I. INSTRUCTOR CONTACT INFORMATION

Toby Citrin\textsuperscript{a,b} 
4605 SPH Tower 
Campus Zip 2029 
ph.: 734-936-0936 
FAX: 734-764-1357 
e-mail: tcitrin@umich.edu 
Office hrs.: By Appointment

Stephen Modell\textsuperscript{a,b} 
4605 SPH Tower 
Campus Zip 2029 
ph.: 734-615-3141 
FAX: 734-764-1357 
e-mail: mod@umich.edu 
Office hrs.: M-F 10am – 4pm

\textsuperscript{a}Primary mailbox in Life Sciences, Genomics, and Community Collaborative area, 4605 Tower 
\textsuperscript{b}Additional mailbox in central HMP mail room, M-3149A, 3rd floor, SPH-II Bldg.

II. COURSE DETAILS AND DESCRIPTION

Class sessions will be held in SPH Crossroads Room 2610, Tues. / Thurs., 3:00-4:30.

This course focuses on ethical, legal, and social issues and analysis arising from the increasing application of genetic technologies to the health of individuals and populations. The four course segments cover: (1) what we mean by policy-making and the various ways in which genetics issues are being framed and genetics policies are being developed and adopted; (2) issues arising from the application of genetics technology in health care and public health services, and the way these applications affect individual, family, professional and societal interests, with consideration of the role genetics might play in either widening or reducing health disparities; (3) issues arising from the ownership and application of genetics technology by the health industry; and (4) an historical view of genetics and its impact on society. Each segment involves didactic presentations, class discussion and break-out sessions. Two of the segments end with class exercises in which students in “real world” settings will grapple with current and anticipated dilemmas. The segments collectively are linked by a case study relevant to each portion of the course.
III. COURSE OBJECTIVES AND COMPETENCIES

This course is an overview of major issues in public health genetics. It is designed to follow introductory and epidemiology courses in the Certificate Program and Interdepartmental Concentration in Public Health Genetics, but can also be taken as an independent unit by students with a scientific grounding in genetics. Using basic genetics as a foundation, the course will supply students with the setting, background and societal issues presented by the current molecular biologic era, and will show how various quantitative and humanistic, ethical-legal-social perspectives relate to policy formation addressing these issues. The course is intended for students seeking to gain a broad knowledge of this growing field, and for students from multiple disciplines planning to use the knowledge and skills gained in their own careers.

Course learning objectives:
(1) To allow students to penetrate deeply enough into frequently used methodology (e.g., screening criteria evaluation, ethical and policy analyses, the public deliberative process) within the cultural context of past and present genetic programs to provide a basic working knowledge of the problems public health and health care professionals and policymakers must face in the field.

(2) To present students with essential terminology and techniques so that they might apply this knowledge to cases that will be revisited throughout the course, and take part in problem-based, community decision making and legislative policy exercises.

(3) To engage students in using the computer for researching the relevant literature and for communicating their questions and findings.

Exit competencies:
The objectives of the course are expressed by the following competencies to be gained by each student –

(1) Through examination of historic and current case studies, students will be able to apply a variety of analytical approaches to the identification and resolution of ethical, legal and social issues in public health genetics.

(2) Students will be able to describe the role of quantitative and qualitative frameworks adopted by consumers, professionals, and policymakers in assessing the acceptability of genetic policies and programs.

(3) Students will gain experience in the researching and design of a variety of practical societal and community-oriented approaches aimed at resolving competing interests in genetics policy formation.

(4) Students will be able to access a wide range of existing computer database resources offering technical, ethical, and policy information on genetics.
IV. COURSE MATERIALS

(1) Assigned Readings – located in the HMP517 individual session folders on CTools.

(2) Optional (Supplementary) Readings – located in the HMP517 individual session folders on CTools. See Stephen for access to additional Supplementary Readings from past years.

V. ASSIGNED READINGS

The list of specific readings for a particular session will be posted in the introductory materials for that session. (Pathway: CTools (http://ctools.umich.edu/portal) -> Login -> HMP 517 001 F12 tab -> Resources -> particular session -> introductory materials -> assigned / required readings list.)

Readings will be available for downloading on CTools under the readings file for each individual session. (Pathway: CTools (http://ctools.umich.edu/portal) -> Login -> HMP 517 001 F12 tab -> Resources -> particular session -> Assigned Readings box (click on box to get in; to re-close, click on blue HMP 517 001 F12 Resources heading at top, then click twice on particular session box).

Keeping up with these readings in advance of each class session is essential for full participation in class discussions and class exercises.

VI. SUPPLEMENTARY READINGS

Supplementary readings, related to but not assigned for the sessions, will be listed in the introductory materials session folders on CTools after the assigned / required readings list. They will be accessible in the Supplementary readings box for every session under Resources on course CTools (e.g., 04s = Session 4 Supplementary Reading). Additional accumulated readings relating to course topics are available on request. These readings are meant to enrich students’ fund of knowledge and to be helpful as background material for the class exercises and final term paper, but students are not required to read them.

VII. GRADING POLICY

Your grade in the course will be determined by applying the following weights to the items indicated. All grades given on individual assignments will be converted to the numerical 9 point scale (A+ =9; A=8; A- =7; B+ =6; B=5; B- =4; C+ =3; C=2; C- =1) for purposes of calculating the course grade.

40% - divided equally between the two class exercises, one individual and one group. All members of each team in group exercises will receive an identical grade.
45% - based upon your term paper. Dates: Oct. 11 – term paper topic due; Nov. 8 – term paper outline due; Dec. 11 – term paper due.

15% - based upon the frequency, creativity, and depth of your participation in class sessions and CTools discussions. While class members are required to read assigned materials and to follow the flow of discussion on the CTools Discussion site, the participation grade will be based solely on active involvement in these activities. The goal here is to have active sharing of ideas amongst class members.

VIII. CTOOLS DISCUSSIONS

The course will be utilizing "CTools", a web-based support system for U-M courses. This syllabus, assignments, and a computer conference (consisting of sets of discussions) will all be located on our CTools web site. Accessing the web-site will be described at the first session of the course. You can find the web-site for HMP 517 by going to: http://ctools.umich.edu. Included in the CTools web-site for this course is an area marked “Forums / General Discussion,” enabling students and faculty to discuss issues raised in class sessions, topics suggested by the readings, and topics relevant to the course which are initiated by any course participant. Participation in the discussion will be limited to the course instructors, students, and guest faculty.

IX. RELEVANT WEB SITES

Several key genetics web sites on the HMP 517 CTools site will be displayed the first day of class. You are encouraged to visit these sites and share your comments on them with the rest of the class and instructors, utilizing the CTools Discussion site. CTools provides students with the opportunity to share other useful web sites and readings with their fellow classmates.

X. CLASS CONDUCT AND EXPECTATIONS

Class format is seminar style. Laptops may be used for typing notes, but should not obstruct student participation in class flow. Students are expected to abide by University standards of ethical and professional conduct in the classroom. Academic misconduct will not be tolerated. Students may share background material for the individual class exercise, but must write the paper for the exercise on their own. The formal group exercise is expected to be collaborative. All participants in the group exercise are expected to be involved from the time the group forms and to carry a fair share of the work load. Failure to participate in a way that respects other members’ efforts can result in loss of a full grade point for the individual on the group exercise. Students may share term paper references but need to write the entirety of the term paper on their own.

XI. COURSE SCHEDULE AND OUTLINE

Brackets [ ] indicate that confirmation of guest lecturer(s) is currently pending.
(V) indicates video-conferenced session. Reading lists and readings will appear on course CTools for each session. All class sessions will be held in Rm. 2610, SPH Tower / Crossroads.

A. POLICY DEVELOPMENT

Public health genetics touches on areas that are highly complex and value-laden. This segment introduces the course and the fundamentals of genetics policymaking. It explores alternative methods of policymaking and their socio-ethical bases. Methods examined include community-oriented, institutional, and legislative means of deliberation. Use of the CTools Discussion for the course and genetics databases are covered.

Tuesday, September 4
1) **Introduction and Computer Orientation** (Toby Citrin, Stephen Modell)
Course purpose, objectives, schedule and outline, introduction to policy, demonstration of CTools and its Discussion features, accessing genetics databases and web sites on the Internet.

Thursday, September 6
2) **Issues and Policies** (Stephen Modell)
Distinction between issues and policies. Presentation of a formal definition of policy, and of categories of policies. Informal discussion of genomics issue areas of interest to the class, and how they translate into policymaking. Small team break-out to hold group preliminary discussions of the interlinking class case study on personalized medicine.

Tuesday, September 11
3) **Case Study and Policy** (Toby Citrin, Stephen Modell)
Framework for considering ethical-legal-social implications (ELSI) and how they can be addressed by various types of policymaking. Discussion of principles of policymaking and the different bodies involved. Small team reporting followed by whole-group discussion of this year's case study, which will concentrate on policy considerations connected with the growth of personalized medicine in genomics. The case study focuses on discussion within a Congressional committee of content that might contribute to a Genomics and Personalized Medicine Act of 2013 and satisfy both legislators and consumers.

Thursday, September 13
4) **Policymaking Process** (Toby Citrin, Stephen Modell)
Steps involved in policymaking, overview of the roles of government, institutions, professional organizations, and their interaction in the making of health policy, conflicts that can arise in the principles they employ, means used to resolve competing demands in policymaking, input of experts, the public, interest groups, and the media, through two genetics case examples – (1) newborn screening policies influenced by advisory bodies, rules and legislation, and (2) regulation of direct-to-consumer genetic testing.
Tuesday, September 18

5) **Genetics Law** (Ellen Wright Clayton)(V)
Jurisdictional levels for approaching health policy issues. Role of the courts in establishing genetic and reproductive policy, imminent harm and physician duty to disclose to others, wrongful birth and wrongful life, reasonable physician and patient-based standards of informed consent, ownership of biologic material, group protections and genetic privacy, potential conflicts between right to privacy and public safety.

Thursday, September 20

6) **Genetics Legislation** (Toby Citrin, Stephen Modell)
Discussion of the variety of genetic and reproductive legislation, touching on how issues get on the legislative agenda, the interests and contending factors that come into play in the translation of issues to policies, federal and state legislative processes, and the variety of ways in which states have dealt with common issues. Consideration of the various governmental players and public stakeholders involved.

Tuesday, September 25

7) **Public Deliberation** (Toby Citrin)
Function and aims of rational public deliberation in a liberal democratic society, relationship between the public and experts in coming to public judgment, models of deliberation such as involvement in advisory panels, public dialogues, deliberative opinion polls, and interactive voting, comparison of examples of consensus building - Oregon Health Decisions, the Michigan / Tuskegee Communities of Color and Genetics Policy Project, the Community Genomics Forums and the creation of the Michigan Neonatal Biobank.

Thursday, September 27

8) **Genetics and the Media** (Emilia Askari, Kara Gavin, Sarah Mayberry)
Role of the media in reflecting societal concerns, effect of professionals on the media and of the media on public awareness, issues of accuracy of representation and educational level of target audience, comparison of different modalities capturing public attitudes and influencing public policy, relationship between the university, its press channels, and the outside media, reference to recently publicized examples, e.g., cancer genetics, behavioral genetics, stem cell research, advent of the Internet.

Tuesday, October 2

9) **Ethical Perspectives** (Toby Citrin, Stephen Modell)
Ethical frameworks for decision making in the health care and public health settings including basic principles of ethics, ethical theories, normative ethics, and their application to the implementation of screening programs, the right to know and not-to-know, and disclosure to third parties. Alternative communitarian and values-oriented modes of decision making. Public health considerations including individual vs. community interests, benefits vs. burdens to society, social justice and equal access, voluntary vs. mandatory screening.
Thursday, October 4

10) Religious Perspectives (Invited Panel; Susan King, moderator)
An interdenominational panel of religious leaders from the Washtenaw County faith community will explore the interface between genetics/genomics, religion and spirituality. The discussion will consider areas of conflict and consistency between genomic science and faith traditions as well as the role that faith leaders can play in furthering the understanding of these science-faith relationships among faith communities.

B. INDIVIDUAL, COMMUNITY, AND PROFESSIONAL ISSUES

This section contrasts individual patient-oriented and population-wide approaches to health management. It illustrates frameworks different professionals use in the design of genetic testing and screening programs, paying particular attention to decision making criteria used in program implementation. Discussion of the relative interests of patient/parent, fetus or child, and consumers/society, with special attention to racial-ethnic concerns.

Tuesday, October 9

11) Genetic Tools for Public Health Practice: Testing, Family History
(Toby Citrin, Stephen Modell)
A major challenge facing departments of public health is the expansion of genetics from newborn screening programs and clinical services for rare genetic disorders to the implementation of educational and screening programs and the use of family histories in addressing chronic disease problems, and the utilization of individualized, genetically-determined risk data in the implementation of environmental and occupational regulation. This session will look at the issues that arise in the spheres of research and application when public health expands in these directions. Topics to be covered include privacy and consent issues in epidemiologic research involving third parties such as family members, considerations in accessing alternative sources of information on morbidity and cause of death, types of programs that require community-based data and that will have a population-wide impact.

Thursday, October 11

12) Health Disparities (Toby Citrin and Stephen Modell or Guest)
Discussion of existent disparities with respect to major genetically-associated conditions. Impact of racial-ethnic categorizing on the direction of research and allocation of resources. Discussion of broader considerations such as representation of minority groups in research design and in genetic practice, appropriateness of genetic research conducted with select racial-ethnic groups, types of research that may be expected to benefit rather than harm populations, protective policies to be established.

Tuesday, October 16

● Fall Study Break
Thursday, October 18

13) **Issues of Race and Ethnicity** [Toby Citrin and Stephen Modell or Guest]
Examination of past programs (sickle cell screening, Tuskegee syphilis study) leading to disadvantage and discrimination in racial-ethnic groups, concerns engendered by current programs (e.g., research into human genetic variation, haplotype mapping, genealogic research). Relation of genetics and racial-ethnic identity to health. Controversy connected with use of race-ethnicity as a proxy for genotype. Examination of criteria for racially and ethnically sensitive research and practice.

Tuesday, October 23

14) **Genetics Education** (Louisa Anne Stark)(V)
Public information needs with respect to genetics. Communication of ethical, legal, and social issues and the multifactorial nature of genetics. Challenges faced by K-12, professional and public genetics educators, e.g., conveying an appreciation of the nature of scientific advancement, its complexity, including genetic variation and gene-environment interaction, and of genetic technology and its consequences. Role of professional societies, science educators, and the scientific community in interpreting genetics to the public at different age levels. New educational techniques such as use of the Internet.

Thursday, October 25

15) **Cascade Screening Class Exercise** (Toby Citrin, Stephen Modell)
Cascade screening – genetic testing of family members once a proband has tested positive – has received increased attention in the last several years. A stakeholder consultation report on the future of public health genomics through 2017 recommended the expansion of public health screening programs to include cascade and life course screening. The Evaluation of Genomic Applications (EGAPP) Working Group recommended that cascade screening be offered to all at-risk relatives of those newly diagnosed with Lynch syndrome, the most common cause of inherited colorectal cancer. The CDC has classified this form of testing as a Tier 1 (highest level of evidence) genomic application. Despite the benefits, many questions remain if cascade screening were to take place on a widespread level. Policies must take into account the sensitivity of a proband knowing that other family members may be at-risk, the need for follow-up in those discovered to have heightened risk, and assurance of coverage amongst all groups in need. The Centers for Disease Control and Prevention has convened a meeting to hammer out the pluses and minuses of large-scale implementation, especially focusing on the ELSI issues inherent in cascade screening. Students will choose roles as group representatives, suggesting ways in which ELSI issues might be addressed to optimize the use of familial genetic testing where it is most needed while minimizing direct and indirect harms from the release of genetic information and broadened use of genetic testing in the family setting.

Tuesday, October 30

- **APHA Meeting, San Francisco, CA**
No class session.
C. HEALTH INDUSTRY ISSUES

This cluster offers an assortment of issue areas and policy tools relating to genetics and the health industry. University and commercial positions with respect to ownership, technology transfer, distribution of benefits, and health care coverage are presented. Sessions cover ethical-legal and socioeconomic methods useful in analyzing the issues presented by genetic research and its applications.

Thursday, November 1
16) Biotechnology Patenting and Ownership (Shobita Parthasarathy)
History, basis and motivation for gene patenting and patent rights on biotechnology, patent proliferation, international perspectives, relationship between the commercial sector, university R&D, and the public domain, case example related to BRCA1.

Tuesday, November 6
17) Ownership of Genetic Information (Toby Citrin, Stephen Modell)
Overview of genetic information infrastructure, examination of types of genetic databases, including recent human gene banks. Guiding ethical principles, confidentiality in a variety of settings (individual, family, institutional, public), professional-patient relations including duty to warn. Privacy assurance in genomics research and public health surveillance. HIPAA privacy regulations. Uniqueness of genetic information with respect to other types of medical information - issue of "genetic exceptionalism". Mid-term evaluation.

Thursday, November 8
18) Marketing Issues [To Be Named]
Consideration of the issues involved in the translation of research to genetic tools and applications of commercial value, and the various forces motivating the process. Commercial and scientific interests in the marketing and promotion of genetic tests, e.g., BRCA, ApoE. Examination of recent developments, such as direct-to-consumer advertising and marketing, and the offering of online Family History and personalized risk assessment. Discussion of ethical-legal-social considerations, e.g., the targeting of tests and drugs to specific racial-ethnic groups.

Tuesday, November 13
19) Public-Private Research Issues [Michael Boehnke, Susan Kornfield, 3rd Guest]
Discussion of issues connected with patenting of newly identified genes, therapeutics, and processes in genetic and biomedical research. The panel will examine the administrative, legal, and ethical complexities of patenting and technology transfer in the university research setting, including university-industry relations, academic freedom, intellectual property rights, exclusivity, confidentiality, and social benefit. Research development, pharmaceutical, and biotechnology examples.

Thursday, November 15
20) Consumer Perspectives [D.L., C.M., E.N.]
Discussion of ethical-social issues of genetic testing and other applications of genetic technology from the perspective of consumers and consumer representatives who have had
personal experience with specific genetic conditions. This session will address key questions dealing with human valuation and genetic testing, the multiple effects of genetic knowledge such as stigmatization and/or increased tolerance for human difference, and availability of insurance and outside support. Topics covered: public perceptions and misperceptions of genetic conditions, disability rights perspective, awareness-raising in public and professional spheres, patient-caregiver communication, disclosure within families.

Tuesday, November 20

21) **Personalized Medicine Class Exercise** (Toby Citrin, Stephen Modell)

It has been said that a personalized medicine act is an idea that has come of age, yet initial efforts in 2006 by then Senator Barack Obama and Ted Kennedy, and the most recent introduction of a Genomics and Personalized Medicine Act by Congressman Patrick Kennedy and Congresswoman Anna Eschoo in 2010 have not yet succeeded in converting this legislation into a full-fledged act. The FDA has called for a new major focus on “building the infrastructure to drive and support personalized medicine and create a rapid drug development pathway for important targeted therapies.” In one Congressional briefing, Anna Eschoo said what is needed is “an infusion of new ideas.” The ensemble of new ideas must be broad-brushed, addressing public needs, the needs of public health and health care professionals, and what must be undertaken by the relevant federal agencies. Policies to be considered, if they are to affect the population, need to address the harnessing of personalized medicine and personalized risk assessment for prevention, their affordability, and given the current political climate, how they will make health care more economical, and will make diagnostic and therapeutic combinations more effective at serving public health goals. A coalition of medical and public health groups has sent representatives to Capitol Hill to testify before Congress on a potential bill to be introduced in 2013. They will make recommendations on whether such a bill should be passed, and will propose content for the legislation or alternative policies.

D. LOOKING BACK AND LOOKING FORWARD

This cluster acquaints students with the phases of development in genetics as a field and their scientific bases. It examines the range of historical and contemporary developments, including discussion of cutting edge technologies. A look back at the course as a whole.

Thursday, November 22

- **Thanksgiving Recess**

Tuesday, November 27

22) **Genetics, Environment and Behavior as Determinants of Health** (Toby Citrin, Stephen Modell)

Exploration of social and policy issues relating to the balance between genetics, environment, and self-willed behavior. Historical developments at the interface between genes, behavior and environment. Critical look at the range of positions taken - genetic determinism, personal culpability, and “victim-blaming” approaches adopted by some public health authorities. Consideration of environmental factors including physical and socio-economic
variables, and of genetically-associated conditions susceptible to environmental influence. Implications for public health policy.

Thursday, November 29
23) Gene Research and Therapy (Stephen Modell)
Exploration of issues that arise in the research context: value of genetic testing and gene therapy clinical trials, stages from research to application, research with particular racial-ethnic groups and with third parties, institutional policies for subject and population protection in research, overview of current gene therapy applications, somatic vs. germ-line distinction - recent events in the news, phenotypic vs. genotypic prevention.

Tuesday, December 4
24) Reprogenetics (Toby Citrin, Stephen Modell)
Review of traditional (amniocentesis, chorionic villus sampling) and advanced (preimplantation genetic diagnosis, ICSI, nuclear and cytoplasmic transfer) reproductive technologies, and the issues that arise in their application, from social justice concerns to fears of “designer babies”. Discussion of the current level of oversight in the U.S. and abroad. Coverage of federal and state laws in the United States. Analysis of the various broad policy approaches that could be applied (market-based, governmental regulation, restricted regulation).

Thursday, December 6
25) Social Darwinism, Eugenics and Genetics [Martin Pernick]
Overview of eugenic developments in the U.S., specific states, and abroad. Discussion of the movement’s origins, the involvement of scientists, groups affected, and relevance to present day medical science and human genetics. Comparison between aims of public health and eugenic goals. Implications for current communicable disease practice, screening programs, and the growing ability to select for characteristics in future generations.

Tuesday, December 11
26) Class Debriefing; Course Evaluation (Toby Citrin, Stephen Modell)
Review of topics covered, student comments and suggestions, course evaluation.