BIOGRAPHICAL SKETCH

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NAME: Ellen Wright Clayton

eRA COMMONS USER NAME (credential, e.g., agency login):claytoew

POSITION TITLE: Craig-Weaver Chair and Professor of Pediatrics, Professor of Law, Co-Founder, Center for Biomedical Ethics and Society

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
Duke University, Durham, North Carolina	BS	05/1974	Zoology
Stanford University, Stanford, California	MS	06/1976	Biology
Yale Law School, New Haven, Connecticut	JD	05/1979	Law
Harvard Medical School, Boston, Massachusetts	MD	05/1985	Medicine

A. Personal Statement

My work focuses on the appropriate conduct of genomics research, addressing issues ranging from the roles of consent and governance, and the implementation of its fruits into clinical care, including developing criteria and defining the roles of various decision makers, including patients, physicians, family members, professional organizations, and regulators. I use a variety of methodologies in these studies: legal analysis, normative ethical analysis, and qualitative and quantitative research assessing the views of patients, and research participants, most recently regarding pharmacogenomic testing and in the eMERGE consortium's large population-based survey of opinions about broad consent for research use and data sharing. I have had the opportunity to address many of these critical policy issues in real time, having served as Co-Chair of the ELSI Working Group of the International HapMap Project, as well as playing a leadership role in developing and guiding Vanderbilt's innovative BioVU resource. Concerns about risk to privacy and adverse use of information loom large in all this work, and have led me to believe that our understanding of these worries and where they come from as well as our society's responses is woefully inadequate and that a more complete understanding is needed to develop responses that will permit the optimal use of genomic data. My role on this project will first to help guide the multi- and transdisciplinary research needed to unpack these concerns. I will devote additional attention to issues of the role of family as well as the role of law and institutional practices that address risk to privacy.

B. Positions and Honors

Positions and Employment

1985: Visiting Assistant Professor (Spring Semester), Law School and Program in Medical Ethics, University of Wisconsin
1988-96: Assistant Professor of Pediatrics, Vanderbilt University Medical School Assistant Professor of Law, Vanderbilt University School of Law
1996-99: Associate Professor of Pediatrics with tenure, Vanderbilt University Medical School
Associate Professor of Law, Vanderbilt University School of Law
Faculty Member, Vanderbilt Program in Human Genetics
1999-05: Director, Center for Genetics and Health Policy
1999-2010: Rosalind E. Franklin Professor of Genetics and Health Policy
2005-2011: Director, Center for Biomedical Ethics and Society

Currently: Craig-Weaver Professor of Pediatrics with tenure, Professor of Health Policy, Vanderbilt University Medical School
Professor of Law, Vanderbilt University School of Law

Selected Other Experience and Professional Memberships

1989-95: Member, Committee on Bioethics, American Academy of Pediatrics
1995-8: Member, National Advisory Committee, National Center for Human Genome Research
1997-2000: Member, ELSI Research Program & Evaluation Group, NHGRI
1997-2001: Editor-in-Chief, Journal of Law, Medicine, and Ethics, now member editorial board
1998-2000 Member, Ethical, Legal, and Social Issues Working Group, Newborn Screening Taskforce, Maternal and Child Health Bureau, Health Resources Services Administration
2000-2002 Consultant, Council of International Organizations of Medical Sciences, Ethical Guidelines for International Research
2001-2005 Co-Chair, ELSI component of international effort to develop a human haplotype map
2006- Institute of Medicine (have served on 10 committees, chaired 5, member of Advisory Council and its Executive Committee, chair Board on Population Health and Public Health Practice, member of Report Review Committee
2012- Member, HUGO Committee on Ethics, Law, and Society
2013- Chair, International Paediatric Platform, P3G

Selected Honors

2006: Member, Institute of Medicine
2010: William G. Bartholome Award for Ethical Excellence, American Academy of Pediatrics
2012: Fellow, American Association for the Advancement of Science
2013: Member, American Pediatric Society
2013: Recipient, David P. Rall Medal, Institute of Medicine
2015: Frank H. Morriss, Jr., Leadership Award, University of Iowa Department of Pediatrics and University of Iowa Foundation

C. Contributions to Science

1. One contribution to science has been in helping to identify and address ethical and legal issues that arise nationally and internationally in the conduct of genetic and genomic research. I began by focusing on the role of informed consent for this research but have increasingly become convinced of the importance of strengthening governance and security of biobanks. I have also carefully explored arguments for and against treating genetic/genomic information differently, an issue salient to the structure and conduct of biobanks. My work is not merely hypothetical as I have been intimately involved in such projects as the International HapMap Project as well as BioVU.

   a. Ellen Wright Clayton, Karen K.Steinberg, Muin J. Khoury, Elizabeth Thomson, Lori Andrews, Mary Jo Ellis Kahn, Loretta M. Kopelman, Informed consent for genetic research on stored tissue samples, Journal of the American Medical Association 1995; 274: 1786-1792
   b. Dan M. Roden, Jill M. Pulley, Melissa Basford, Gordon R. Bernard, Ellen Wright Clayton, Jeffrey R. Balser, Daniel R. Masys, Development of a large-scale deidentified DNA biobank to enable personalized medicine, Clinical Pharmacology and Therapeutics 2008; 84 (3): 362–369 PMC3763939
   c. Kyle B. Brothers, Matthew J. Westbrook, M. Frances Wright, John A. Myers, Daniel R. Morrison, Jennifer L. Madison, Jill M. Pulley, Ellen Wright Clayton, Patient Awareness and Approval for an Opt-Out Genomic Biorepository, Personalized Medicine 2013;Jun;10(4). PMC3882901
   d. Ellen Wright Clayton, Biospecimen Exceptionalism in the ANPRM, In: I. Glenn Cohen and Holly Fernandez Lynch, Human Subjects Research Regulation: Perspectives on the Future, MIT Press: Cambridge, MA 193-206 (2014)

e. Zhiyu Wan, Yevgeniy Vorobeychik, Weiyi Xia, Ellen Wright Clayton, Murat Kantarcioglu, Ranjit Ganta, Raymond Heatherly, Bradley A. Malin, A game theoretic framework for analyzing re-identification risk., PLoS One 2015 Mar 25;10(3):e0120592. PMCID: PMC4373733

2. I have been highly engaged in the debate about return of genetic and genomic research results particularly in the context of biobanks, exploring the ethical and legal consequences of returning results, especially those that are secondary to the purpose for which the participant originally engaged in research. In addition to the primary articles listed below, I have participated in numerous collaborative papers on this topic, including eMERGE, CSER, the Paediatric Platform of P3G, and Susan Wolf's research projects in which guidelines are proposed.

   a. Ellen Wright Clayton, Incidental Findings in Genetics Research Using Archived DNA, Journal of Law, Medicine, and Ethics 2008; 36(2): 286-91 PMCID: PMC2576744
   b. Amy L. McGuire, Ellen Wright Clayton, The Legal Risks of Returning Results of Genomics Research, Genetics in Medicine 2012; 14(4):473-7 PMCID: PMC3779603
   c. Ellen Wright Clayton, Susanne Haga, Patricia Kuszler, Emily Bane, Krysta Shutske, Wylie Burke, Managing Incidental Genomic Findings: Legal Obligations of Clinicians, Genetics in Medicine 2013; 15: 624-629 PMC3805501
   d. Wylie Burke, Armand H. Matheny Antommaria, Robin Bennett, Jeffrey Botkin, Ellen Wright Clayton, Gail E. Henderson, Ingrid A. Holm, Gail P. Jarvik, Muin J. Khoury, Bartha Maria Knoppers, Nancy A. Press, Lainie Friedman Ross, Mark A. Rothstein, Howard Saal, Wendy R. Uhlman, Benjamin Wilfond, Susan M. Wolf, Ron Zimmern, Recommendations for Returning Genomic Incidental Findings? We Need to Talk? Genetics in Medicine 2013;15(11):854-9 PMC3832423
   e. Gail P. Jarvik, Laura M. Amendola, Jonathan S. Berg, Kyle Brothers, Ellen W. Clayton, Wendy Chung, Barbara J. Evans, James P. Evans, Stephanie M. Fullerton, Carlos J. Gallego, Nanibaa' A. Garrison, Stacy W. Gray, Ingrid A. Holm, Iftikhar J. Kullo, Lisa Soleymani Lehmann, Cathy McCarty, Cynthia A. Prows, Heidi L. Rehm, Richard R. Sharp, Joseph Salama, Saskia Sanderson, Sara L. Van Driest, Marc S. Williams, Susan M. Wolf, Wendy A. Wolf, eMERGE ROR Committee & CERC Committee, CSER Act-ROR Working Group, Wylie Burke, Return of Genomic Results to Research Participants: The floor, the ceiling, and choices in-between, American Journal of Human Genetics 2014;94(6):818-826 PMC4121476

3. I have been a leader in ethical and legal issues in pediatrics in three main domains. I began with newborn screening, arguing for evidence-based processes and articulating the need for parental permission. I have also written about issues about child abuse and neglect and more recently, commercial sexual exploitation of minors in the United States. Finally, I continue to explore issues around predictive genetic testing, research, and return of primary and secondary findings.

   a. Ellen Wright Clayton, Screening and Treatment of Newborns, Houston Law Review 1992; 29:85-148
   b. Jeffrey R. Botkin, Ellen Wright Clayton, Norman C. Fost, Wylie Burke, Thomas H. Murray, Mary Ann Baily, Benjamin Wilfond, Albert Berg, Lainie Friedman Ross, Newborn Screening Technology: Proceed with Caution, Pediatrics 2006; 117(5): 1793-99 PMID 16651338
   c. Ellen Wright Clayton, Laurence B. McCullough, Leslie G. Biesecker, Steven Joffe, Lainie Friedman Ross, Susan M. Wolf, Addressing the Ethical Challenges in Genetic Testing and Sequencing of Children, American Journal of Bioethics 2014;14(3):3-9 PMCID: PMC3950962
   d. Heidi Howard, Bartha Knoppers, Martina Cornel, Ellen Clayton, Karine Sénécal, and Pascal Borry, Whole genome sequencing in newborn screening? A Statement on the continued importance of targeted approaches in newborn screening programmes, European Journal of Human Genetics, 2015 PMID: 25626707 Jan 28 epub ahead of print
   e. Ellen Wright Clayton, How much control do children and adolescents have over genomic testing, parental access to their results, and parental communication of those results to others? Journal of Law, Medicine, and Ethics (in press, 2015)

4. I have long been interested in the ways that individuals and their adult family members deal with information about genetics, conducting both empirical studies and legal analyses.

a. Ellen Wright Clayton, What Should the Law Say About Disclosure of Genetic Information to Relatives, Journal of Health Care Law & Policy 1998; 1: 373-390
b. Diana L. Jones, Joanne C. Sandberg, Mary J. Rosenthal, Robert C. Saunders, Vickie L. Hannig, Ellen W. Clayton, What patients and their relatives think about testing for BMPR2, Journal of Genetic Counseling 2008; 17(5): 452-8 PMC3730255
c. Diana L. Jones, Ellen Wright Clayton, The Role of Distress in Uptake and Response to Predisposition Genetic Testing: The BMPR2 Experience, Genetic Testing and Molecular Biomarkers 2012; 16(3): 203-209 PMCID: PMC3306587

Complete List of Published Work in MyBibliography:
http://www.ncbi.nlm.nih.gov/sites/myncbi/1xqKvouDu5n/bibliography/47375981/public/?sort=date&direction=ascending

D. Research Support

Ongoing Research Support

5UL1 RR024975-05 (Bernard) 06/27/2012- 05/31/2017
National Center for Research Resources
The Vanderbilt Institute for Clinical and Translational Research (VICTR)
Project Goal: To re-engineer processes to remove impediments, produce inspired personnel trained in the bi-directional process of translational research, support translational research with broad resources, foster innovation by stimulating contribution from collaborators, and enrich the translational research environment
Role: Co-Investigator

1U01 HG006378 (Roden) 08/15/2011- 07/31/2015
NHGRI
Vanderbilt Genome-Electronic Records Project
Project Goal: This proposal supports Vanderbilt's participation in an NHGRI-supported network to evaluate the utility of DNA biobanks associated with electronic medical record systems by generating data sets for genome-wide association. The project has four Specific Aims: (1) perform a genome-wide association comparing samples from subjects with QRS durations on the ECG at the extremes of the normal range, and validate by genotyping high likelihood associations in prospectively ascertained clinical trial sets for QRS duration and for arrhythmia susceptibility; (2) evaluate the validity and utility of structured and unstructured components of electronic medical record data for genome-phenome correlations; (3) assess the ethical, scientific, and societal advantages and disadvantages of the "opt-out" model adopted in the Vanderbilt databank model, and determine best practices for oversight, community involvement, and communication as the resource grows; and (4) develop and evaluate formal privacy protection models for data derived from databanks and electronic medical record, establishing data sharing and integration practices. The proposal includes development of an Administrative Coordinating Center for the network.
Role: Co-Investigator

1 R01 HG006844 (Malin) 09/30/2012 – 9/29/2016
NIH/NIGMS
A Risk Management Framework for Identifiability in Genomics Research
The goals of this research project are to develop an interdisciplinary framework to a) model genomic data re-identification risks, b) measure the risks given computational and socio-legal constraints, and c) assist in determining which data protection strategies are the most appropriate to specific data sharing scenarios.
Role: Co-Investigator

R01HHL126492 (Rice) 09/15/2014-07/31/2017
NHLBI
Using real world decisions to develop a modified central IRB model
This project will explore how IRBs determine what review model to use for a particular study, which is necessary to inform any national movement to broader use of a given model.
Role: Co-Investigator

Completed Research Support

R21 HG00612 (Clayton) 09/23/2011-08/31/2014
NIH/NCRR
Returning Research Results of Pediatric Genomic Research to Participants
Project Goal: Determining what criteria should govern the return of individual results of pediatric genomics research has to date received remarkably little attention. This issue must be resolved if this research, which is vital to understanding the contributions of genetic variation to the health of children, is to proceed. This project brings together three internationally known lawyers, each of whom has written extensively about legal and policy issues in genomics research and in pediatrics, as well as an internationally known pediatrician-philosopher as a consultant, to define the applicable legal rules and to develop guidelines for returning results of genomic research involving minors.
Role: PI