCLAIMER

This syllabus is intended to give the student guidance in what may be covered during the semester as well as course grading, schedule, policies, and regulations and it will be followed as closely as possible. However, the professor reserves the right to modify, supplement, and make changes in the syllabus as the course needs arise.

Course Objectives:

The objective of this course is to familiarize students with the basic concepts of epidemiology

including the understanding of descriptive, observational, experimental, and genetic epidemiologic studies. Students will learn various forms of epidemiological study designs and data analyses and how to calculate and interpret measures of effect in order to compare the risk of disease between populations and subgroups.

Specific Intended Student Learning Outcomes and Assessment Tools:

At the end of the course, the students will be able to:

1. Outline the role of epidemiology in public health. This will be measured via class participation / discussion and midterm exam.
2. Discuss the role of epidemiology in public health. This will be measured via class participation / discussion and midterm exam.
3. Discuss disease concepts in epidemiology. This will be measured via class participation / discussion and midterm exam.
4. Discuss the historic development of breast cancer epidemiology. This will be measured via class participation / discussion and midterm exam.
5. Discuss statistical methods in descriptive epidemiology. This will be measured via class participation / discussion and midterm exam.
6. Identify common indices used in identifying the health status of a population. This will be measured via class participation / discussion and midterm exam.

Course Assignments and Calendar:

There will be 3 midterm examinations during the course of the semester. **A final project will substitute for the final comprehensive exam.** Exam I will be on **Sept. 24th**, exam II on **Oct. 22nd**, exam III on **Nov. 12th**. Deadlines for the draft and final project plans are listed on the outline below and the projects' presentations are on **Dec. 5th**.

Grading Policy:

Three Midterm Exams	45%
Quizzes/Class Assignments	10%
Student Project	15%
Student Presentation	15%
Class Attendance and Participation	<u>15%</u>
	100%

Letter grades are assigned as follows:

A+=98-100%, A=94-97 %, A-=90-93%,
B+=88-89%, B= 84-87%, B-=80-83%,
C+=78-79%, C=74-77%, C-=70-73%,
D+=68-69%, D=64-67%, D-=60-63%,
F= Below 60%

Attendance Policy and Course Regulations:

- 1- Tardiness will not be tolerated in this course.
- 2- During examinations / Quizzes:
 - a- Pencils will not be provided. So make sure to bring your own.
 - b- No extra time will be given to late arrivals.

- c- Bathrooms and drinking fountains are not to be visited.
- d- Students who leave the exam / quiz will not be allowed back.
- e- No electronic devices of any kind (cell phones, iPhones, Ipads, PDAs, calculators etc.) are allowed.
- 3- All forms of misconduct are neither allowed nor tolerated in this course.
- 4- Cell phones of all kinds must be turned off during lecture, labs, and exams.
- 5- No photography or videotaping is allowed during class.

Make-Up/ Late Work Policy

If you miss a quiz or one of the midterm exams with a valid excuse e.g. illness that has been documented with a written note from an appropriate office you will have to take a make-up exam. Regular medical examinations are not considered medical emergencies. They should be scheduled around exams. Car trouble is also not considered a valid excuse. The make-up exam might have a complete different format than the original exam. Documentation for valid excuses has to be presented to me upon your return to class.

If you are participating in a scheduled HU activity (sports, scientific meeting, etc.) that conflicts with a scheduled exam/activity you need to let me know **at least one week before the scheduled event** and you will be allowed to take the exam before its scheduled date.

A 5% reduction in the grade per day will be applied to all late work. No late work will be accepted later than **one week after its original deadline**.

Tentative Course Outline and Schedule:

<u>Dates</u>	<u>Lecture Topic</u>	<u>Chapter</u>	<u>Instructor</u>
9/3-9/5	Introduction		Hampton
	Foundations of Epidemiology	1	Hampton
	Historic Developments in Epidemiology	2	Hampton
9/10-9/12	Practical Disease Concepts in Epidemiology Chap	3	Hampton
9/17- 9/19	General Health and Population Indicators	6	Hampton
9/24	<u>Class Test 1 (Chaps 1, 2, 3, 6 and supplements)</u>		
9/26-10/01	Descriptive Epidemiology According to Person, Place & Time	5	Dr. Marlon Joseph
10/03-10/08	Design Strategies & Statistical Methods in Epidemiology	7	Dr. Bian Liu
10/10-10/15	Cancer Health Disparities		Dr. Alicia McDonald

10/17-10/22	Design Strategies	4	Dr. Marlene Camacho
10/24	<u>Class Test II (Chaps 4, 5, 7, and supplements)</u>		
10/29-10/31	Ethics Approval Process (IRB) and Study Implementation		Samantha Kerath, MSc
11/5-11/07	Chronic Disease Epidemiology	11	Dr. Emanuela Taioli
11/12-11/14	STUDENT PROJECTS		
11/19	<u>Class Test III (Chap. 11 and supplements)</u>		
11/21	STUDENT PROJECTS (draft research plan due)		
11/26	STUDENT PROJECTS		
11/28	Happy Thanksgiving		
12/3	STUDENT PROJECTS (research plan due)		
12/5/13	<u>STUDENT PRESENTATIONS</u>		

The following information applies to ALL students in the School of Science:

In addition to the minimum grade requirements established by Hampton University, all majors within the School of Science must pass all required courses offered within the School of Science with a grade of “C” or better in order to satisfy degree requirements. The minimum grade requirement is in effect for all science courses taken during fall 2001 and beyond.

Americans with Disabilities Act Compliance:

Students with disabilities which require accommodations should (1) register with the Office of Testing Services and 504 Compliance to provide documentation and (2) bring the necessary information indicating the need for accommodation and what type of accommodation is needed. This should be done during the first week of classes or as soon as the student receives the information. If the instructor is not notified in a timely manner, retroactive accommodations may not be provided.

STANDARDS OF CONDUCT

**Hampton University
Academic Dishonesty**

An act of academic dishonesty, even a first offense, places the student in jeopardy of severe forms of disciplinary action, including dismissal. A student is in jeopardy of severe forms of disciplinary action, including dismissal, if he or she is guilty of committing one of the following violations:

I. Cheating

A student is considered to be cheating if, in the opinion of the person administering an examination/test (written or oral), he or she gives, seeks, or receives aid during the process of the examination/test; buys, sells, steals, or

otherwise possesses or transmits an examination/test without authorization; or, he or she substitutes for another or permits substitution for himself or herself during an examination/test.

- A. A student must not use external assistance on any “in class” or “take home” examination, unless the instructor specifically has authorized such assistance. This prohibition includes, but is not limited to, the use of tutors, books, or notes.
- B. A student must not submit substantial portions of the same academic work for credit or honors more than once without permission of the present instructor.
- C. A student must not allow others to conduct research or to prepare any work for him or her without advance authorization from the instructor. This prohibition includes, but is not limited to, commercial term-paper companies and files of past papers.
- D. Several people must not collaborate on a single project and turn in multiple copies; all represented implicitly or explicitly as individual work.

II. Fabrication

A student must not intentionally falsify or invent any information or citation in an academic exercise.

III. Plagiarism

The American College Dictionary defines plagiarism as “copying or imitating the language, ideas, and thoughts of another person and passing of the same as one’s original work.” A student must not intentionally adopt or reproduce ideas, words, or statements of another person without acknowledgment. He or she must give due credit to the originality of others and honestly pay his or her literary debts and acknowledge indebtedness:

- A. Whenever he or she quotes another person’s actual words.
- B. Whenever he or she uses another person’s ideas, opinion, or theory.
- C. Whenever he or she borrows facts, statistics, or other illustrative material—unless the information is common knowledge.

IV. Interference

A student must not steal, change, destroy, or impede another student’s work. Impeding another student’s work includes, but is not limited to, the theft, defacement, or mutilation of common resources so as to deprive others of the information they contain.

V. Facilitating Academic Dishonesty

A student must not intentionally help or attempt to help another commit an act of academic dishonesty.

Hampton University Code of Conduct

Joining the Hampton Family is an honor and requires each individual to uphold the policies, regulations, and guidelines established for students, faculty, administration, professional and other employees, and the laws of the Commonwealth of Virginia. Each member is required to adhere to and conform to the instructions and guidance of the leadership of his/her respective area. Therefore, the following are expected of each member of the Hampton Family.

1. To respect himself or herself.

Each member of the Hampton Family will exhibit a high degree of maturity and self-respect and foster an appreciation for other cultures, one's own cultural background, as well as the cultural matrix from which Hampton University was born. It is only through these appreciations that the future of our University can be sustained indefinitely.

2. To respect the dignity, feelings, worth, and values of others.

Each member of the Hampton Family will respect one another and visitors as if they were guests in one's home. Therefore to accost, cajole, or proselytize students, faculty or staff, parents or others, to engage in gender and sexual harassment, use vile, obscene or abusive language or exhibit lewd behavior, to possess weapons such as knives or firearms, or to be involved in the possession, use, distribution of and sale of illegal drugs is strictly prohibited and is direct violation of the Hampton University Code, on or off campus.

3. **To respect the rights and property of others and to discourage vandalism and theft.**
Each member of the Hampton Family will refrain from illegal activity, both on and off campus, and will be subject to all applicable provisions listed in the Faculty Handbook, Personnel Policies Manual for Administrative, Professional and Non-exempt Employees, the Official Student Handbook, and the Hampton University Code.
4. **To prohibit discrimination, while striving to learn from differences in people, ideas, and opinions.**
Each member of the Hampton Family will support equal rights and opportunities for all regardless of age, sex race, religion, disability, ethnic heritage, socio-economic state, political, social, or other disaffiliation, or sexual preference.
5. **To practice personal, professional, and academic integrity, and to discourage all form of dishonesty, plagiarism, deceit, and disloyalty to the Code of Conduct.**
Personal, professional, and academic integrity is paramount to the survival and potential of the Hampton Family. Therefore, individuals found in violation of Hampton University's policies against lying, cheating, plagiarism, or stealing are subject to disciplinary action, which could possibly include dismissal from the University.
6. **To foster a personal professional work ethic within Hampton University Family.**
Each employee and student of the Hampton Family must strive for efficiency and job perfection. Each employee must exhibit a commitment to serve and job tasks must be executed in a humane and civil manner.
7. **To foster an open, fair, and caring environment.**
Each member of the Hampton Family is assured equal and fair treatment on the adjudication of all matters. In addition, it is understood that intellectual stimulation is nurtured through the sharing of ideas. Therefore, the University will maintain an open and caring environment.
8. **To be fully responsible for upholding the Hampton University Code.**
Each member of the Hampton Family will embrace all tenets of the Code and is encouraged to report all code violators.

Hampton University Student Dress Code

This code is based on the theory that learning to use socially acceptable manners and to select attire appropriate to specific occasions and activities are critical factors in the total educational process. Understanding and employing these behaviors improve the quality of one's life, contribute to optimum morale, and embellish the overall campus image. They also play a major role in instilling a sense of integrity and an appreciation for values and ethics.

The continuous demonstrations of appropriate manners and dress insures that Hampton University students meet the very minimum standards of quality achievement in the social, physical, moral and educational aspects of their lives - essential areas of development necessary for propelling students toward successful careers.

Students will be denied admission to various functions if their manner of dress is inappropriate. On this premise students at Hampton University are expected to dress neatly at all times. The following are examples of appropriate dress for various occasions:

1. Classroom, Cafeteria, Student Union and University offices - neat, modest, casual, or dressy attire.
2. Formal programs in Ogden Hall, the Convocation Center, the Little Theater and the Memorial Chapel - business or dressy attire.
3. Interviews, - business attire.
4. Social/Recreational activities, Residence hall lounges (during visitation hours) - modest, casual or dressy attire.
5. Balls, Galas, and Cabarets - formal, semi-formal and dressy respectively.

Examples of inappropriate dress and/or appearance include but are not limited to:

1. Caps, or hoods for men and women in classrooms, the cafeteria, Student Union or other indoor activities. This policy item does not apply to headgear considered as a part of religious or cultural dress. **Do-rags, stocking caps, skullcaps and bandanas are prohibited at all times on the campus of Hampton University (except in the privacy of the student's living quarters).**
2. Midriffs or halters, mesh, netted shirts, tube tops or cut-off tee shirts in classrooms, cafeteria, Student Union and offices;

3. Bare feet;
4. Short shorts;
5. Shorts, blue or other type jeans at major programs such as Musical Arts, Fall Convocation, Commencement, or other programs dictating professional, dressy, or formal attire,
6. Clothing with derogatory, offensive and/or lewd messages either in words or pictures;
7. Undershirts, for men, of any color outside of the private living quarters of the residence halls.

All administrative, faculty and support staff members will be expected to monitor student behavior applicable to this dress code and report any such disregard or violations to the Dean of Men or Dean of Women for the attention of the Dean of Students.

Hampton University-Feinstein Institute for Medical Research

8-Week Summer Prostate Cancer Research Internship

The Feinstein Institute of Medical Research, in collaboration with Hampton University, is seeking 4 highly-motivated students in the scientific disciplines

-MUST BE A JUNIOR OR SENIOR-

INTERNSHIP GOALS:

- Learn the basics of epidemiology through data collection and analysis
- Provide students with training in a research driven atmosphere
- Develop research, epidemiological and statistical analysis skills
- Opportunity to take graduate coursework
- Continuing mentorship by Hampton faculty members
- Housing and stipends provided

**For Consideration Submit the Following To
Contact Below**

- Personal Statement
- GPA and Coursework listing
- 2 Letters of Recommendation

QUESTIONS?

Cecile Andraos-Selim, MBBCh, PhD
DU 117; 757-727-5015
cecile.andraos-selim@hamptonu.edu

**DEADLINE
MARCH 15th, 2013**