OMB No. 0925-0001/0002 (Rev. 08/12 Approved Through 8/31/2015)

BIOGRAPHICAL SKETCH

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NAME: Amy L. McGuire

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

POSITION TITLE: Leon Jaworski Professor of Biomedical Ethics

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
University of Pennsylvania, Philadelphia, PA	B.A.	05/95	Psychology
University of Houston Law Center, Houston, TX	J.D.	05/00	Law
Institute for Medical Humanities, University of Texas Medical Branch, Galveston, TX	Ph.D.	12/04	Humanities/Ethics

A. Personal Statement

I have a long track record of conducting ELSI research using a range of qualitative, quantitative, legal, and mixed methods and experience leading large research groups as PI or Co-PI. My research focuses on legal and ethical issues in human genomics, and my group is currently working on projects related to research ethics in areas such as genomic data sharing and return of genetic research results, informed consent and governance in biobanking, and the psychosocial impact and policy challenges of the clinical integration of whole genome and whole exome sequencing. I presently serve on the Advisory Council for the National Human Genome Research Institute (NHGRI) and its Genomics and Society Working Group and have served as a member of several other national committees that explore ethical issues in genome research and its responsible integration into clinical practice, including: NIH 1000 Genomes Samples/ELSI Workgroup, NIH Electronic Medical Records in Genomics Network (eMERGE), Consent and Community Participation Workgroup, NIH Advisory Committee to the Director Working Group on Participant and Data Protection, and the X Prize in Genomics Ethics Advisory Board. I have contributed my expertise to the development of policies surrounding genomic data sharing, and have experience successfully leading a study that engages expert stakeholders to identify key policy challenges, and models for approaching them, in the next generation sequencing industry. I will draw on these skills and expertise, and will be fortunate to have these skills complemented by Dr. Cook-Deegan's background in medicine, science, and public policy, to ensure the success of this proposal.

B. Positions and Honors

Positions:

2004-2009	Assistant Professor, Center for Medical Ethics and Health Policy, Baylor College of Medicine (BCM), Houston, TX
2009-2012	Associate Professor, Center for Medical Ethics and Health Policy, BCM, Houston, TX
2009-2012	Associate Director of Research, Center for Medical Ethics and Health Policy, BCM, Houston, TX
2012-present	Professor, Center for Medical Ethics and Health Policy, BCM, Houston, TX
2012-present	Director, Center for Medical Ethics and Health Policy, BCM, Houston, TX

Honors:

1995	BA, *summa cum laude,* University of Pennsylvania
2000	JD, *summa cum laude,* University of Houston Law Center
2004	PhD, *with distinction,* Institute for the Medical Humanities, University of Texas Medical Branch
2008	Fulbright & Jaworski L.L.P. Faculty Excellence Award for Educational Leadership
2009	Fulbright & Jaworski L.L.P. Faculty Excellence Award for Teaching and Evaluation
2012	Leon Jaworski Professorship in Biomedical Ethics

Competitive Teaching Fellowships:

2001-2004	Medical Jurisprudence Fellowship, University of Texas Medical Branch (UTMB)
2005-2007	Educational Scholars Fellowship, Baylor College of Medicine (BCM)

Committees and Service Responsibilities:

2014-present	Association of Bioethics Program Directors, Vice President and President-elect
2012-present	Genomics and Society Working Group
2011-present	National Advisory Council for Human Genome Research, NIH-NHGRI, Member
2007-2011	NIH Electronic Medical Records in Genomics Network (eMERGE), ELSI Consent and Community Participation Workgroup, Coordinator: Ellen Wright Clayton (Vanderbilt University), Member, Data Sharing Focus Group, Chair
2008-2011	NIH 1000 Genomes Project, Samples/ELSI Workgroup, Member
2007-2009	NIH Advisory Committee to the Director (ACD), Working Group on Participant and Data Protection (PDP) for the Genetic Association Information Network (GAIN) and Genome-wide Association Studies (GWAS), Member
2007-2009	Personalized Health Care Working Group (PHC), American Health Information Community (AHIC), Office of the National Coordinator for Health Information Technology (ONC HIT), Secretary of the Department of Health and Human Services (DHHS), Member; Confidentiality, Privacy, and Security Sub-Committee, Co-Chair
2001-present	American Society for Bioethics and the Humanities, Member
2004-present	BCM Institutional Review Board, Member
2006-present	American Society for Human Genetics, Member
2006-present	X Prize Foundation, X Prize in Genomics, Ethics and Social Issues Advisory Board, Member

C. Contribution to Science

1. I was a co-investigator and ethics consultant on the first whole genome sequence and have written extensively on ethical issues arising in the field of genomics. My subsequent publications related to these ground breaking achievements in science identified and provided recommendations for the responsible management of ethical issues in genomic science, such as the return of research results, obligations to third-party relatives, and future use of genomic information. These publications have been critical to informing practical guidelines, for example for reporting genomic research results and reporting incidental findings in genomic medicine, both of which I helped co-author.
    a. Wheeler DA, Srinivasan M, Egholm M, Shen Y, Chen L, McGuire A, He W, Chen YJ, Makhijani V, Roth GT, Gomes X, Tartaro K, Niazi F, Turcotte CL, Irzyk GP, Lupski JR, Chinault C, Song XZ, Liu Y, Yuan Y, Nazareth L, Qin X, Muzny DM, Margulies M, Weinstock GM, Gibbs RA, Rothberg JM; The complete genome of an individual by massively parallel DNA sequencing. Nature, 452, 872-877, 2008. [PMID 18421352].
    b. McGuire AL, Caulfield T, Cho M. Research ethics and the challenge of whole genome sequencing. Nature Reviews Genetics 2008; 9: 152-156. PMCID: PMC2225443.
    c. McGuire AL, Cho MK, McGuire SE, Caulfield T. The future of personal genomics. *Science* 317, 2007: 1687.
    d. McGuire AL, Joffe S, Koenig BA, Biesecker BB, McCullough LB, Blumenthal-Barby JS, Caulfield T, Terry SF, Green RC. Ethics and Genomic Incidental Findings. Science 340, 2013: 1047-1048. PMCID: PMC3772710.

2. In addition to the contributions described above, along with my scientific collaborators, I brought to the forefront the issue of the uniquely identifiable nature of DNA data and the accompanying privacy concerns

this raises. Given this, and the desire to share genomic data amongst researchers, I was among the first to empirically study research participants' perspectives on sharing their genomic information with other researchers. As the primary investigator on a randomized controlled trial exploring this issue, we found that individuals differ in their desire to control how broadly they are willing to share their genomic information and emphasized the need to account for individual preferences to this end. This body of work also discussed the trade-offs individuals make when weighing the risks and benefits of ensuring privacy protection versus advancing research and suggested that participants' value transparency and openness when being consented for this type of research.

a. McGuire AL, Gibbs RA. No longer de-identified. Science. 2006; 312: 370-371. PMID 16627725.
b. McGuire AL, Oliver JM, Slashinski MJ, Graves JL, Wang T, Kelly PA, et al. To share or not to share: A randomized trial of consent for data sharing in genome research. Genet Med. 2011; 13(11): 948-955. PMCID: PMC3203320.
c. Burstein MD, Robinson JO, Hilsenbeck SG, McGuire AL, Lau CC. Pediatric Data Sharing in Genomic Research: Attitudes and Preferences of Parents. *Pediatrics*, 133(4), 2014: 690-697.
d. Gymrek M, McGuire AL, Golan D, Halperin E, Erlich Y. Identifying Personal Genomes by Surname Inference. *Science* 339, 2013: 321-324.

3. The Human Microbiome Project (HMP), funded by the NIH Common Fund beginning in 2008, set forth to characterize the microbial communities found on the human body and to look for correlations between changes in these microbial communities and human health. I served as a co-investigator in a project conducted during the first phase of the HMP, providing ethical oversight for the project and conducting an empirical study on HMP participants and scientists in order to understand their perspectives on what ethical or social issues were related to this type of research. From this research, we found that many of the ethical issues overlap with issues already identified in genomic research, such as return of research results, data sharing, and complexities in informed consent, and we proposed sound strategies to manage these issues in future research.

    a. McGuire AL, Colgrove J, Whitney SN, Diaz CM, Bustillos D, Versalovic J. Ethical, Legal, and Social Considerations in Conducting the Human Microbiome Project. Genome Research 18(12), 2008: 1861-1865. PMCID: PMC4024738.
    b. Gevers D, Knight R, Petrosino JF, Huang K, McGuire AL, Birren BW, Nelson KE, White O, Methe BA, Huttenhower C. The Human Microbiome Project: A Community Resource for the Healthy Human Microbiome. PLoS Biology 10(8), 2012:e1001377. PMCID: PMC3419203.
    c. McGuire AL, Achenbaum LS, Whitney SN, Slashinski MJ, Versalovic J, Keitel WA, McCurdy S. Perspectives on Human Microbiome Research Ethics. Journal of Empirical Research on Human Research Ethics. 7(3), 2012: 1-14. PMCID: PMC4065416.
    d. Slashinski MJ, Whitney SN, Achenbaum LS, Keitel WA, McCurdy SA, McGuire AL. Investigators' Perspectives on Translating Human Microbiome Research into Clinical Practice. *Public Health Genomics* 16, 2013: 127-133.

4. As genomic sequencing is rapidly being introduced into the clinical setting, a goal is to do so responsibly and with attention to the ethical, legal and social implications (ELSI). In 2010 the NIH launched a new initiative to develop the Clinical Sequencing Exploratory Research program to research the challenges of incorporating genomic sequence data into the routine practice of medicine in a variety of clinical settings. In 2013, the Newborn Sequencing in Genomic Medicine and Public Health (NSIGHT) program was launched to study the impact of sequencing newborns. I am Co-PI and co-investigator on two of the nine funded studies in the CSER program and Co-PI on one of the funded NSIGHT studies, specifically leading the ELSI component of these projects examining the psychosocial and ethical issues expected to arise from this research. I was also the inaugural co-chair of the Outcomes and Measures Working Group of the CSER Consortium and coordinated efforts across all 9 sites to harmonize measures to facilitate consortium-wide analyses. These projects are ongoing and to date have generated several publications related to the ethical issues of clinical integration of genomic sequencing.

    a. McGuire AL, Burke W. Raiding the Medical Commons: An Unwelcome Side Effect of Direct-to-Consumer Personal Genome Testing. *JAMA* 300(22), 2008: 2669-2671.

b. McGuire AL, McCullough LB, Evans JP. The Indispensable Role of Professional Judgment in Genomic Medicine. JAMA 309, 2013: 1465-1466. PMCID: PMC3760691.
c. Gray SW, Martins Y, Feuerman LZ, Bernhardt BA, Biesecker BB, Christensen KD, Joffe S, Rini C, Beenstra D, McGuire AL. Social and Behavioral Research in Genomic Sequencing: Approaches from the Clinical Sequencing Exploratory Research Consortium Outcomes and Measures Working Group. *Genetics in Medicine* 16(10) 2014: 727-735.
d. Green RC, Lautenbach D, McGuire AL. GINA, Genetic Discrimination, and Genomic Medicine. NEJM 2015: 372(5): 397-399. PMC in Process.

5. As the next generation sequencing (NGS) industry continues to grow, a challenge is to address policy concerns related to the clinical uptake of this technology. In this area, I serve as the primary investigator on a study exploring key policy challenges in the areas of regulation, reimbursement, intellectual property, and data sharing. These publications identify existing laws and guidelines that may be applicable to genomic research and medicine in order to discern where gaps in regulations and policies have arisen or may occur. This study has also led to the development of ethically appropriate recommendations for new approaches to these existing methods.

a. McGuire AL, Evans BJ, Caulfield T, Burke W. Regulating Direct-to-Consumer Personal Genome Testing. *Science* 330, 2010: 181-182.
b. Deverka PA, Kaufman D, McGuire AL. Overcoming the reimbursement barriers for clinical sequencing. *JAMA* 2014; 312(18): 1857-1858. PMC in Process.
c. Curnutte MA, Frumovitz KL, Bollinger JM, **McGuire AL**, Kaufman DJ. Development of the clinical next-generation sequencing industry in a shifting policy climate. *Nat Biotechnol*. 2014; 32(10): 980-982. PMC in Process.
d. Kaufman D, Curnutte M, **McGuire AL**. Clinical integration of next generation sequencing: A policy analysis. *J Law Med Ethics*. 2014; 42 Suppl 1: 5-8. PMC in Process.

Complete List of Published Work in MyBibliography:
http://www.ncbi.nlm.nih.gov/sites/myncbi/amy.mcguire.1/bibliography/40721086/public/?sort=date&direction=ascending

D. Research Support
Ongoing Research Support

U19 HD0077671 (Green, Beggs) 9/5/2013 – 8/31/2018
Genome sequence-based screening for newborn illness and childhood risk
The major goals of this study are to explore the implications, challenges, and opportunities associated with the use of genomic sequence information in the newborn period by generating high-quality whole exome sequencing data and returning the results of this data to research participants.
Role: Co-PI Project 3

R01 NR014792 (Aagaard-Tillery) 9/1/2013 – 8/31/2018
A Multi'omics Approach towards Deciphering the Influence of the Microbiome on Preterm Birth
The goal of this project is to describe a longitudinal case-cohort based approach to multi'omics studies of women at considerable risk of preterm birth, including metagenomic DNA sequencing, metatranscriptomics, and metabolomics of the oral, vaginal, placental and stool microbiome.
Role: Co-Investigator

R01 HG007063 (Phillips) 2/15/2013 – 12/31/2016
Evaluating Benefit-Risk Trade-offs for Clinical Use of Whole Genome Sequencing
The goals of this study are to develop and test an approach to examine how individuals and physicians make benefit-risk trade-off decisions about whole genome sequencing and the implications of these decisions in the healthcare system and society.
Role: Co-Investigator

R01 HG006460 (McGuire) 8/1/2012 – 7/31/2015
Clinical Integration of Whole Genome Sequencing: A Policy Analysis

The major goal of this study is to identify and prioritize the gaps in current regulatory structures that must be addressed in order to effectively integrate whole genome sequencing into clinical practice.

U54 HG006542 (Valle, Lupski) 12/05/2011-11/30/2015
Baylor-Johns Hopkins Center for Mendelian Genetics
The major goal of this collaborative project is to determine the molecular basis of human Mendelian phenotypes by establishing the Baylor-Hopkins Center for Mendelian Genomics (BHCMG).
Role: Co-Investigator

U01 HG006500 (Green) 12/05/2011-11/30/2015
Integration of Whole Genome Sequencing into Clinical Medicine
The major goal of this collaborative multi-disciplinary project is to accelerate the use of genomics in clinical medicine by creating and safely testing novel methods for integrating information from whole genome sequencing into physicians' care of patients.
Role: Co-PI Project 3

U01 HG006485 (Plon, Parsons) 12/05/2011-11/30/2015
Incorporation of Genomic Sequencing into Pediatric Cancer Care
The major goal of this Exploratory Clinical Sequencing Project is to study the integration of CLIA-certified germline and tumor exome sequencing information generated by whole genome sequencing into the care of childhood cancer patients with high-risk solid tumors and brain tumors at the Texas Children's Cancer Center.
Role: Co-Investigator

2U54 HG003273 (Gibbs) 11/1/2011-10/31/2015
The Human Genome Sequencing Center
The major goals of the Human Genome Sequencing Center at Baylor College of Medicine are to support a broad range of activities that address biomedical questions using high-throughput sequencing.
Role: Co-Investigator

Completed Research Support

R21 10822967 (Clayton) 09/23/2011-08/31/2014
Returning Research Results of Pediatric Genomic Research to Participants
Role: Co-Principal Investigator

UH3 DK083990-02 (Versalovic) 08/01/2010-08/31/2014
The Human Microbiome in Pediatric Abdominal Pain and Intestinal Inflammation
Role: Co-Investigator

Cancer Prevention and Research Institute of Texas (CPRIT) RP101353-P04 (Gibbs) 8/1/2010 – 1/31/2014
Tumor Banking for Genomic Research and Clinical Translation
Role: Co-Principal Investigator

NIH R01 HG004853 (McGuire) 07/01/2009-06/30/2013
Ethical, Legal, and Social Dimensions of Human Microbiome Research
Role: PI