BIOGRAPHICAL SKETCH

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NAME	POSITION TITLE
Ellen Wright Clayton, J.D., M.D.	Professor of Pediatrics Professor of Law Co-Director, Center for Biomedical Ethics and Society
eRA COMMONS USER NAME claytoew	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	YEAR(s)	FIELD OF STUDY
Duke University, Durham, North Carolina	B.S.	1970-1974	Zoology
Stanford University, Stanford, California	M.S.	1974-1976	Biology
Yale Law School, New Haven, Connecticut	J.D.	1976-1979	Law
Harvard Medical School, Boston, Massachusetts	M.D.	1981-1985	Medicine

A. Positions and Honors

1985 Visiting Assistant Professor (Spring Semester), Law School and Program in Medical Ethics, University of Wisconsin, Madison, WI
1985-1988 Resident, Department of Pediatrics, University of Wisconsin Hospital and Clinics, and Lecturer, Program in Medical Ethics, Madison, WI
1988-1996 Assistant Professor of Pediatrics, Vanderbilt University School of Medicine, Nashville, TN, Assistant Professor of Law, Vanderbilt University School of Law, Nashville, TN
1996-1999 Associate Professor of Pediatrics, Vanderbilt University School of Medicine, Nashville, TN
1996-1999 Associate Professor of Law, Vanderbilt University School of Law, Nashville, TN
1989-1995 Member, Committee on Bioethics, American Academy of Pediatrics
1995-1998 Member, National Advisory Council, National Human Genome Research Institute
1997-2000 Member, ELSI Research Program & Evaluation Group, Nat'l Human Genome Research Institute
1997-2001 Editor-in-Chief, *Journal of Law, Medicine and Ethics*
1999-Pres Professor of Pediatrics, Vanderbilt University School of Medicine, Nashville, TN
1999-Pres. Professor of Law, Vanderbilt University School of Law, Nashville, TN
1999-Pres. Rosalind E. Franklin Professor of Genetics and Health Policy, Vanderbilt University Medical Center, Nashville, TN
1991-Pres. Member, Genetics Advisory Committee, Tennessee Department of Health
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
2002-Pres. Member, Health Sciences Policy Board, Institute of Medicine
2002-Pres. Member, Ethics Working Group, National Children's Study, NICHD
2003-2004 Member, Committee on the Use of Third Party Toxicity Research with Human Participants, Science, Technology, and Law Program, Institute of Medicine
2004-2005 Member, Committee on Genomics & the Public's Health in the 21st Century, Institute of Medicine
2005: Chair, Roundtable on Translating Genomic Information into Improved Health, Institute of Medicine
2005-2006 Member, Committee on Disposition of the Air Force Health Study, Institute of Medicine
2005-2006 Member, Committee on Assessing Interactions Among, Social, Behavioral, and Genetic Factors of Health, Institute of Medicine
2006- Member, Institute of Medicine

Honors

Excellence in Resident Education, Department of Pediatrics, Vanderbilt University School of Medicine (2004); Jay Healey Award for Outstanding Health Law Teacher (1999); Sigma Xi, Vanderbilt University (1997); Henry M. Castello Memorial Award for Outstanding Resident, University of Wisconsin Hospitals and Clinics (1985-1986); Editor, *Yale Law Journal* (1978-1979); NIH Traineeship, Stanford University (1974-1976); Phi Beta Kappa (1974); Summa Cum Laude, Duke University (1974).

B. Selected Publications: (from more than 75 books, articles, book chapters, and position papers)

Clayton EW, Hickson GB. Compensation under the National Childhood Vaccine Injury Act. *J Pediatrics*. 116:508-513, 1990.

Clayton EW. Screening and treatment of newborns. *Houston Law Review*. 29:85-148, 1992.

Hickson GB, Clayton EW, Githens PB, Sloan FA, Factors that prompted families to file medical malpractice claims following perinatal injuries. *JAMA*. 267:1359-1363, 1992.

Hannig VL, Clayton EW, Edwards KM. Whose DNA is it anyway? Relationships between families and researchers. *American Journal of Medical Genetics*. 47:257-260, 1993.

Clayton EW. Removing the shadow of the law from the debate about genetic testing of children. *American Journal of Medical Genetics*. 57:630-634, 1995

Clayton EW, Hannig VL, Pfotenhauer JP, Parker RA, Campbell III PW, Phillips III JA. Teaching about cystic fibrosis carrier screening by using written and video information. *American Journal of Human Genetics*. 57: 171-181, 1995.

Clayton EW, Steinberg KK, Khoury MJ, et al. Informed consent for genetic research on stored tissue samples. *JAMA*. 274:1786-1792, 1995

Clayton EW, Hannig VL, Pfotenhauer JP, Parker RA, Campbell, III PW, Phillips, III JA. Lack of interest by nonpregnant couples in population based cystic fibrosis carrier screening. *American Journal of Human Genetics*. 58:617-627, 1996.

Clayton EW. Genetic testing in children. *Journal of Medicine and Philosophy*. 33:233-251, 1997.

Clayton EW. What should be the role of public health in newborn screening and prenatal diagnosis? *American Journal of Preventive Medicine*. 16:111-1115, 1999.

Clayton, EW. What should the law say about disclosure of genetic information to relatives? *Journal of Health Care Law & Policy*. 1:373-390, 1998.

Clayton EW. Genetics, public health, and the law. In: Khoury MJ, Burke W, Thomson E, eds.: *Genetics and Public Health in the 21st Century: Using Genetic Information to Improve Health and Prevent Disease*. 2000, pp. 489-504, 2000.

Clayton EW Genetics research: toward international guidelines. In: Levine RJ, Gorovitz S, Gallagher J, eds.: *Biomedical Research Ethics: Updating International Guidelines -- A Consultation*. Geneva: Council of International Organizations of Medical Sciences. 2000, pp. 152-169.

Clayton EW. Using newborn blood samples for genetics research: thinking about the context. *Annual Review of Law and Medicine*. 9:21-31, 2001.

Clayton EW. Through the lens of the sequence. *Genome Research*. 11:659-664, 2001.

Clayton EW. You have to protect physician reporters if you want to protect children from abuse and neglect. *Houston Journal of Health Law and Policy.* 1:133-146, 2001.

Clayton EW. Genetics, populations, and public health: a complex relationship. *Journal of Law, Medicine, and Ethics*. 30:290-297, 2002

Shapiro M, Spece R, Dresser R, Clayton EW. *Bioethics and Law*, 2d edit., St. Paul, MN: Thompson-West Publishing Co., 2002. 1495 pp.

Clayton EW. Genomic medicine in the real world. Ethical, legal, and social implications. *New England Journal of Medicine*. 349:562-569, 2003.

The International HapMap Consortium [includes Dr. Clayton]. The International HapMap Project. *Nature*. 426:789-796, 2003.

The International HapMap Consortium [includes Dr. Clayton]. Addressing ethical issues in the International HapMap Project. *Nature Reviews Genetics*. 5:467-475, 2004.

Clayton EW. Informed consent and biobanks. *Journal of Law, Medicine and Ethics* 33:15-21, 2005.

Clayton EW, The web of relations: Thinking about physicians and patients, *Yale Journal of Health Policy, Law, and Ethics* 2006; 6(2): 465-77

C. Research Support:

Ongoing:

R25 TW007697-01 (Heitman) 9/18/2006-6/30/2010
NIH/Fogarty
“Creating Collaborative Research Ethics Education with Costa Rica”
This series of interrelated educational and practical training activities, will 1) Create a cadre of Costa Rican leaders in biomedical research with in-depth knowledge and practical skills in both research design and the ethical conduct of clinical and epidemiologic research, through tailored masters programs for early-career investigators in clinical and public health science and mentored research in research ethics at VUMC; 2) Create a cadre of Costa Rican research ethics review directors with comprehensive practical knowledge of research ethics and skills in protocol review, administration of research ethics review committees, and instruction in research ethics, through a five-week Practicum in Research Ethics at VUMC; 3) Enhance the knowledge and practical skills of Costa Rican research ethics committee members and administrators regarding research ethics and protocol review, through a four-day Research Ethics Committee Members Course at the Hospital Nacional de Niños; 4) Increase the knowledge and practical skills of Costa Rican biomedical science educators in research ethics and the responsible conduct of research (RCR) to improve their teaching of new investigators, through a four-day Research Educators Course at the Hospital Nacional de Niños; and 5) Create, evaluate, and distribute curricular materials in Spanish on research ethics and RCR that are tailored to the Central American context and that can be further developed for local, regional, and multinational collaborative research, through an open-access website and professional publications and presentations.

6-FY05-85 (Clayton) 6/1/2005-5/31/2008
March of Dimes
“Impact of Newborn Screening on Families”
Interviewing parents whose children have received abnormal newborn screening results, we will assess the following hypotheses: Receiving abnormal screening results will affect levels of parental stress as well as their utilization of health care and early intervention services; 2.Referral to metabolic centers will improve parental responses to abnormal screening results; 3. Many parents will value learning in the newborn period about serious disorders that affect their children whether or not they can be effectively treated**.**

P01 HL 072058 (Loyd) 8/4/2003 - 7/31/2008
NIH/NHLBI
"Genetic and Environmental Pathogenesis of PPH "
This program project will utilize the unique resources of a database and specimen bank developed from 116 PPH families across the US. The target goals are to identify the modifying genes and environmental features that regulate the clinical expression of mutations in BMPR2; to develop understanding about how BMPR2 mutations result in disease; and to identify the undiscovered mutations which cause PPH. Dr. Clayton's role on this project is to understand how people at risk for the inherited form of this Primary Pulmonary Hypertension and their relatives understand and respond to their risk and the possibility of genetic testing and genetic counseling.

5 T32 HD 044328-02 (Strauss) 6/1/2003 - 4/30/2008
NIH/NICHD
NICHD Institution Training for Pediatricians
This training program in Pediatrics recruits well-qualified trainees into the program who are planning a career in clinical investigation in pediatrics. This program implements a strategy to encourage and support women and minority applicants and trainees, evaluates the success of the training program through both process and outcomes evaluation, and Implement continuous quality improvement procedures that will enhance the PPOR

components, curriculum, and overall program. Dr. Clayton's role on this program is teaching research ethics and mentoring trainees in their research.

Completed:

R03 HG 003031 (Clayton, Jay) 9/1/2004 - 8/31/2005
NIH/NHGRI
Genetics in Literature, Film, and Popular Culture
The grant funds a working group of scholars in literature, film, and media studies to examine the representation of genetics in literary and popular culture. Using research methods traditional to the humanities, and particularly, to literary studies, the working group will (1) identify and classify this body of literary and popular texts; (2) compose critical assessments of these works; (3) gauge the accuracy of their representations of genetics; (4) discuss the social and ethical issues they raise; and (5) trace the history and nature of their influences on public understandings of genetics. Dr. Clayton's role on this project is to contribute her knowledge of genetics and the social implications of genetics to these discussions and to incorporate the insights of this project into her own work.

R03 HG 002845 (Freund) 9/8/2003 - 8/31/2005
NIH/NHGRI
Clinical Use of Research Genetic Tests in Arrhythmia
The primary paradigms for this exploratory grant are Long QT and Brugada syndromes, which often present as sudden death, outcomes that can sometimes be averted by medical intervention. These disorders are genetically complex and as yet incompletely understood and so do not meet general criteria for clinical use. This study seeks to understand why clinicians nonetheless seek genetic testing for these disorders, and why investigators sometimes provide it. The results of this inquiry will provide insight into how likely it is that clinicians and researchers will adhere to the recommendations of bodies such as the SACGT and legal requirements such as CLIA, insights that could inform the regulatory approach.

R01 HG 001720 (Clayton) 9/1/2002 - 3/31/2005
NIH/NHGRI
University of California-San Francisco (Kwok-P-Y)
Characterization of SNP Markers
The specific aims of this project are to identify 100,000 candidate SNPs in dbSNP that have not been characterized and to estimate the allele frequencies of these SNPs in 3 populations using a comparative pooled DNA sequencing approach. We will deposit updated SNP information on a weekly basis to dbSNP. Even at out initial pace of characterization, 500 SNP markers in the public database will be updated each week and. As soon as our project gets under way, the community will have all the information necessary for choosing SNPs most suitable for their particular studies. Dr. Clayton as the co-Chair of the ELSI Working Group as well as a member of the Writing Working Group for this project, Dr. Clayton has a major role in shaping sample collection, in explicating ethical issues, and in presenting this project to diverse audiences.

R01 HL 048164 (Loyd) 3/1/1999 - 7/31/2003
NIH/NHLBI
"Pulmonary Hypertension: Mechanisms and Family Registry"
This project expanded the National FPPH Registry established in 1994 to track Familial Primary Pulmonary Hypertension, in order to obtain enough families to localize and clone the PPH gene. It also supported the DNA bank for these and further studies. Dr. Clayton's work on this project continues under the above P01, "Genetic and Environmental Pathogenesis of PPH."