GEORGE MASON UNIVERSITY

Program Approval Form

For approval of new programs and deletions or modifications to an existing program.

Action Requested:

[X] Create New (SCHEV approval required except for minors and certificates)
[ ] Delete Existing
[ ] Modify Existing (check all that apply) – M.S. Biology
    [ ] Title (SCHEV approval required except for minors, certificates)
    Concentration (Choose one): [ ] *Add* [ ] *Delete* [ ] *Modify*
    [ ] Degree Requirements
    [ ] Admission Standards
    [ ] Application Requirements
    [ ] Other Changes: _____

Type (Check one)**:**

[ ] B.A.	[ ] B.S. [ ] Minor
[ ] Undergraduate Certificate	
[ ] M.A.	[ ] M.S. [ ] M.Ed.
[ ] Ph.D.	[X] Graduate Certificate
[ ] Other:	

College/School: College of Science   **Department:** School of Systems Biology
Submitted by: Ancha Baranova, PhD   **Ext:** 571-334-1145   **Email:** abaranov@gmu.edu

Effective Term: Fall [2015]   **Please note:** For students to be admitted to a new degree, minor, certificate or concentration, the program must be fully approved, entered into Banner, and published in the University Catalog.

Justification: (attach separate document if necessary)

See attached.

	Existing	New/Modified
Program Title: (Required) Title must identify subject matter. Do not include name of college/school/dept.		Graduate Certificate in Personalized Medicine
Concentration(s):		
Admissions Standards / Application Requirements: (Required only if different from those listed in the University Catalog)		See attached.
Degree Requirements: Consult University Catalog for models, attach separate document if necessary using track changes for modifications		See attached.
Courses offered via distance: (if applicable)		N/A
TOTAL CREDITS REQUIRED:		15

Approval Signatures

_____   _____   _____
Department   Date   College/School   Date   Provost's Office   Date
                                                              Interdisciplinary Council Use Only

If this program may impact another unit or is in collaboration with another unit at Mason, the originating department must circulate this proposal for review by those units and obtain the necessary signatures prior to submission. Failure to do so will delay action on this proposal.

Unit Name	Unit Approval Name	Unit Approver's Signature	Date
	.		

For Graduate Programs Only

_____   _____   _____
Graduate Council Member   Provost Office   Graduate Council Approval Date

Justification for the Proposed Graduate Certificate in Personalized Medicine (15 credits)

Response to Current Needs

Personalized Medicine is a medical model that proposes the customization of healthcare, with decisions and practices being tailored to the individual patient by use of genetic or other information. Using a Personalized Medicine approach in the clinic requires acquisition of knowledge on many fronts, including the building and use of large professionally designed databases of genes and their corresponding proteins, metabolites and mutations. Discovery of how drugs and foods interact with an individual's genes and their variations is also required to affect this objective. It is one thing to identify a mutation or a change in a gene sequence, but it is another entirely to know exactly what these differences mean in terms of a biological response, or to interpret the meaning of this mutation in the context of current knowledge of its biological functions.

Since the late 1990s, the advent of high-throughput research and biobanking has brought advances in molecular biology, technologies in proteomics, metabolomic analysis, genetic testing and molecular medicine. Such information about a patient's proteomic, genetic and metabolic profile could allow medical care tailored to that individual's needs. One idea of this medical model is the development of companion diagnostics. Molecular assays that measure levels of proteins, genes or specific mutations are used to provide a specific therapy for an individual's condition through stratification of patients according to their individual prognoses, selecting the proper medication and tailoring dosages to that patient's specific needs. Additionally, molecular diagnostics might be used to assess a patient's predisposition for a number of conditions and tailor individual preventive treatments such as tailored diets and other life style modifications.

Personalized Medicine is a promising, rapidly developing branch of science. Its significance is reflected in the number of publications in this area. Since 1999, PubMed accumulated 2585 references covering "Personalized Medicine" (while no references were found on this topic before 1999); and the journal "*Personalized Medicine* "was established in 2004. "*Personalized Medicine*" (ISSN 1741-0541) translates recent genomic, genetic and proteomic advances into the clinical context, with intended audience being academic and clinical researchers, pharmaceutical companies, regulatory authorities, healthcare management organizations, patient organizations and others in the healthcare community.
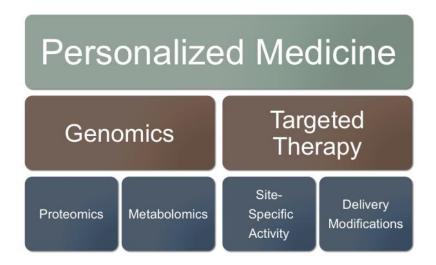

Figure 1. *Personalized Medicine mainly relies on the study of genomics to predict drug effects in specific patients. Targeted therapies can also fall in this category because many times a drug is designed to target a specific receptor or physiological property of the diseased tissue. Patients with a particular drug receptor, for example, would be given a target-specific drug while others without the receptor would not. PM thus improves medical efficiency by optimizing prescribing so only the most effective drugs are used on a patient, thus reducing side effects and their associated costs (taken from the blog of Randy Burn : http://seekingalpha.com/article/419851-the-age-of-personalized-medicine-has-arrived)*

The governmental support for the development of Personalized Medicine is evident from the NIH Pharmacogenomics Research Network (PGRN) established in 2000. PGRN aims at advancement of understanding the genetic basis of individual drug responses, thus, being within the scope of Personalized Medicine. This nationwide alliance of research groups involved in studies of genes (genomics) includes the following organizations: NIGMS, NHLBI, NCI, NIDA, NICHD, NHGRI, NIMH, NIAMS, ORWH.

Given the intense interest of many parties in development of this branch of science, it is important to ask if any educational institutions are preparing specialists in Personalized Medicine. It is somewhat surprising that only a few colleges are ready to offer training appropriate to this objective (Data summarized in Table 1 and Table 2).

Table 1.

	The HHMI/ Vanderbilt University Medical Center	Department of Informatics Medicine and Personalized Health at the University of Missouri-Kansas city School of Medicine	University of Maryland, School of Medicine	Anadolu University Eskişehir, Turkey
Program Title	Certificate program in molecular medicine/ 3 years for graduate students (135 hours), 2 years for postdoctoral trainees (85 hours)	Graduate Certificate in Clinical Research (15 credit hours). The program consists of five core courses (3 credit hours each) from the Master of Science in Bioinformatics Clinical Research Track curriculum.	Program in Personalized and Genomic Medicine	1st International Certificate Program of Predictive and Personalized Medicine September 13-16, 2012
Postdocs	Yes (2 postdocs a year)	Yes	Yes	Yes
PhD students	Yes (8 PhD students a year)	Yes	Yes	Yes
Undergraduate students	**No**	**No**	Yes	Yes
Physicians /nurses / pharmacists	**No**	Yes	Yes	Yes
Other healthcare professionals	**No**	Yes	Yes	Yes

Table 2.

	The California State University	Keck Graduate Institute of Applied Sciences, Claremont, CA	University of California San Diego	Center for Personalized Genetic Medicine at Harvard Medical School
Title of program	**Post-Baccalaureate Certificate Programs in Clinical Laboratory Science and Clinical Genetic Molecular Biologist Scientist (CGMBS) (1-year long)**	Post-Baccalaureate Premedical Certificate Program (PPC)	In Vitro Diagnostics Certificate (Molecular Diagnostics and Personalized Medicine course is a part of this training)	Continuing Medical Education Online (various genetic courses, no program certificate is offered)
Postdocs	Yes	**No**	Yes	Yes
PhD students	Yes	**No**	Yes	Yes
Undergraduate students	**No**	**No**	**No**	Yes
Physicians /nurses / pharmacists	Yes	**No**	Yes	Yes
Other healthcare professionals	Yes	**No**	Yes	Yes
Post-Baccalaureate Premedical students	Yes	Yes	Yes	Yes

These tables could be summarized as follows:

Only a few educational institutions currently offer training in Personalized Medicine, none are located in Virginia and only a few are available on the East Coast of the USA. There is such a degree program offered by Anadolu University in Eskişehir, Turkey.

Offering of Certificate in Personalized Medicine at George Mason University will respond to the need for an educated workforce that is able to understand, interpret and implement recent discoveries in genomics, proteomics, and metabolomics obtained from both basic and clinical research programs. Training individuals for this kind of data analysis and application is within the charge of the School of Systems Biology in the College of Science here at George Mason University.

Clinical and Translational Research expertise at Mason has grown exponentially during the last ten years. In 2006, in the School of Systems Biology, a multidisciplinary research team studying Chronic Liver Disease proposed and developed the "Center for the Study of Genomic Liver Diseases" (CSGLD). This Center arose through collaborative efforts between George Mason University and Inova Fairfax Hospital's Center for Liver Diseases (CLD). The Center's strengths derive from the expertise that currently exists in the two institutions, namely the clinical expertise of Inova Health System as lead by Dr. Zobair Younossi and the functional genomics expertise of SSB faculty. The Center brings together the strengths and the expertise of the members from each institution in a collaborative and cohesive environment that enhances the performance of the team pursuing this research. In 2012-2014, CSGLD faculty made tremendous strides toward discovering and validating novel biomarkers for chronic liver diseases and understanding the pathogenesis of these conditions. This resulted in a total of 29 research and review publications (2012-2014 window), 12 of which were co-authored by GMU students. This burst of research activity expanded the Center's expertise and broadened its focus. Hence, CSGLD changed its name to the Center for the Study of Chronic Metabolic Diseases (CSCMD).

CSCMD is just one example of the multidisciplinary research teams in which SSB and COS faculty perform research in a variety of biomedical fields. Another Team that is working precisely in the field of Personalized Medicine is the Center for Applied Proteomics and Molecular Medicine (CAPMM). CAPMM's mission is to: a) create new technologies and make basic science discoveries in the field of disease pathogenesis; b) apply these discoveries and technologies to create and implement strategies for disease prevention, early diagnosis and individualized therapy. The primary emphasis of CAPMM disease research is cancer, but new technologies developed in the center are being applied to a number of important human diseases including cardiovascular disease, diabetes, and obesity, as well as liver, ocular, neurodegenerative and infectious diseases.

Hence, the proposed Certificate program is endorsed by existing expertise of the School of Systems Biology and plays to the strengths of faculty within the School.

It should be noted that the proposed Graduate Certificate in Personalized Medicine is **NOT** offered in parallel with the G^2 ABS Graduate Certificate Program and it is not a competitor of that program. (The G^2 program is a joint endeavor offered by George Mason University and Georgetown University Medical Center at the Prince William Campus of Mason. The majority of the students who enter the G^2 ABS Program are interested in admission to medical school, dental school, optometry and physical therapy graduate programs.) Whereas the G2 graduate certificate program appeals to students who need to better prepare for professional schools (such as medical or dental), the Graduate Certificate in Personalized Medicine is designed to generate specialists trained in the use of large professional databases of genes and their corresponding proteins, metabolites and mutations, in the interpretation of possible biologic functions derivable from the biologic clinical or research data under analysis. Ideal candidates for this certificate already have a strong background in biological, medical or computer sciences, and are either currently working in or planning to enter into the fields of clinical research or the drug development industry. The certificate is especially designed for professionals who are

interested in advancing their career goals, but who may not have adequate time available to undertake a graduate degree program.

The 15-credit certificate is based upon the set of core courses currently supporting the Biology/Biosciences/Bioinformatics M.S. and Ph.D. degree programs, along with a set of elective courses. Students completing the Certificate in Personalized Medicine will receive the most up-to-date advanced education available in the region. Completion of the certificate will enhance the careers of those students who are already working in this area, and can also serve as a useful intermediate step towards later enrollment in the M.S., or Ph.D. programs.

Courses are generally offered in the late afternoon or early evening to accommodate students with full-time employment outside of the university. Students may not enroll initially in any COS non degree, M.S., or Ph.D. program, then later transfer into this certificate program. The Certificate in Personalized Medicine charges students a differential tuition rate of $100 per credit hour, which is added to the standard GMU graduate tuition rate (regardless of in or out of state status).

Student Demand

Personalized Medicine is a large umbrella term describing the use of patient information, usually genetic or biological, to tailor medical treatments that are specific to the characteristics of each individual. In 2009, an in-depth report by PricewaterhouseCoopers focused on the growing science of PM and pegged the market value of the field at $232 billion and projected a staggering growth rate of 11% annually to $452 billion by 2015. As health care budgets force us to use more rational and efficient medications, PM will eventually be a standard of care.

There is a critical shortage of a genetically literate workforce in the community-based healthcare settings. For example, healthcare professionals are increasingly requested to interpret results of the genetic risk assessments obtained by over-the counter NextGen sequencing companies, but many are inadequately prepared to provide these services.

Additionally, the pharmaceutical industry is emerging as a driving force in this field. The list of early Personalized Medicine adopters includes some industry giants: Roche, Pfizer, Novartis, and Lilly. The field is also populated with upstart companies such as Genomic Health, XDx, and Prometheus Labs that offer specialized approaches to segmenting patient populations, as well as the recognized pioneers in personal genomics: 23andMe, deCODE Genetics, and DNA Direct. In adopting Personalized Medicine, they are all embracing a new healthcare model that emphasizes decisions and practices tailored to individuals or small groups. These companies imply business model based on differentiated products in order to reduce the system-wide costs and complications of one-size-fits-all medications and to seek new opportunities for marketing.

There are a number of government- and private-supported initiatives that aim to evaluate and implement evidence-based best practices in the implementation of personalized medicine. Some examples of organizations that employ individuals trained in Personalized Medicine include the member organizations of NIH Pharmacogenomics Research Network mentioned above, the Food and Drug Organization and the Coriell Personalized Medicine collaborative. The graduates of the proposed Certificate Program in Personalized Medicine may be also seeking jobs at various clinical research centers all over the country.

The following groups are identified as target groups for enrollment in the proposed Certificate Program in Personalized Medicine
1) Non-Physician Healthcare professionals currently employed as healthcare administrators, physician assistants, nurses and healthcare technicians, nutritionists, dieticians, etc
2) Healthcare IT professionals, computational biologists and bioinformaticians

3) R&D professionals in the Drugs and Diagnostics fields
4) Sales and other professional in biomedical and insurance industry
5) Bench scientists in different branches of biology (predominantly at BS and MS levels)
6) Health industry economists, Government policy makers and regulators, Patient advocates and media experts
7) Employees and associates of biomedicine-related investment funds

Recent BS in Biology graduates are not the target audience for this Certificate Program in Personalized Medicine, however, they would be welcome. This program is targeted to working professionals who are already in the field.

In 2013, a round of preliminary conversations took place with representatives of INOVA Health System (Prof. Younossi, the Chairman of the Department of Medicine, Inova Fairfax Hospital, and Vice President for Research of Inova Health System) as well as representatives of the mid-level management of ATCC, Mediatech, Johnson and Johnson, Strand Genomics, Sequenom, Applied Physics Lab – JHU and other companies local to NoVa and neighboring states, with a positive outcomes and endorsement that these companies would endorse their employees for certification in Personalized Medicine.

Admission Requirements

Prospective students should submit standard application materials, including the university application form, undergraduate transcript(s), General GRE scores, personal statement, and three letters of recommendation. Recommended minima include GRE scores of 1100 on the old scale or approximately 303 on the new scale or MCAT scores that exceed 26, each section being scored not less than 5 (Score of 26 being a national test average), an undergraduate GPA of 3.00 or current employment in Clinical or Translational Research, diagnostics lab or biological data analysis field, strong letters of recommendation, and statement of interests consistent.

Note: Dr. Baranova will serve as the coordinator for review of applications under CPER. With respect to this certificate, we will allow students to submit either MCAT or GRE scores as part of the admissions requirements.

Degree Requirements

The Certificate in Personalized Medicine requires a total of 15 credit hours. Students are required to take three core courses, plus two courses selected from the list of electives indicated below.

Curriculum

Proposed Curriculum for Graduate Certificate in Personalized Medicine (15 credits)

Required Core Courses:

- BIOS 743 - Genomics, Proteomics & Bioinformatics (3 credits)
- BIOL 572 – Human Genetics   or   BIOL 666 Genetics Concepts for Healthcare (3 credits)
- BIOL 562 - Personalized Medicine

Elective Courses: (choose any of these electives as approved by the coordinator)

- BIOL 568 - Advanced Topics in Molecular Genetics (3 credits)
- BIOL 575 - Topics in Molecular Biology (3 credits)

- BIOL 566 – Cancer Biology (3 credits)
- BIOL 682 - Advanced Eukaryotic Cell Biology (3 credits)
- BIOS 701 – Biochemical Systematics (3 credits)
- BIOL 695 - Seminars in Molecular/Micro/Cell Biology (1 credit, may be repeated)
- BIOS 741 – Genomics (3 credits)
- BIOL 669 – Pathogenic Microbiology (3 credits)
- BIOL 553 - Advanced Topics in Immunology (3 credits)
- BINF 630 - Bioinformatics Methods (3 credits)
- BINF 633 - Molecular Biotechnology (3 credits)
- BINF 733 - Gene Expression Analysis (3 credits)

Students may also take up to 4 credits of BIOL 693 Directed Studies in Biology, or BINF 796 - Directed Reading and Research or their combination. These classes are the electives that may be taken only if the research topic is relevant to Personalized or Translational Medicine. BIOL693/BINF796 are not required for completion of certificate.

It is anticipated that certain proportion of the graduates of Certificate Program may wish to apply to MS in Biology program at SSB, GMU. These would be considered for MS in Biology program on the same ground as all other applicants, however, their completed credits would be transferred toward MS in Biology as part of required credits for MS in Biology with selected concentration.

RELEVANT CORE COURSES AND ELECTIVES

BIOS 743 - Genomics, Proteomics, and Bioinformatics
Credits: 3 (NR)

Fundamental methods for analyzing genomic and proteomic data, including nucleic acid and protein sequences, pair-wise and multiple alignment, database search methods, clustering and presentation of data, prediction modeling, and survey of available software and freeware tools.

Prerequisite(s): Admission to Biosciences PhD or Biology MS program.

BIOL 666 - Human Genetics Concepts for Health Care
Credits: 3 (NR)

 Principles of genetically determined diseases with emphasis on clinical aspects of these diseases, genetic counseling, and laboratory methods used in human genetics.

Prerequisite(s): BS degree or enrollment in accelerated MS program.

BIOL 572 – Human Genetics
Credits: 3 (NR)

 Inheritance of humans emphasizing current problems, including genetic control of metabolic diseases, effects of radiation and chemical agents in environment, and directed genetic change.

Prerequisite(s): BIOL 311, or permission of instructor.

BIOL 562 – Personalized Medicine
Credits: 3 (NR)

 Covers basic principles of molecular medicine, including the definition and the need for

individualized diagnostics and therapeutics. Students will study the application of proteomics, genomics and bioinformatics as they relate to individualized therapy, and review the major advances in these fields which have relevance to molecular medicine of the future.

Prerequisite(s): Advanced undergraduate coursework in Genetics and Molecular Cell Biology.

BIOL 568 - Advanced Topics in Molecular Genetics
Credits: 3 (RD)

Comprehensive study of regulatory mechanisms controlling gene expression in viruses, prokaryotes, and eukaryotes, emphasizing current research.

Prerequisite(s): BIOL 482, or permission of instructor.

BIOL 695 - Seminar in Molecular, Microbial, and Cellular Biology
Credits: 1 (RD)

Review and discussion of recent literature in specialized area. Includes student presentations.

Notes: May be repeated for credit. May be taken if topic is relevant to Personalized Medicine after approvals by Certificate Director.

BIOL 682 - Advanced Eukaryotic Cell Biology
Credits: 3 (NR)

Structure and function of biomembranes, cytoskeleton, and transport systems. Also discusses protein trafficking, cell cycle, and cell adhesion molecules.

Prerequisite(s): BIOL 483, CHEM 313, 314; or permission of instructor.

BIOL 566 – Cancer Genomics
Credits: 3 (NR)

Review of modern concepts in cancer biology including taxonomy of human tumors, common cancer syndromes, and genome instability. Genetic and molecular studies of tumor cell proliferation, migration, invasion, and death.
Prerequisite(s): course in Genetics or Biochemistry.

BIOS 701 - Biochemical Systematics
Credits: 3 (NR)

Introduces biochemical systems to investigate complex, multicomponent, dynamic functions of cellular systems. Readings include articles from current literature in molecular biosciences. Application of molecular techniques within biosciences is now universal, and the underlying question remains "What is the structure of a cell, and how does it function?"

BINF 630 - Bioinformatics Methods
Credits: 3 (NR)

Introduction to methods and tools for pairwise sequence comparison, multiple sequence alignment, phylogenetic analysis, protein structure prediction and comparison, database similarity searches, and discovery of conserved patterns in protein sequence and structures.

Prerequisite(s): Graduate standing, or permission of instructor.

BINF 633 - Molecular Biotechnology
Credits: 3 (NR)

Introduction to the theory and practice of molecular biotechnology, with emphasis on the application of tools in today's society. Includes study of recombinant DNA technology, genomics, and bioinformatics as applied to commercially important products. Lectures reflect more recent advances and applications in the commercial aspects of biology.

Prerequisite(s): Graduate standing or permission of instructor.

BIOS 741 - Genomics
Credits: 3 (NR)

Genetic structure and function at whole genome level. Includes some sequence analysis, comparative genomics, classical genetics, and developmental genetics, as well as analysis of synteny groups, isochores, gene families, genetic complexity, C value paradox, directed discovery of gene functions, and animal models of human disease. Readings from recent texts and primary research literature. Students expected to give one or two oral presentations of primary research papers, as well as complete midterm and final exams.

Prerequisite(s): At least one undergraduate course in genetics and molecular biology, or permission of instructor.

RESEARCH CREDITS

BIOL 693 – Directed Studies in Biology (1-3 credits)
Credits: 1-8 (RD)

Study of topic not otherwise available in graduate program. May involve any combination of reading assignments, tutorials, lectures, papers, presentations, or laboratory or field study, determined in consultation with instructor.

Prerequisite(s): Permission of instructor, chair, and graduate committee.

Note: This class may be taken only if the research topic is relevant to Personalized or Translational Medicine. A sum of BIOL 693 and BINF 796 credits may not be larger than four.

BINF 796 - Directed Reading and Research
Credits: 1-6 (RD)

Reading and research on specific topic in computational sciences and informatics under direction of faculty member.

Prerequisite(s): Permission of instructor.

Note: This class may be taken only if the research topic is relevant to Personalized or Translational Medicine. A sum of BIOL 693 and BINF 796 credits may not be larger than four.