

Genetics, Ethics and the Law

Human genetics is a rapidly evolving field in medicine. While the field holds great promise, it also creates special legal and ethical issues. This course will explore the legal and bioethical implications of genetic practice and research from American and international perspectives. Topics of discussion will include the application of ethical concepts in genetics ('Genethics'); the nature of informed consent concerning genetic testing and genetic research, confidentiality and the duty to warn about genetic-related conditions; liability and risk management to avoid malpractice; individual and group privacy interests concerning identifiable genetic data; ethical analysis of public health initiatives (genetic screening, national repositories); insurance and employment discrimination based on genetic predispositions; sex selection; genetic and intellectual property issues; and a survey of cutting-edge genomic research.

Organizing Committee: R. Bonnie, M. Riley, G. Siegal, ¹ L. Silverman (UVA)

N. Callanan, S. Schmerler

Program (minor changes possible)

DAY 1 (Friday, May 29, 2009)

Morning Session — Introduction

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| 11- 11:15 | General introduction to the course (Deans, Organizing Committee) |
| 11:15-12 | Basic concepts in modern bioethics
<i>Keynote speaker James F. Childress (UVA)</i> |
| 12-12:45 | 'Gene-ethics' – Applying bioethical concepts to genetics and genomics
<i>Lois Shepherd</i> |
| 12:45-13:45 | Working lunch break and workshops – case discussion and analysis, applying previous session topics, genetic testing and adoption
<i>(Moderators – course staff)</i> |

Afternoon Session — Patients and Their Families

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| 2-2:45 | Patients' rights – consent, confidentiality
<i>Sonia M. Suter/Gil Siegal</i> |
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- 2:45-3:30 Genetic information and the right to know/not to know; genetic information and family's rights
Madaline Harrison (UVA)
- 3:30 Coffee break
- 4-5 Post GINA – genetic information and the insurance/employment arenas
Keynote speaker Mark Rothstein (Louisville)
- 5-5:30 Discussion

DAY 2 (Saturday, May 30, 2009)

Morning Session — Public Health and Screening Policies

- 9-9:20 Introduction to ethics and law in public health genetics
Ruth Gaare Bernheim (UVA)
- 9:20-10 Managing genetic samples and information – access, security and privacy
Mark Rothstein (Louisville)
- 10-10:40 Legal and ethical challenges of genetic testing and screening (A)
Margaret Riley (UVA)
- 10:30 Coffee break
- 11-11:45 Legal and ethical challenges of genetic testing and screening (B) – carriers, pre-marital, chronic diseases
Sonia M. Suter/G. Siegal (UVA)
- 11:45-12:30 Biobanks – comparative ethico-legal analysis
G. Siegal (UVA)
- 12:45-1:45 Working lunch break and workshops - nonmedical sex selection
(Moderators – course faculty)

Afternoon Session — Genetic Research

- 2-2:45 Genetic research – the ethical and legal framework; special issues in genetics research
Myra Roche
- 2:45-3:30 Pharmacogenomic research – *Mark Rothstein (Louisville)*
- 3:30 Coffee break

- 4-4:40 What is happening in genetic and genomic research?
Josyf Mychalecki (UVA)
- 4:40-5:30 Personalized medicine, direct-to-consumer marketing and the FDA
Margaret Riley (UVA)

DAY 3 (Sunday, May 31, 2009)

Morning Session – Genetic Research — Intellectual Property Issues

- 9-9:45 Introduction to intellectual property
Margo Bagley/Chris Sprigman (UVA)
- 9:45-10:30 Intellectual property in genetics
Beckie Anderson
- 10:30 Coffee Break
- 11-11:45 Another look at free markets – regulating genetic tests
L. Silverman (UVA)
- 11:45-12:30 Pipeline pharmacogenetics - changing the industry from the inside
I. Grossman (Cabernet Pharmaceuticals)
- 12:45-1:45 Working lunch break and workshops: Direct-to-consumer genetic testing
(Moderators – course faculty)

Afternoon Session – Liability Issues

- 2-2:45 Genetics and malpractice/negligence – introduction
Gil Siegal (UVA)
- 2:45-3:30 Genetics and malpractice/negligence – standard of care, wrongful life cases, the limits of informed consent in modern genetics
Susan Schmerler
- 3:30 Discussion
- 4 Concluding session: ELSI issues for a new AD diagnostic, and a PGX-informed Alzheimer Disease prevention drug trial
Keynote speaker Allen D. Roses (Shiraz Pharmaceuticals)
- 4:40 Adjourn and awarding certificates