BIOGRAPHICAL SKETCH

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NAME: Shawneequa Lauren Callier

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

POSITION TITLE: Associate Professor

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
Princeton University (Princeton, New Jersey, USA)	B.A.	05/2000	Politics
Monash University (Melbourne, Australia)	M.A.	10/2003	Bioethics
Georgetown University Law Center (Washington, DC, USA)	J.D.	06/2006	Law
Georgetown Law Center's International Women's Human Rights Clinic (Washington, DC, USA and Swaziland, Africa)			
Case Western Reserve University School of Medicine (Cleveland, Ohio, USA) (Postdoctoral Scholar)		06/2011	ELSI

A. Personal Statement

I am a lawyer and bioethics professor with extensive experience conducting legal analyses of US and international laws. I practiced health law at a large private law firm for three years before transitioning into academia. I taught a course on genetics and the law periodically as a professorial lecturer of law at the George Washington University Law School. In recent years, I published an analysis of research laws and guidelines that influence the use of racial and ethnic categories in precision medicine research. I also analyzed federal laws and research ethics guidelines to assess the ethical and legal implications of medical and pharmaceutical education programs that use direct-to-consumer genetic tests as educational tools. Earlier in my career, I analyzed the impact of federal evidence laws and litigation involving genetic tests and developed a training session on international laws governing specimens and data as a collaborator on the H3Africa funded project, "Administrative Supplement to Build Capacity of Research Ethics Committee Members in Africa." Currently, I am a co-investigator (U01 MH127693) in and steering committee member of an African consortium funded by the NIH Common Fund's Harnessing Data Science for Health Discovery and Innovation in Africa (DS-I Africa) program. My role on the DS-I Africa grant is to research global data science laws and their impact on equity in Nigeria. In addition, I work with interdisciplinary teams to assess barriers to diversity, equity, and inclusion in genomics (2R01HD090019) and polygenic score calculations (1R01HG012402-01) as a co-investigator and conduct empirical research and legal analyses related to community partnerships in genomics research (R01HG012841) as a co-principle investigator.

Over the past 18 years, I have remained committed to health equity through my work and training in the ethical, legal, and social implications (ELSI) of genomic research. I have explored emerging global ELSI issues through postdoctoral research funded by NIH at the Center for Genetic Research Ethics and Law (Case Western Reserve University); an appointment as a Special Volunteer at the Center for Research on Genomics and Global Health, NHGRI, NIH; and research collaborations with members of the Duke University Center on Genomics, Race, Identity, and Difference. As a Special Volunteer at NIH, I co-authored a paper (published in *Ethnicity and Disease*) that promoted diversity and inclusion in genomic research by outlining opportunities to overcome barriers that have impeded inclusion in genomic research on a global scale. Based on the value of

our analysis, my colleagues and I were recognized with a 2017 Genome Recognition of Employee Accomplishments and Talents (GREAT) Award from NHGRI. In 2019 and 2020, we went on to publish two reports on capacity building to conduct genomics research in Africa and evaluated the potential of projects led by African researchers to contribute to the understanding of global human population genomics. These studies were significant in that they showcased the advantages of research led by diverse African scientists. In 2021, we published the *Science* article "Complicated Legacies: The Human Genome at 20," in which we argued in favor of further investment in genomic research infrastructure in Africa. **I am eager to apply my legal, bioethics, and ELSI expertise to the proposed project by examining how institutional processes and infrastructures promote equitable and trustworthy partnerships and proposing concrete recommendations.**

1. Jones, K.M., Cook-Deegan, R., Rotimi, C.N., **Callier, S.L.**, Bentley, A.R., Stevens, H., Phillips, K.A., Jansen, J.P., Weyant, C.F., Roberts, D.E. and Zielinski, D. Complicated legacies: The human genome at 20. Science. 2021 Feb 5;371(6529):564-569. Epub 2021 Feb 4. PMID: 33542123.
2. Bentley, A. R., **Callier, S. L.**, & Rotimi, C. N. Evaluating the promise of inclusion of African ancestry populations in genomics. NPJ Genom Med. 2020 Feb 25;5:5. PMID: 32140257; PMCID: PMC7042246.
3. Bentley, A. R., **Callier, S.**, & Rotimi, C. The Emergence of Genomic Research in Africa and New Frameworks for Equity in Biomedical Research. Ethn Dis. 2019 Feb 21;29(Suppl 1):179-186. PMID: 30906167; PMCID: PMC6428180.
4. Bentley, A. R., **Callier, S.**, & Rotimi, C. N. Diversity and inclusion in genomic research: why the uneven progress? J Community Genet. 2017 Oct;8(4):255-266. Epub 2017 Jul 18. PMID: 28770442; PMCID: PMC5614884.

B. Positions, Scientific Appointments, and Honors

Positions and Employment

2011-Current Associate Professor, Department of Clinical Research and Leadership, The George Washington University (GW), School of Medicine and Health Sciences (Assistant Professor, 2011–2017; Director of Doctoral Research, Translational Health Sciences Ph.D. Program, 2017–2019), Washington, DC
2016-2018 Professorial Lecturer of Law, The GW University School of Law, Washington, DC
2014 & 2019 Visiting Researcher, Kennedy Institute of Ethics, Georgetown University, Washington, DC
2011-Current Special Volunteer, Center for Research on Genomics and Global Health, NHGRI, NIH, Bethesda, MD
2006-2009 Health Care Attorney, Mintz, Levin, Cohn, Ferris, Glovsky & Popeo, Washington, DC
2003 Intern, Nuffield Council on Bioethics, London, England
2002-2003 Fellow, World Health Organization, Geneva, Switzerland
2000-2002 Litigation Legal Assistant, Cravath, Swaine & Moore, New York, NY

Other Experience and Professional Memberships

2023-Current Member, Novel and Exceptional Technology and Research Advisory Committee, NIH
2021-Current Member, Genomics and Society Working Group, NHGRI, NIH
2018-2021 Convener, Genomics in the Public Square University Seminars
2008-Current Washington, DC Law License
2007-Current New York Law License

C. Contributions to Science

1. **Genomics and minoritized racial, ethnic, and ancestry groups: empirical and legal research**. I am leveraging my experiences and expertise to evaluate geneticists' use of race and ancestry in research, conduct empirical research on African American perspectives about genomics, and assess barriers to diversity and inclusion in genomics. In 2019, I co-facilitated key informant interviews with over 80 cardiologists, synthesized data, and co-authored the paper "Cardiologists' Perspectives on Race-Based Drug Labels and Prescribing within the Context of Treating Heart Failure." This project, led by Dr. Charmaine Royal (Duke University) and funded by the Greenwall Foundation, assessed

healthcare providers' beliefs and knowledge related to how race-based guidance affects the treatment of patients with heart failure. For this, we explored drug-prescribing practices related to BiDil and found that nearly half of all participants expressed skepticism or strongly disapproved of race-based drug labels yet still considered race when prescribing BiDil or its generic components. To advocate for guidelines that account for more nuanced factors than race in drug prescribing, I have presented this research at conferences and medical schools. On the heels of this research, I co-authored a manuscript with six colleagues at Howard University (funded by the Latham Foundation). Our investigation responded to a widely-reported narrative that African Americans are unwilling to participate in genomic research. Ultimately, we provided qualitative evidence of barriers and enablers that researchers and policymakers could use to foster engagement among this underrepresented group. Separately, I authored a paper on the use of racial categories in genomic research to demonstrate how federal biomedical research policies incentivize racial categories in genomic and precision medicine research. The publication was supported by an NIH-funded project (1R01HG008605) led by the principal investigators of a project entitled "LawSeq: Mapping and Shaping the Law of Genomics."

In recent years, I collaborated with members of the Broad Institute at Harvard and MIT to communicate ELSI in a "Frequently Asked Questions" web-based publication, referring to a recent pan-ancestry genetic analysis of the UK Biobank and a separate FAQ and publication on the Multi-Ancestry Meta-Analysis method. I look forward to continuing this type of work.

a. **Callier**, **S.L.** The Use of Racial Categories in Precision Medicine Research. Ethn Dis. 2019 Dec 12;29(Suppl 3):651-658. PMID: 31889770; PMCID: PMC6919973.
b. Rockcliffe, F., Olopoenia, O., Johnson, D., **Callier, S.** Attitudes and experiences regarding genetic research among persons of African descent. J Community Genet. 2020 Jan;11(1):65-72. PMID: 31062230; PMCID: PMC6962413.
c. **Callier**, **S.L.**, Cunningham, B.A., Powell, J., McDonald, M.A., Royal C.D.M. Cardiologists' Perspectives on Race-Based Drug Labels and Prescribing Within the Context of Treating Heart Failure. Health Equity. 2019 May 22;3(1):246-253. PMID: 31289785; PMCID: PMC6608680.

2. **Global genomics and research ethics: training programs in law and bioethics**. As part of an NIH-funded project (R25TW011505) led by my colleagues at the GW Milken Institute School of Public Health, I am helping to build the capacity of researchers in Mali to evaluate the ethics of genomics investigations and technologies. Through lectures, case studies, and group discussions, we evaluate international laws and guidelines and the ethics of different genomic research studies expanding in Mali and on the African continent. I was also a faculty member on an H3Africa-funded project (see personal statement above) that developed a training program for ethics committees reviewing genomic research projects in the West African region. The course I developed focused on biospecimens and data-sharing laws and governance strategies. In 2021, I became a funded co-investigator on the NIH/OD project, "Bridging Gaps in the ELSI of Data Science Health Research in Nigeria (BridgELSI)" awarded to the Center for Bioethics and Research, Ibadan, Nigeria (U01 MH127693). **I am analyzing African and global guidelines, policies, agreements, laws, and customary practices in collaboration with African law professors, and engaging with the team in empirical research to co-develop a framework for ethical data science research in Nigeria.**

   a. Training Course on Review of Genomics Research for Ethics Committee Members in Africa, available on the Center for Bioethics and Research website.

3. **Machine learning, artificial intelligence, data protection and discrimination at local and global levels: bioethics, law, and policy**. My recent scholarship explores data science, artificial intelligence, and machine learning. Recently, I co-authored an article published in *Science* describing how artificial intelligence is set to exacerbate exclusion cycles in medicine. As an invited co-author, I contributed my bioethics, legal, and policy expertise to evaluate whether unregulated mobile health research practices and algorithms disproportionately harm under-represented minorities. The NIH-funded working group (5R01CA207538-02) published a series of articles in the *Journal of Law, Medicine, and Ethics* that outlined the difficult policy challenges of promoting the welfare and interests of research participants

alongside innovation, especially in the absence of regulatory requirements. Prior to that, I served as a member of the steering committee for a working group (Building a Consumer Privacy Framework for Health Data) to address gaps in legal protections for commercial health data, a project that was co-funded by the Robert Wood Johnson Foundation, eHealth Initiative and Foundation, and the Center for Democracy and Technology. In 2013, I worked with a bioethics colleague and long-term collaborator to write a response to the Nuffield Council on Bioethics' request for comments on the project, "Biological and Health Data — The Collection, Linking, Use and Exploitation of Biological and Health Data: Ethical Issues." Ultimately, we argued in favor of using new methods to convey the identifiability of genetic samples to the public (e.g., a scoring system). In this submission and a subsequent peer-reviewed publication, we proposed that terms such as 'anonymized,' 'anonymous' or 'non-identifiable' should be removed from policies and laws governing research samples, especially those aimed at the public. Briefly here, those terms fail to acknowledge the significant challenges of maintaining the anonymity of samples and data in large, shared datasets that increasingly contain rich details about participants. Earlier in my career, in response to an effort by a university to collect employees' DNA samples after the passage of the Genetic Information Nondiscrimination Act, I co-authored an ethical and legal analysis of the university's proposal under GINA. We concluded that the university's actions were illegal.

a. Bracic A., **Callier S.L.**, Price W.N. 2nd. Exclusion cycles: Reinforcing disparities in medicine. Science. 2022 Sep 9;377(6611):1158-1160. Epub 2022 Sep 8. PMID: 36074837.
b. **Callier, S.**, Fullerton, S.M., Diversity and Inclusion in Unregulated mHealth Research: Addressing the Risks. J Law Med Ethics. 2020 Mar;48(1_suppl):115-121. doi: 10.1177/1073110520917036. PMID: 32342751.
c. Schmidt, H., **Callier, S.** How anonymous is 'anonymous'? Some suggestions towards a coherent universal coding system for genetic samples. J Med Ethics. 2012 May;38(5):304-9. PMID: 22345546.
d. **Callier, S.L.**, Huss J., Juengst, E.T. GINA and preemployment criminal background checks. Hastings Cent Rep. 2010 Jan-Feb;40(1):15-9. doi: 10.1353/hcr.0.0219. PMID: 20169652; PMCID: PMC3380532.

4. **Research on precision medicine and polygenic scores: bioethics, law, and policy**. Since 2016, I have continued to investigate the ELSI of personalized and precision medicine. In 2016, as a co-investigator on an NIH-funded project (R01 PA-08–012), I led a literature review of the ELSI of comparative effectiveness research on personalized genomic medicine (PGM). We found that further analyses and efforts were required to determine how ELSI scholarship can serve the increasingly global, interdisciplinary, and diverse PGM research community. Among my publications, I explored the opportunities and challenges of moving beyond the use of race as a proxy for genetic information in medical research (co-authored for the *New England Journal of Medicine*). My colleagues and I argued that precision medicine might revolutionize our understanding of race and its utility (or lack thereof) in clinical practice. The article has been referenced in a growing number publications, contributing to the debate about race in medicine. I have also served as a member of a working group, "Wrestling with Social and Behavioral Genomics: Risks, Potential Benefits, and Ethical Responsibility," that explored the ethics of polygenic scores. Our objective was to develop advice for various stakeholders about conducting research and disseminating results to minimize harms and maximize benefits. The working group was co-funded by the Robert Wood Johnson Foundation, Russell Sage Foundation, and JPB Foundation (PIs: Erik Parens and Michelle Meyer). Finally, as co-investigator on an R01 funded project, Beyond the Medical: The ELSI of Polygenic Scores for Social Traits (1R01HG012402-01), I am examining the legal implications of our empirical research examining perspectives on behavioral polygenic scores among biobank participants (PIs Anya Prince and Jean Cadigan).

a. Sabatello, M., **Callier, S.**, Garrison, N.A., Cohn, E.G. Trust, Precision Medicine Research, and Equitable Participation of Underserved Populations. Am J Bioeth. 2018 Apr;18(4):34-36. PMID: 29621444; PMCID: PMC5890957.
b. **Callier, S.L.**, Abudu R, Mehlman M.J., Singer, M.E., Neuhauser, D., Caga-Anan, C., Wiesner G.L. Ethical, Legal, and Social Implications of Personalized Genomic Medicine Research: Current Literature and Suggestions for the Future. Bioethics. 2016

Nov;30(9):698-705. PMID: 27767224.

c. Bonham, V.L., **Callier, S.L.**, Royal C.D. Will Precision Medicine Move Us beyond Race? N Engl J Med. 2016 May 26;374(21):2003-5. PMID: 27223144; PMCID: PMC5621043.

5. **Consumer genomics: bioethics, law, and policy**. In 2012, as a postdoctoral scholar at the Center for Genetic Research Ethics and Law, I examined the use of direct-to-consumer genetic testing technologies by undergraduate and graduate students to assess the ELSI of genetic testing in educational settings. At the time, universities began announcing the use of commercial genetic testing services as pedagogical tools for students to provide experiential learning about commercial genomics, pharmacogenomics, and other emerging genomics uses and tools. Not only did I find that universities often blurred the distinctions between medicine, education, and research, I was one of the first ELSI scholars to analyze educational DNA testing programs and publish my work in the *American Journal of Bioethics*. Building upon this work, in 2016, I collaborated with GW faculty to publish research on whether personal *CYP2D6* testing in the classroom could advance students' understanding of pharmacogenomics. We found that personal *CYP2D6* testing improves both knowledge and comfort with pharmacogenomics among students. Subsequently, our article was cited in numerous papers about pharmacogenomics education in student and community environments. In 2019, I was invited to participate in a roundtable discussion on race, ancestry, and consumer genomics (at the National Academies of Sciences, Engineering, and Medicine). Essentially, I argued that consumer genomics provides an entry point for African American genetic genealogists to consider medical genomics and that positive or negative experiences could impact their beliefs and attitudes about genomics more generally. Tied to this, I also concluded that commercial genomics technologies have the power to bolster or undermine efforts to increase African American participation in medical genomics education and research activities.

    a. National Academies of Sciences, Engineering, and Medicine; Health and Medicine Division; Board on Health Sciences Policy; Roundtable on Genomics and Precision Health. Exploring the Current Landscape of Consumer Genomics: Proceedings of a Workshop. Beachy, S.H., Alper, J., Addie S., Hackmann, M., editors. Washington (DC): National Academies Press (US); 2020 Mar 19. PMID: 32721146, Available at https://www.ncbi.nlm.nih.gov/books/NBK559862/
    b. O'Brien, T.J, LeLacheur, S., Ward, C., Lee, N.H., **Callier, S.**, Harralson, A.F. Impact of a personal CYP2D6 testing workshop on physician assistant student attitudes toward pharmacogenetics. Pharmacogenomics. 2016 Mar;17(4):341-52. PMID: 26907849.
    c. **Callier, S.L.** Swabbing students: Should universities be allowed to facilitate educational DNA testing? Am J Bioeth. 2012;12(4):32-40. PMID: 22452475; PMCID: PMC3390747.