MARYLAND HIGHER EDUCATION COMMMISSION
ACADEMIC PROGRAM PROPOSAL

PROPOSAL FOR:

✓ NEW INSTRUCTIONAL PROGRAM

____ SUBSTANTIAL EXPANSION/MAJOR MODIFICATION

____ COOPERATIVE DEGREE PROGRAM

✓ WITHIN EXISTING RESOURCES or ____ REQUIRING NEW RESOURCES

(For each proposed program, attach a separate cover page. For example, two cover pages would accompany a proposal for a degree program and a certificate program.)

Johns Hopkins University
Institution Submitting Proposal

Spring 2017
Projected Implementation Date

Master of Science
Award to be Offered

Individualized Genomics and Health
(with AOCs in Laboratory Diagnostics, Genomics, Regulatory Science, and Policy)
Title of Proposed Program

0499-52
Suggested HEGIS Code

26.0807
Suggested CIP Code

Advanced Academic Programs
Krieger School of Arts and Sciences
Department of Proposed Program

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Sunil Kumar R **9/26/2016**
Signature and Date

President/Chief Executive Approval

N/A
Date

Date Endorsed/Approved by Governing Board

The Johns Hopkins University
Krieger School of Arts and Sciences
Proposal for New Academic Program

Master of Science in Individualized Genomics and Health with Areas of Concentration in Laboratory Diagnostics, Genomics, Regulatory Science, and Policy

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A. Centrality to institutional mission statement and planning priorities

1. Program description and alignment with mission

The Johns Hopkins University Krieger School of Arts and Sciences is pleased to submit a proposal for a new Master of Science in Individualized Genomics and Health, including four areas of concentration: Laboratory Diagnostics, Genomics, Regulatory Science, and Policy. The newly proposed program will be delivered both online and on-site.

Offered through the Krieger School's Advanced Academic Programs (JHU-AAP), the M.S. in Individualized Genomics and Health is designed to produce a highly skilled workforce with the theoretical knowledge and practical skills to meet the demands of the academic, research, and business communities. Individualized Genomics and Health is a rapidly growing area of research and applied science. The growth is due in large part to our increasing dependence on DNA and RNA sequence analysis of human and microbial genomes for diagnosis and treatment of disease. This emerging field requires a workforce with multi-disciplinary skills in bioinformatics, bioscience, regulatory science, policy and ethics. These disciplines are already part of JHU-AAP's Advanced Biotechnology Studies curriculum.

The mission of Johns Hopkins University is to educate its students and cultivate their capacity for life-long learning, to foster independent and original research, and to bring the benefits of discovery to the world. In addition, the mission of JHU-AAP is to offer high quality graduate courses, certificates, and degree programs containing a mixture of theory and practice that serve the current and long-term needs of today's adult learners. The proposed program is consistent with the Johns Hopkins mission and the State of Maryland's goals for maintaining and strengthening a preeminent statewide array of postsecondary institutions recognized nationally for academic excellence and effectiveness in fulfilling the educational needs of students, the State and the nation; and for promoting economic growth and vitality through the advancement of research and the development of a highly qualified workforce.

2. Alignment with institutional strategic goals

The proposed M.S. in Individualized Genomics and Health program advance the Johns Hopkins mission by offering life-long learning for those developing new skills, exploring new careers, or expanding their professional knowledge. As a program that will be offered online (except for lab classes) and on-site, the mission of life-long learning can be

extended outside of the Baltimore-Washington Metropolitan area. The program will cultivate knowledge and specific skills intended to prepare graduates to deal with the complex and pressing issues discussed above.

B. Adequacy of curriculum design and delivery to related learning outcomes

1. Program outline and requirements

See Appendix A for a complete list of courses and course descriptions. The proposed program consists of 10 courses required for completion of the degree. After completion of the core requirements, students have the option of pursuing one of four concentrations Laboratory Diagnostics, Genomics, Regulatory Science, or Policy. Alternatively, students may elect three courses from among the four concentrations. In addition, all students can take one elective course from beyond the areas of concentration.

As this field requires practitioners to have multiple competencies, the core of the proposed program will include foundation courses such as Epigenetics, Human Molecular Genetics, Ethical, Legal and Regulatory Aspects of Individualized Genomics, bioinformatics, and individual genome analysis.

Required Core Courses (6)

410.XXX	Ethical, Legal and Regulatory Aspects of Personalized Medicine
410.612	Human Molecular Genetics
410.610	Epigenetics and Gene Organization and Expression
410.736	Personalized Medicine and Genomics
410.629	Genes and Disease
410.633	Introduction to Bioinformatics

Concentrations

Lab Diagnostics (3 courses)

410.641	Clinical and Molecular Diagnostics
410.659	Advanced Recombinant DNA class
410.656	Recombinant DNA Lab
410.671	Gene Expression Data Analysis
410.666	Next Generation Sequencing and Analysis

Genomics (3 courses)

410.666	Next Gen Sequencing and Analysis
410.634	Practical Computer Concepts
410.635	Bioinformatics: Tools for Genome Analysis
410.671	Gene Expression Data Analysis
410.734	Practical Introduction to Metagenomics
410.XXX	Pharmacogenomics
410.XXX	Cancer Genomics

Regulatory Science (3 courses)

410.676	Food and Drug Law
410.702	Biomedical Software Regulation
410.XXX	In Vitro Diagnostic Regulation

Policy (3 courses)

410.XXX	Ethics in Personalized Medicine
410.XXX	Legal Aspects of Personalized Medicine
410.XXX	In Vitro Diagnostic Regulation
410.XXX	Healthcare Economics
410.XXX	Medical Product Reimbursement

One Elective

2. Educational objectives and student learning outcomes

Upon completion of the M.S. in Individualized Genomics and Health, students will:

- Explain the molecular and genetic basis for human disease including the role of epigenetics
- Analyze a human genome to identify possible indicators of health and disease
- Apply bioinformatics tools to the analysis of human DNA sequences
- Explain the ethical legal and regulatory aspects of individualized genomics and health
- Understand the laboratory methods required to identifying genes responsible for disease

3. General education requirements

Not applicable.

4. Specialized accreditation/certification requirements

Not applicable.

5. Contract with another institution or non-collegiate organization

Not applicable.

C. Critical and compelling regional or statewide need as identified in the State Plan

1. Demand and need for the program

There is a tremendous need for trained individuals in individual genomic analysis. It has been reported that one of the major barriers to expansion of personalized medicine is the lack of a trained workforce. For example, one of the most common reasons physicians state for not ordering pharmacogenomics testing is lack of knowledge about what test to

order and how to interpret test results (Johansen et al. 2014. Pharmacogenomics Pers. Med. 7:145-62.). Moreover, the CDC reports that genomics plays a role in nine of the ten leading causes of death.[1] "Less than 1 percent of all opportunities are being realized with respect to genetic testing," said Felix Frueh, president and head of genomics initiatives at Medco. "There's a long way until this new technology is going to see the translation".[2] A skilled workforce will be required to realize the full potential of individual genomics and health.

2. Alignment with Maryland State Plan for Postsecondary Education

The 2013–2017 Maryland State Plan for Postsecondary Education articulates six goals for postsecondary education: 1) quality and effectiveness; 2) access, affordability and completion; 3) diversity; 4) innovation; 5) economic growth and vitality; and 6) data use and distribution.

The proposed degree program addresses each of these goals, by combining the strengths of the arts and sciences biotechnology faculty in the various areas that compose the current advanced biotechnology studies degree programs for the outcome of better preparing students to promote growth and vitality in the advancing field of biotechnology.

D. Quantifiable and reliable evidence and documentation of market supply and demand in the region and State

1. Market demand

An analysis done by the Educational Advisory Board (EAB) reported that in the last year over 3,800 jobs were created for individuals with graduate degrees in this area. The industry suggests a 10% growth in jobs each year in this area, and there will be a continuing demand for highly skilled and trained individuals for this life science sector. The EAB study states, "The Battell Impact Analysis concluded that the U.S. genetic and genomic clinical laboratory testing sector supported more than 116,000 jobs in the U.S. economy in 2009 (45,563 direct jobs and an additional 72,723 indirect and induced jobs)" (EAB 2015). The White House has established a $250 million precision medicine initiative for the purpose of analyzing the genomes of over one million volunteers. This project will require a significant number of genomics-trained professionals. Finally, the EAB report indicated that there is a greater demand among employers for individuals with graduate degrees than with bachelor's degrees because of the highly technical skills required for this field.

Taken together, the employment outlook for graduates from this program is very positive. As mentioned above there are very few master's program that provide the training needed for this emerging field.

[1] http://www.cdc.gov/genomics/public

[2] http://www.the-scientist.com/?articles.view/articleNo/30684/title/The-ghost-of-personalized-medicine

2. Educational and training needs in the region

A survey done using the Monster.com search engine found identified 65 jobs in Molecular Diagnostics and 170 jobs in Genomics in the state of Maryland.[3] Indeed, the job search engine returned 270 jobs in Genomics for the state of Maryland.[4] As this is a new and emerging field, it is difficult to determine exactly the number of new jobs over the next five years but as stated above, the industry expects a 10% increase in jobs over the next several years.

3. Prospective graduates

Initially, approximately 10 to 15 students are expected, gradually climbing to 35 to 40 graduates annually.

E. Reasonableness of program duplication

1. Similar programs

To our knowledge, no comparable program is offered elsewhere in the State of Maryland. Globally, few programs exist at the master's level that specifically address individualized genomics and health. The University of Connecticut offers a professional master's degree in Applied Genomics; Rutgers University offers a Master of Business and Science in Biotechnology and Genomics; the University of British Columbia offers a Master of Science in Genome Science and Technology; the University of Utah offers a Certificate in Genome Sciences that is open only to current graduate and postdoctoral students; and George Mason University offers a Graduate Certificate in Personalized Medicine. In addition, Stanford University offers a non-credit graduate Certificate in Genetics and Genomics, which is targeted at non-scientists. None of these programs offer the curriculum proposed by JHU-AAP, which includes the integration of science, policy, and regulation.

2. Program justification

There is a tremendous need for trained individuals to serve the industry, academia and government in this new field. There are no training programs in the state of Maryland geared toward educating professionals with the specialized training in individualized genomics and health. Students currently have to go out of state to obtain training in this field. Even then, as described above, the programs that are currently available do not provide the depth or breadth of the education offered by the proposed program.

As mentioned previously, the expectation is a 10% yearly increase in growth in this sector. Meeting the demands of the workforce will require a significant increase in the number of master's level programs. As a fully online and on-site program, JHU-AAP is positioned to fulfill needs both regionally and nationally. The proposed program will be housed in an interdisciplinary unit that is unique among the currently existing programs.

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[3] Retrieved 10/27/2015 from http://jobsearch.monster.com/search/?q=Genomics&where=Maryland

[4] http://www.indeed.com/q-Genomics-l-Maryland-jobs.html

Students will have coursework taught by experts from the fields of bioscience, bioinformatics, regulatory science, and policy, and access to robust academic resources from across these domains.

F. Relevance to Historically Black Institutions (HBIs)

Any student meeting the admissions requirements after attending an accredited institution and completing a baccalaureate degree, including any HBIs, could apply to the program. The program could serve as an extension of the opportunities provided by HBIs, since, as far as we know, no HBIs offer an equivalent program. Graduates of HBIs could improve their competitiveness and reach their professional goals by enrolling in and completing this degree program. Johns Hopkins is strongly committed to cultural diversity and the recruitment and retention of underrepresented minority students. Specific outreach to HBIs is planned to help ensure students at these schools are aware of this new program and its potential to improve their competitiveness in the job market and reach their professional goals if they are admitted to it and successfully complete the degree program.

G. Evidence of the Principles of Good Practice

See Appendix B for the evidence that this program complies with the Principles of Good Practice.

The Higher Education Opportunity Act (HEOA) enacted in 2008 requires that an academic institution that offers distance education opportunities to students 1) has a process established to verify that the student who registers is the same student who participates in and completes the offering and receives academic credit for it, 2) has a process established, to verify that student privacy rights are protected, and 3) has a process established that notifies the student at about any additional costs or charges that are associated with verification of student identity. In this graduate program, the following actions have been taken to satisfy these requirements: 1) students may only enter the academic website for the online courses they take by providing their unique student ID and password they receive when they are admitted to the programs, 2) all FERPA privacy rights are preserved by limiting access very specifically in the University student information system to only those permitted by law to have access to restricted student information, and 3) there are no additional costs assessed to the student for the measures we use to verify student identity.

H. Adequacy of faculty resources

See Appendix C for a representative list of full-time and part-time faculty who will teach in the proposed program.

As with all JHU-AAP programs, the use of part-time adjunct faculty is both intentional and important. JHU-AAP is committed to marrying theory and practice, and this is particularly important in a master's program designed for current and aspiring professionals and practitioners in Individualized Genomics and Health. It is vital that faculty have practical experience in the fields of bioscience, bioinformatics, regulatory science and policy specifically, as well as advanced degrees. All JHU-AAP have at least the equivalent of a

master's degree, and more than 90% have a Ph.D. or other terminal degree in their field. Most of the faculty for this proposed program have already been teaching for JHU-AAP for some time. The associate dean who oversees JHU-AAP, senior members of the Biotechnology program, and the program chair for biotechnology programs all have been involved in the development of the program and this proposal, and will continue to support the program once launched.

I. Adequacy of library resources

The Milton S. Eisenhower Library is the university's principal research library and the largest in a network of libraries at Johns Hopkins. It is ranked as one of the nation's foremost facilities for research and scholarship. Based on the Homewood campus, the library also includes a site at the university's Washington Center. In addition to more than 3.7 million books, the libraries provide 24/7 access to a rich collection of electronic resources, including more than 121,000 print and e-journals, and more than 985,000 full text e-books. The library's materials and services reflect the development and increasing diversification of resources used for teaching, research, and scholarship. Librarians with subject expertise serve as liaisons to the academic departments, build electronic and print collections, and provide research consultation and instructional services to meet the teaching and research needs of the university.

J. Adequacy of physical facilities, infrastructure and instructional equipment

All courses in the proposed program will be offered online and onsite. The program will have no discernible impact on the use of existing facilities and equipment beyond the standard requirements already in place; primarily, faculty office space in an existing university facility location.

K. Adequacy of financial resources with documentation

See Appendix D for detailed financial information.

L. Adequacy of provisions for evaluation of program

JHU-AAP has an online student course evaluation process that is completed at the midterm of each semester and after the offering of each course. This process will be applied to the proposed program. This evaluation also includes student reviews of the faculty for each course offered. Besides course grades, learning outcomes will be assessed through significant writing assignments, including the drafting of regulatory documents. Students will be surveyed for their satisfaction with courses and instructors at the end of each completed semester as well as at the completion of the program. Evaluations will provide valuable feedback on how well students believe their expectations are being met. The JHU-AAP course evaluation process also allows student input on faculty, and all JHU-AAP full-time faculty are evaluated annually by program chairs or directors.

M. Consistency with the State's minority student achievement goals

Any student meeting the admissions requirements can apply to the M.S. in Individualized Genomics and Health. The program will work to help all accepted students improve their workplace competitiveness and reach their professional goals, an aim consistent with Section XIII of the State's Minority Student Achievement Goals.

N. Relationship to low productivity programs identified by the Commission

Not applicable.

Appendix A

Course List and Descriptions

Required Core Courses

410.XXX Ethical, Legal and Regulatory Aspects of Personalized Medicine
This course provides an overview of the important ethical, legal and regulatory issues that are critical to development and implementation of personalized medicine technologies. The course reviews current trends and issues with these interrelated disciplines. Ethical issues will cover how personalized medicine challenges the bioethics foundations of medicine and its implications for enabling personalized medicine treatment. Key and emerging ethical issues such as confidentiality, informed consent, direct to consumer marketing, access to treatment and conveying results to the patient will be explored. Legal issues as it applies to the public policies of privacy, discrimination, and intellectual property will be evaluated. Finally, the regulatory oversight and reimbursement policies of personalized medicine, including targeted therapies, *in vitro* diagnostics, and laboratory developed tests by the FDA and CMS and other organizations will be discussed.

410.612 Human Molecular Genetics
In this course students learn to use the tools of modern genomics to elucidate phenotypic variation within populations. The course uses human disease (from simple Mendelian disorders to common complex disorders) to exemplify the types of studies and tools that can be used to characterize cellular pathophysiology as well as to provide genetic diagnostics and therapies. Students become facile with linkage analysis, cancer genetics, microarray analysis (oligo and DNA arrays), gene therapy, SNP studies, imprinting, disequilibrium mapping, and ethical dilemmas associated with the Human Genome Project. Prerequisites: 410.601 Biochemistry; 410.602 Molecular Biology

410.610 Epigenetics and Gene Organization and Expression
Students use genetic analysis and molecular biology techniques to investigate chromosome organization, chromatin structure, functional genomics, and mechanisms of differential gene expression. Other topics include DNA methylation, silencers, enhancers, genomic imprinting, and microarray analysis. Prerequisites: 410.601 Biochemistry; 410.602 Molecular Biology

410.736 Genomics and Personalized Medicine
This integrative course will be of interest to a wide variety of students in different concentration areas. Applying knowledge from their core courses and introductory bioinformatics, students will examine the current applications of whole genome sequencing and genome wide association studies in clinical medicine, and explore evolving applications and their impact on future medical diagnoses and treatments. Students will review both established and emerging sequencing platforms in detail. This course will closely examine whole genome sequencing applications in inherited and heritable diseases and cancer, amongst others. Class discussions will include ethical, legal, regulatory, and economic implications of genomic medicine. Students and faculty will regularly report on new developments in the field as they emerge throughout the course.

410.XXX Genes and Disease
Because of recent advances in next generation sequencing, powerful diagnostics tools can now detect nucleotide changes that are responsible for genetic diseases as well as defects that can influence metabolism of drugs, susceptibility to microbial infection, cancer, cardiac disease and gastrointestinal disease. In this course, students will analyze a reference human genome, to identify sequence variants using publicly available tools. Students will use available literature in PubMed and other databases to determine the significance of the sequence variants in human health and disease. Students will discuss the ethical considerations of the information.

410.633 Introduction to Bioinformatics
Retrieval and analysis of electronic information are essential in today's research environment. This course explores the theory and practice of biological database searching and analysis. In particular, students are introduced to integrated systems where a variety of data sources are connected through World Wide Web access. Information retrieval and interpretation are discussed, and many practical examples in a computer laboratory setting enable students to improve their data mining skills. Methods included in the course are searching the biomedical literature, sequence homology searching and multiple alignment, protein sequence motif analysis, and several genome analytical methods.

Optional Concentrations

Laboratory Diagnostics (3 courses)

410.641 Clinical and Molecular Diagnostics
This course covers basic concepts and practical applications of modern laboratory diagnostic techniques. Topics include the principles of testing methodology, quality assurance, and the application of molecular methods to the clinical and research laboratory. The test methods to be covered include nucleic acid-based methods such as hybridization, amplification, and sequencing; non-nucleic acid methods such as HPLC, GLC, and protein analysis; and technologies such as PFGE, ribotyping, RFLP, and serological testing methodologies. In addition to the test procedures, students are exposed to aspects of statistics, quality control, regulatory issues, and applications of these methods to the diagnosis and prognosis of human disease. *Prerequisites: 410.601 Biochemistry; 410.602 Molecular Biology 410.659Adv Recombinant DNA class.*

410.659 Advanced Recombinant DNA Lab
This course is a continuation of Recombinant DNA Laboratory (410.656), intended for those who have completed the introductory course, or who have extensive molecular biology laboratory experience. This second course consists of a series of integrated laboratory exercises designed to give students hands-on experience with a variety of advanced recombinant DNA techniques. Exercises include molecular cloning; PCR optimization; site directed mutagenesis; mutation detection; measuring gene expression by quantitative real time PCR (qRT-PCR); and control of gene expression by RNA interference (RNAi). Students will be introduced to high throughput/high content screening procedures such as robotic liquid handling, microarray analysis, and utilization of bioinformatics techniques. *Prerequisites: 410.601 Biochemistry;*

410.602 Molecular Biology; 410.656 Recombinant DNA Laboratory; or consent of program committee.

410.656 Recombinant DNA Lab
This laboratory course introduces students to methods for manipulating and analyzing nucleic acids. Students gain extensive hands-on experience with plasmid purification, restriction mapping, ligations, bacterial transformations, gel electrophoresis, as well as applications of the polymerase chain reaction. This course is not recommended for students with substantial experience in these methodologies. *Prerequisites: 410.601 Biochemistry; 410.602 Molecular Biology.*

410.671 Gene Expression Data Analysis and Visualization
This course will introduce students to various methods for analyzing and interpreting transcriptomics data generated from technologies such as oligonucleotide or two-channel microarrays, qRT-PCR, and RNA sequencing. Topics will include scaling/normalization, outlier analysis, and missing value imputation. Students will learn how to identify differentially expressed genes and correlate their expression with clinical outcomes such as disease activity or survival with relevant statistical tests; methods to control for multiple testing will also be presented. An introduction to linear and nonlinear dimensionality reduction methods and both supervised and unsupervised clustering and classification approaches will be provided. Open source tools and databases for biological interpretation of results will be introduced. Assignments and concepts will make use of publicly available datasets and students will compute and visualize results using the statistical software R. *Prerequisites: 410.601 Biochemistry; 410.602 Molecular Biology; 410.645 Biostatistics; 410.634 Practical Computer Concepts for Bioinformatics, or an undergraduate computer programming course.*

410.666 Next Generation Sequencing and Analysis
The recent revolution in DNA sequencing technologies has transformed biology within a few short years, dropping the cost and ease of sequencing dramatically to the point where the "$1,000 Human Genome" is in sight. Armed with complete genome sequences, biologists need to identify the genes encoded within and the variation in these genes between individuals, assign functions to the genes, and to put these into functional and metabolic pathways. This course will provide an overview of next generation sequencing technologies in the historical context of DNA sequencing, the pros and cons of each technology, and the bioinformatics techniques used with this sequence information, beginning with quality control assessment, genome assembly and annotation. *Prerequisites: 410.602 Molecular Biology; 410.633 Introduction to Bioinformatics; 410.634 Practical Computer Concepts for Bioinformatics.*

Genomics (3 courses)

410.666 Next Gen Sequencing and Analysis
The recent revolution in DNA sequencing technologies has transformed biology within a few short years, dropping the cost and ease of sequencing dramatically to the point where the "$1,000 Human Genome" is in sight. Armed with complete genome sequences, biologists need to identify the genes encoded within and the variation in these genes between individuals, assign functions to the genes, and to put these into functional and metabolic pathways. This course will

provide an overview of next generation sequencing technologies in the historical context of DNA sequencing, the pros and cons of each technology, and the bioinformatics techniques used with this sequence information, beginning with quality control assessment, genome assembly and annotation. *Prerequisites: 410.602 Molecular Biology; 410.633 Introduction to Bioinformatics; 410.634 Practical Computer Concepts for Bioinformatics.*

410.634 Practical Computer Concepts for Bioinformatics
This course introduces students with a background in the life sciences to the basic computing concepts of the UNIX operating system, relational databases, structured programming, object-oriented programming, and the Internet. Included is an introduction to SQL and the Perl scripting language. The course emphasizes relevance to molecular biology and bioinformatics. It is intended for students with no computer programming background but with a solid knowledge of molecular biology. *Prerequisites: 410.601 Biochemistry; 410.602 Molecular Biology.*

410.635 Bioinformatics: Tools for Genome Analysis
Several large-scale DNA sequencing efforts have resulted in megabase amounts of DNA sequences being deposited in public databases. As such, the sequences are of less use than those sequences that are fully annotated. Assigning annotations such as exon boundaries, repeat regions, and other biologically relevant information accurately in the feature tables of these sequences requires a significant amount of human intervention. This course instructs students on computer analytical methods for gene identification, promoter analysis, and introductory gene expression analysis using software methods. Additionally, students are introduced to comparative genomics and proteomic analysis methods. Students will become proficient in annotating large genomic DNA sequences. Students complete two large sequence analysis projects during the course. *Prerequisites: 410.601 Biochemistry; 410.602 Molecular Biology; 410.633 Introduction to Bioinformatics; or all Bioinformatics core courses.*

410.671 Gene Expression Data Analysis and Visualization
This course will introduce students to various methods for analyzing and interpreting transcriptomics data generated from technologies such as oligonucleotide or two-channel microarrays, qRT-PCR, and RNA sequencing. Topics will include scaling/normalization, outlier analysis, and missing value imputation. Students will learn how to identify differentially expressed genes and correlate their expression with clinical outcomes such as disease activity or survival with relevant statistical tests; methods to control for multiple testing will also be presented. An introduction to linear and nonlinear dimensionality reduction methods and both supervised and unsupervised clustering and classification approaches will be provided. Open source tools and databases for biological interpretation of results will be introduced. Assignments and concepts will make use of publicly available datasets and students will compute and visualize results using the statistical software R. *Prerequisites: 410.601 Biochemistry; 410.602 Molecular Biology; 410.645 Biostatistics; 410.634 Practical Computer Concepts for Bioinformatics, or an undergraduate computer programming course.*

410.734 Practical Introduction to Metagenomics
The emerging field of metagenomics allows for the study of entire communities of microorganisms at once, with far-reaching applications in a wide array of fields such as medicine, agriculture and bioremediation. Students will learn the principles of metagenomics

through exploration of published project data and guided readings of recent literature. Using data from the Human Microbiome Project, students will explore practical analysis tasks including sequence assembly, gene prediction and annotation, metabolic reconstruction, taxonomic community profiling and more. *Prerequisites: 410.601 Biochemistry, 410.602 Molecular Biology; 410.634 Practical Computer Concepts for Bioinformatics.*

410.XXX Pharmacogenomics
This course will explore the relationship between an individual's genetics, epigenetics and microbiome and the efficacy of drugs and biologics. Through the use of case studies from disease states such as cancer, immunological deficiencies, metabolic issues students will understand the interplay of genetics and treatment. Students will be introduced to concepts and assays, including prognostic genotyping and diagnostic expression used to determine an individual's treatment options including individual genetic profiling.

410.XXX Cancer Genomics
Alterations to the genome are the basis of cancer development, but not all mutations cause cancer. Cancer genomics is the study of cancer cell genomes to elucidate how changes in the genome drive cancer development, and how these changes can be targeted for better prevention, diagnosis and treatment of cancer. In this course, students learn about the multi-step process of tumorigenesis and the confounding development of passenger mutations. Students will use bioinformatics tools to analyze human cancer genomic data sets to understand the genetic basis of cancer and how to identify genetic signatures that differentiate one type of cancer from another. Activities include the identification of actionable mutations and biomarkers in hypothetical patients and their assignment to appropriate individualized cancer therapies. Topics also include the development of drug resistance, combinatorial therapies, and understanding the laboratory tests used to inform cancer therapy. Discussions about the ethical challenges raised by the use of genomic information to make personal care decisions is included in the course. *Prerequisites: All four core courses or equivalent; 410.633 Introduction to Bioinformatics; 410.638 Cancer Biology is recommended.*

Regulatory Science (3 courses)

410.676 Food and Drug Law
The Food, Drug, and Cosmetic Act (FD&C Act) governs the regulatory approval process for bringing a drug, biologic, medical device, food, or cosmetic to market. The class will discuss administrative procedures followed by the FDA. The course includes an overview of the drug, biologic and medical device approval processes and the regulation of food and dietary supplements. Students then will be exposed to the enforcement activities of the FDA, including searches, seizure actions, injunctions, criminal prosecutions, and civil penalties authorized under the FD&C Act, as well as other statutes like the Public Health Service Act (which regulates the development and approval of biologics).

410.702 Biomedical Software Regulation
Software continually grows more complex and is becoming relied upon by healthcare professionals in the treatment of patients. This course describes how the U.S. government regulates software used in delivering healthcare including the regulations utilized by the Food

and Drug Administration (FDA), as well as, the Center for Medicare and Medicaid Services (CMS). This course covers a wide range of topics, including: FDA regulation of software as a medical device and software validation, medical imaging software regulation, electronic recordkeeping and software used in clinical trials, laboratory information management systems (LIMS), and HIPAA privacy rules and security standards.

410.XXX In Vitro Diagnostic Regulation (new course)
This course provides a comprehensive overview of *in vitro* diagnostic (IVD) devices and how they are regulated by the U.S. Food and Drug Administration (FDA) and internationally, including the European Union (E.U.). Topics that will be covered include: (1) a summary of the U.S. and international laws, regulations, and policies that govern IVD devices, (2) administrative and legal requirements and resources for IVD devices throughout the full product life-cycle, (3) types of IVD devices, (4) coverage and reimbursement of laboratory tests, and (5) current issues and developments.

Policy (3 courses)

410.XXX Ethics in Personalized Medicine
Examines the ethical aspects of individualized genomics and health that have emerged as the science has shaped personalized medicine and companion diagnostics. Key and emerging ethical issues such as confidentiality, informed consent, direct to consumer marketing, access to treatment and conveying results to the patient will be explored.

410.XXX Legal Aspects of Personalized Medicine
Currently, federal and state laws offer only a patchwork of protection against the misuse of genetic information. This course will cover a number of key acts of federal legislation which provide the foundation for the protection of medical and genetic information in the United States, including the Privacy Act of 1974 (5 U.S.C. § 552a), the Electronic Communications Privacy Act (ECPA) of 1986 (18 U.S.C. §2510-2521, 2701-2710), the Americans with Disabilities Act (ADA) of 1990 (42 U.S.C. § 12101 et seq.), and the Health Insurance Portability and Accountability Act (HIPAA) of 1996 (42 U.S.C. § 1320d et seq.) Furthermore, in the absence of uniform federal regulations around genetics privacy and discrimination, many states have established their own regulations, resulting in an uneven landscape of protection.

410XXX In Vitro Diagnostic Regulation
This course provides a comprehensive overview of *in vitro* diagnostic (IVD) devices and how they are regulated by the U.S. Food and Drug Administration (FDA) and internationally, including the European Union (E.U.). Topics that will be covered include: (1) a summary of the U.S. and international laws, regulations, and policies that govern IVD devices, (2) administrative and legal requirements and resources for IVD devices throughout the full product life-cycle, (3) types of IVD devices, (4) coverage and reimbursement of laboratory tests, and (5) current issues and developments.

410.XXX Healthcare Economics
This course studies basic health economic concepts such as opportunity cost, production of good health, the demand for medical care, production and cost theory, cost-benefit analysis, and

healthcare systems and institutions. Other topics of interest include analysis of the behavior of healthcare providers, profit maximization, competition, and the role of government in health matters and medical care markets

410.XXX Medical Product Reimbursement

Medical products brought to market need to have a sound payment, coding, and coverage strategy. Medicare covers over 100 million Americans and it leads the way in all United States insurance policies. This course will provide insight into how medical product reimbursement works and allow students to understand how the Centers for Medicare & Medicaid Services (CMS) considers medical products for coverage, coding, and payment. This course will review the history of Medicare coverage and the regulations, focusing primarily on strategies used to get reimbursement for medical products both at the national and local levels.

Appendix B

Evidence of Compliance with the Principles of Good Practice

(a) Curriculum and Instruction

(i) A distance education program shall be established and overseen by qualified faculty.

The Center for Biotechnology Education (CBE) has been a pioneer in the field of distance education offering its first online course in 2000. All of our faculty have terminal degrees and have significant teaching experience online. Four of the master's degrees with CBE are fully online, including the M.S. in Bioinformatics which was the second master's degree at JHU to be offered fully online. Our faculty have been developing, teaching, and overseeing distance education courses for 15 years.

(ii) A program's curriculum shall be coherent, cohesive, and comparable in academic rigor to programs offered in traditional instructional formats.

The curriculum for the online program has been designed in consultation with experts in the field to ensure its coherence and cohesiveness. All the courses in the online program will be as rigorous as any course offered in JHU-AAP in traditional instructional formats. The courses will follow the same rigor that has been applied to the online courses of the other highly successful online JHU-AAP degree programs. A formal online course development process is used to support online course development. The online course development process is overseen by the Instructional Resource Center within AAP, an academic support unit consisting of instructional technologists, trainers, and instructional designers. The process incorporates the Quality Matters™ research-based set of eight standards for quality online course design to ensure the academic rigor of the online course is comparable or better to the traditionally offered course.

(iii) A program shall result in learning outcomes appropriate to the rigor and breadth of the program.

The program learning outcomes are derived from input from faculty and professionals within the discipline, including the program instructors, program leadership and other program stakeholders.

Upon completion of the proposed program, students will:

- Explain the molecular and genetic basis for human disease including the role of epigenetics
- Analyze a human genome to identify possible indicators of health and disease

- Apply bioinformatics tools to the analysis of human DNA sequences
- Explain the ethical legal and regulatory aspects of individualized genomics and health
- Understand the laboratory methods required to identifying genes responsible for disease

(iv) A program shall provide for appropriate real-time or delayed interaction between faculty and students.

The M.S. in Individualized Genomics and Health will be delivered using Blackboard, JHU's course management system. This platform supports asynchronous interaction between faculty and students. Students and faculty also have the option to participate in real-time interaction through weekly web-conference office hours, supported by Adobe Connect.

(v) Faculty members in appropriate disciplines in collaboration with other institutional personnel shall participate in the design of courses offered through a distance education program.

The proposed program has established a process for identifying the appropriate faculty to design an online course. All the faculty are selected based on discipline expertise, professional and teaching experience and completion of an online course development training course.

(b) Role and Mission

(i) A distance education program shall be consistent with the institution's mission.

See section A-1 of the proposal.

(ii) Review and approval processes shall ensure the appropriateness of the technology being used to meet a program's objectives.

All the courses in the program are designed with the support of an instructional designer, instructional technologists, and multimedia specialists. The instructional designer and multimedia specialists serve as instructional technology consultants to assist in identifying and recommending the most effective learning technologies for accomplishing the course's learning objectives. The course instructor and instructional designer identify all of the learning components of the course, and how the course will be facilitated to achieve the most optimal learning outcome for the students. This is an iterative process whereby the course goes through several levels of review prior to the course actually being developed. Once the course is complete, it undergoes external review using Quality Matters™ online course pedagogic quality criteria. When the course launches (goes live), the design team continually monitors it, and consults with the instructors to make adjustments to the course, if needed. All new online courses participate in a mid-term and end-of-term course evaluation

process. The mid-term feedback is used to determine if any mid-point term corrections are needed. And the end-of-term evaluation is used to assess whether further course refinements are needed prior to the next time the course is offered.

(c) Faculty support

(i) An institution shall provide for training for faculty who teach with the use of technology in a distance education format, including training in the learning management system and the pedagogy of distance education.

Faculty in this program are supported by JHU-AAP's Instructional Resource Center (IRC), the AAP office for Faculty and Student Services, as well as the Program Director and Associate Director. The IRC provides oversight for all online course developments, including faculty training and development. The IRC has a formal, structured faculty development approach for preparing faculty to develop and teach an online course. All faculty are required to complete at least three Blackboard training sessions and a course in the use of Adobe Connect. These training sessions provide an overview of online learning pedagogy and introduce the faculty to some of the technologies they will be using to develop their online courses. Faculty may also sign up for one-on-one training sessions with staff of the IRC, attend faculty development sessions provided by the Office of Faculty and Student Services, and consult with the faculty in the other environmental courses for additional pedagogical or technical support. A third-party help desk as well as internal help desk consultants also assist in faculty technical support.

(ii) Principles of best practice for teaching in a distance education format shall be developed and maintained by the faculty.

The Instructional Resource Center offers training on how to be an effective online instructor based on best practices from research and other related sources. All new online instructors are required to participate in this training prior to teaching their first online course.

(iii) An institution shall provide faculty support services specifically related to teaching through a distance education format.

The Instructional Resource Center of JHU-AAP provides a wide range of faculty support services for faculty engaged in online instruction. Faculty have access to multimedia specialists, instructional designers, technical trainers, and a 24/7 technical help desk to provide the necessary support required to effectively deliver distance education programs. In addition, JHU-AAP offers faculty development training opportunities in online pedagogy and new instructional technologies throughout the year specifically designed for online instructors.

(d) An institution shall ensure that appropriate learning resources are available to students including appropriate and adequate library services and resources.

The students will have online access to the Milton S. Eisenhower Library on the Homewood campus, which is ranked as one of the nation's foremost facilities for research and scholarship. Its collection of more than three million bound volumes, several million microfilms, and more than 13,000 journal subscriptions has been assembled to support the academic efforts of the University. The interlibrary loan department makes the research collection of the nation available to faculty and students. The library also provides easy access to a wide selection of electronic information resources, including the library's online catalog, and numerous electronic abstracting and indexing tools. Many of the databases are accessible remotely. Librarians help students electronically and the library maintains an extensive web site to take visitors through all of its services and materials.

(e) Students and Student Services

(i) A distance education program shall provide students with clear, complete, and timely information on the curriculum, course and degree requirements, nature of faculty/student interaction, assumptions about technology competence and skills, technical equipment requirements, learning management system, availability of academic support services and financial aid resources, and costs and payment policies.

JHU-AAP maintains numerous web-based resources to inform prospective students about the information they may need as an online student. These resources include the JHU-AAP website at http://advanced.jhu.edu and the JHU-AAP online catalog, which includes detailed programmatic information, academic support services, financial aid, costs, policies, and specific information for online learning. As new online students are admitted and enrolled, they receive timely emails with important information to help them prepare to become an online student. These emails include information on how to create their JHU log-in account for the course management systems, technical requirements, available academic support services and new online student orientation course.

(ii) Enrolled students shall have reasonable and adequate access to the range of student services to support their distance education activities.

JHU-AAP online students have access to the following academic support services:

- **Academic Advising.** Students are assigned an advisor when accepted. Students work individually with the advisor to develop a course of study that meets the requirements of the program and the career goals of the student. The advisor regularly contacts the students to check on progress and answer questions. Courses that deviate from the program plan and have not been approved by an adviser may not count toward degree requirements. A degree audit tool is provided so students verify their selections match degree requirements.

- **Library Services.** Students have online access to the Milton S. Eisenhower Library on the Homewood campus, ranked as one of the nation's foremost facilities for research and scholarship. The interlibrary loan department allows students access to resources at any other university in the nation. The library also provides easy access to a wide selection of electronic information resources, including the library's online catalog, and numerous electronic abstracting and indexing tools. Many of the databases are accessible remotely. Librarians are available to assist students remotely and the library maintains an extensive web site to take visitors through all its services and materials.

- **Services with Students with Disabilities.** The Johns Hopkins University is committed to making all academic programs, support services, and facilities accessible to qualified individuals. Students with disabilities who require reasonable accommodations can contact the Student Services Specialist for AAP, Ms. Briggs Rolfsrud and the University's Office of Disability Services.

- **Transcript Access.** Official transcripts will be mailed upon written request of the student at no charge.

- **Student ID JCard.** The JCard serves as the student's University identification card. This card is mailed to the home address of every registered student. The JCard acts as the university library card, which enables students to check out books from the Homewood Eisenhower Library or at any of the campus center libraries, and provides access to many computer laboratories.

(iii) Accepted students shall have the background, knowledge, and technical skills needed to undertake a distance education program.

Prior to admission into an online program, prospective students are invited to "test drive" a course to determine if the online learning environmental is suitable to their learning style. Accepted online students must meet the admissions requirements of graduate students in JHU-AAP and the specific requirements of the M.S. program. New online students are required to complete the "New Online Student Orientation" course prior to beginning their first online course. This course covers a broad range of topics on how to be a successful online student such as, Blackboard basics, online student learning expectations, how to access the library, how to conduct online research, and how to participate in online discussions.

(iv) Advertising, recruiting, and admissions materials shall clearly and accurately represent the program and the services available.

All relevant program information is keep up-to-date on the JHU-AAP web site.

(f) Commitment to Support

(i) Policies for faculty evaluation shall include appropriate consideration of teaching and scholarly activities related to distance education programs.

Faculty teaching online courses are strongly encouraged to participate in minimally one to two professional development opportunities annually to improve their online teaching skills.

(ii) An institution shall demonstrate a commitment to ongoing support, both financial and technical, and to continuation of a program for a period sufficient to enable students to complete a degree or certificate.

Advanced Academic Programs has a commitment to online teaching as demonstrated by the resources of its Instructional Resource Center that provide course development, instructional, and technical support to new and current faculty.

(g) Evaluation and Assessment

(i) An institution shall evaluate a distance education program's educational effectiveness, including assessments of student learning outcomes, student retention, student and faculty satisfaction, and cost-effectiveness.

JHU-AAP has an online student course evaluation process that is completed at the midterm of each semester and after the offering of each course. This process will be applied to the proposed M.S. in Individualized Genomics and Health program. This evaluation also includes student reviews of the faculty for each course offered. Each semester the director for the program evaluates the course offerings and faculty performances based on these reviews. On an annual basis, the curriculum will be reviewed by the chair, program director, faculty, and administrators as appropriate to determine if new topics need to be covered or other changes made following JHU-AAP procedures for such review. Formal processes for academic program review of JHU-AAP graduate programs are also in place.

(ii) An institution shall demonstrate an evidence-based approach to best online teaching practices.

The JHU-AAP Instructional Resource Center, which offers instructional design and faculty support staff, continually participates in professional development activities to keep abreast of evidence-based approaches to online teaching practices. These online teaching practices are then incorporated into the new online instructor training sessions.

(iii) An institution shall provide for assessment and documentation of student achievement of learning outcomes in a distance education program.

As part of the online course design process in JHU-AAP, course assessments are required to be aligned with stated course learning outcomes. The proposed program will incorporate authentic learning assessments that demonstrate student's application of learned concepts.

Appendix C

Representative Faculty

- **Dr. Patrick Cummings**, Director MS in Biotechnology, Center for Biotechnology Education, Senior Lecturer, full-time
- **Dr. Lynn Johnson Langer**, Director, MS in Regulatory and Enterprise programs, Center for Biotechnology Education, Senior Lecturer, full-time.
- **Dr. Kristina Obom**, Director, MS in Bioinformatics, Center Director, Center for Biotechnology Education, Senior Lecturer, full-time
- **Dr. Robert Lessick**, Associate Director, Online Education, Center for Biotechnology Education Senior Lecturer, full-time
- **Dr. Meredith Safford**, Coordinator, Biotechnology, Center for Biotechnology Education Senior Lecturer, full-time
- **Dr. Beatrice Kondo**, Coordinator, Bioinformatics, Center for Biotechnology Education Senior Lecturer, full-time
- **Dr. Kay Wellman**, Coordinator, Biotechnology Enterprise, Center for Biotechnology Education Senior Lecturer, full-time
- **Dr. Karen Wells**, Center for Biotechnology Education, Senior Lecturer, full-time
- **Dr. Thomas Koval**, Center for Biotechnology Education, Senior Lecturer, full-time
- **Dr. Sherry Ogg**, Center for Biotechnology Education, Senior Lecturer, full-time
- **Dr. Thomas Colonna**, Associate Director Regulatory Science, Center for Biotechnology Education, Senior Lecturer, full-time

Appendix D

Finance Information

TABLE 1: RESOURCES:					
Resource Categories	**2017**	**2018**	**2019**	**2020**	**2021**
1. Reallocated Funds	-	-	-	-	-
2. Tuition/Fee Revenue (c + g below)	203,700	534,750	898,400	1,414,800	1,856,990
a. Number of F/T Students	-	-	-	-	-
b. Annual Tuition/Fee Rate	-	-	-	-	-
c. Total F/T Revenue (a x b)	-	-	-	-	-
d. Number of P/T Students	10	25	40	60	75
e. Credit Hour Rate (per course)	4074	4278	4492	4716	4952
f. Annual Credit Hour Rate	-	-	-	-	-
g. Total P/T Revenue (d x e x f)	-	-	-	-	-
3. Grants, Contracts & Other External Sources	-	-	-	-	-
4. Other Sources	-	-	-	-	-
TOTAL (Add 1 – 4)	**203,700**	**534,750**	**898,400**	**1,414,800**	**1,856,990**

Resources narrative

1. Reallocated Funds: The proposed program will be funded by tuition revenue, and will make no use of reallocated funds.

2. Tuition and Fee Revenue: Revenue is based on projected enrollments for the program.

3. Grants and Contracts: No grants or contacts are required for the successful implementation of the program.

4. Other Sources: The program does not expect any funding from other sources.

TABLE 2: EXPENDITURES:					
Expenditure Categories	**2017**	**2018**	**2019**	**2020**	**2021**
1. Faculty (b + c below) adjunct	51,651	56,274	103,113	171,855	219,2974
a. # Sections offered	5	13	20	30	37
b. Total Salary	47,825	50,920	95,475	159,125	203,680
c. Total Benefits	3,826	5,354	7,638	12,730	16,294
2. Admin. Staff/faculty (b+c below)	-	87,435	90,115	92,805	95,495
a. # FTE faculty coordinator	-	1	1	1	1
b. Total Salary	-	65,000	67,000	69,000	71,000
c. Total Benefits	-	22,425	23115	23,805	24,495
3. Support Staff (b+c below)	-	-	-	-	-
a. # FTE	-	-	-	-	-
b. Total Salary	-	-	-	-	-
c. Total Benefits	-	-	-	-	-
4. Equipment	-	-	-	-	-
5. Library	-	-	-	-	-
6. New or Renovated Space	-	-	-	-	-
7. Other Expenses	-	5,000	5,000	5,000	5,000
TOTAL (Add 1 – 7)	**51,651**	**164,699**	**198,228**	**269,660**	**320,469**

Expenditures narrative

1. Faculty: Current adjunct salary is $5,000 per course. For the first three years of the program, costs will consist of that salary (plus possible minor annual increases) for each of the courses offered plus online course development fees.

2. Administrative Staff: The program anticipates hiring one full time administrative staff to support the proposed program.

3. Support Staff: Existing support staff will be used for this program.

4. Equipment: No direct equipment costs are identified.

5. Library: Existing library facilities are sufficient to meet the needs of the program.

6. New or Renovated Space: No new or renovated space will be needed.

7. Other Expenses: Indirect program costs are provided here.