CURRICULUM VITAE

Catherine M. Hammack, MA, JD
Center for Biomedical Ethics and Society
Vanderbilt University Medical Center
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EDUCATION

University of Southern Mississippi — Hattiesburg, MS
Bachelor of Science, *Psychology, Religion* — 2005 - 2009

Wake Forest University School of Law — Winston Salem, NC
Doctor of Jurisprudence — 2011 - 2014

Wake Forest University Graduate School of Arts and Sciences — Winston Salem, NC
Master of Arts, *Bioethics* — 2012 - 2014

Thesis: *The Law and Ethics of Using the Dead in Research*
Nancy M. P. King, Christine N. Coughlin, Tanya Marsh

ACADEMIC APPOINTMENT

Associate in Health Policy — 2017 -
Center for Biomedical Ethics and Society — Nashville, TN
Department of Health Policy
Vanderbilt University Medical Center

PROFESSIONAL EXPERIENCE

Research Assistant — 2005 - 2009
Clinical Psychology Laboratory, University of Southern Mississippi — Hattiesburg, MS

Research Assistant — 2007 - 2009
Behavioral Neuroscience Laboratory, University of Southern Mississippi — Hattiesburg, MS

Research Assistant, *Nancy M.P. King, JD* — 2014
Center for Bioethics, Health, and Society, Wake Forest University — Winston Salem, NC

Research Assistant, *Suzanne Reynolds, JD, Dean of School of Law* — 2012 - 2013
Wake Forest University School of Law, Wake Forest University — Winston Salem, NC

Qualitative Research Consultant — 2016
College Foundation of North Carolina, Inc. — Raleigh, NC

Social Scientist — 2015 - 2017
Program for Empirical Bioethics, Duke Clinical Research Institute — Durham, NC

PROFESSIONAL ACTIVITIES

Awards, honors:

Outstanding Senior in Psychology Award — 2008
University of Southern Mississippi

Merit-Based Scholarship Award — 2011 - 2014
Wake Forest University School of Law

Bioethics Scholarship Award — 2014
Wake Forest University Graduate School of Arts and Sciences

CALI Excellence for the Future Award — 2012
Business Drafting
Wake Forest University School of Law

CALI Excellence for the Future Award — 2013
Health Law and Policy
Wake Forest University School of Law

CALI Excellence for the Future Award — 2013
Secured Transactions
Wake Forest University School of Law

CALI Excellence for the Future Award — 2014
Health-Related Research: Law, Regulation, and Policy
Wake Forest University School of Law

CALI Excellence for the Future Award — 2014
Dispute Resolution
Wake Forest University School of Law

Outstanding Thesis Award — 2014
The Law and Ethics of Using the Dead in Research
Wake Forest University Graduate School of Arts and Sciences

OUT Role Model — 2017
Program for LGBTQ Health, Vanderbilt University Medical Center

Organizations and participation (*selected*)**:**

Psi Chi National Honor Society in Psychology — 2007 - 2008
University of Southern Mississippi Chapter
President (2008), *Vice President* (2007)

Golden Key International Honour Society — 2008 - 2009
Member

Society for Neuroscience — 2008 - 2009
Member

American Psychological-Law Society — 2009
Member

Student Health Law Association — 2013 - 2014
Wake Forest University School of Law
Member

American Society for Bioethics and Humanities — 2015 -
Member

LGBTQ Employee Resource Group — 2018 -
Vanderbilt University Medical Center
Member

American Society for Bioethics & Humanities Annual Conference — 2019
Review Committee, Research Ethics
Competitively-selected member

All of Us Research Program's Ethical, Legal, and Social Implications (ELSI) Priorities Workshop — June 2019, Rockville, MD
Invited New Investigator (nominated and competitively selected)

Ad hoc reviewer:

Genetics in Medicine

Journal of Medical Ethics

Ethics & Human Research (previously IRB)

Journal of Law, Medicine and Ethics (JLME)

Journal of Empirical Research on Human Research Ethics (JERHRE)

American Journal of Bioethics (AJOB): Empirical Bioethics

Other professional service:

Expert reviewer — 2019
Vanderbilt Institute for Clinical and Translational Research (VICTR) Hypothesis Generation Studio
Learning Healthcare System: End of Life Immersion Courses – Assessing Impact on Managing Difficult Conversations with Seriously Ill Persons, Miller, Bonnie (PI)

Expert reviewer — 2019
Vanderbilt Institute for Clinical and Translational Research (VICTR) Research Design Studio
Maternal Perceived Role in Decision Making after Fetal Diagnosis of Complex Structural Cardiac Disease, Harris, Kelly (PI)

Research design consultation — 2019
Maternal Perceived Role in Decision Making after Fetal Diagnosis of Complex Structural Cardiac Disease, Harris, Kelly (PI)

Expert reviewer — 2018
Vanderbilt Institute for Clinical and Translational Research (VICTR) Grant Review Studio
Emotion Regulation in the Courts, Maroney, Terry (PI)

Research design consultation — 2018 -
Factors Influencing Re-enrollment in an Employer Based Community Supported Agriculture Program, Meador, Keith (PI)

Research design consultation — 2018 -
Impact of a Community Supported Agriculture (CSA) Dietary Intervention on Dietary Markers,
Lo, Claire (Student; Supervisor: Rexer, Brent)

TEACHING ACTIVITIES

Undergraduate level:

Statistics for the Behavioral Sciences (PSY 360) — 2007
University of Southern Mississippi Athletic Department — Hattiesburg, MS
Instructor of supplemental education

General Psychology (PSY 110) — 2007
University of Southern Mississippi Athletic Department — Hattiesburg, MS
Instructor of supplemental education

General Psychology Lab (PSY 110L) — 2009
University of Southern Mississippi, Department of Psychology — Hattiesburg, MS
Co-instructor

Death and Dying in America (MHS 3150) — Spring 2018 -
Vanderbilt University — Nashville, TN
Invited lecturer: Law and Ethics of Cadaver Research

Graduate level:

Research Ethics and Scientific Integrity (MSCI 5029) — Fall 2019 -
Master of Science in Clinical Investigation Program — Nashville, TN
Vanderbilt University School of Medicine

PUBLICATIONS AND PRESENTATIONS

Articles in refereed journals:

1. **Catherine M. Hammack**, Pearl P. O'Rourke, Kathleen M. Brelsford, & Laura M. Beskow, *Expert Views on Oversight for Unregulated mHealth Research*, Journal of Law, Medicine and Ethics (forthcoming, March 2020).

2. **Catherine M. Hammack**, Kathleen M. Brelsford, & Laura M. Beskow, *Expert Views on Disclosures and Permissions for Unregulated mHealth Research*, Journal of Law, Medicine and Ethics (forthcoming, March 2020).

3. **Catherine M. Hammack**, Kathleen M. Brelsford, & Laura M. Beskow, *Expert Views on Data Access and Dissemination in Unregulated mHealth Research*, Journal of Law, Medicine and Ethics (forthcoming, March 2020).

4. Mark Rothstein, John Wilbanks, Laura M. Beskow, Kathleen M. Brelsford, Kyle Brothers, Megan Doerr, **Catherine M. Hammack**, Michelle McGowan, & Stacey Tovino, *Recommendations for the Ethical Conduct of Unregulated mHealth Research*, Journal of Law, Medicine and Ethics (forthcoming, March 2020).

5. Kathleen M. Brelsford, Ernesto Ruiz, **Catherine M. Hammack**, & Laura M. Beskow, *Developing Spanish-Language Biobank Consent Materials: Using Cognitive Interviews to Improve Translation and Cultural Appropriateness*, Ethics and Human Research (in press).

6. **Catherine M. Hammack**, Kathleen M. Brelsford, & Laura M. Beskow, *Thought Leader Perspectives on Participant Protections in Precision Medicine Research*, 47 Journal of Law, Medicine and Ethics, 134-48 (2019).

7. **Catherine M. Hammack**, Invited Commentary, *Ethical Use of Social Media Data: Beyond the Clinical Context*, 49 Hastings Center Report 1, 40-2 (2019).

8. Laura M. Beskow, Kathleen M. Brelsford, & **Catherine M. Hammack**, *Patient Perspectives on Use of Electronic Health Records for Research Recruitment*, 19 BMC Medical Research Methodology 1, 42-55 (2019).

9. Laura M. Beskow, **Catherine M. Hammack**, & Kathleen M. Brelsford, *Thought Leader Perspectives on Benefits and Harms in Precision Medicine Research*, 13 PLoS One 11 (2018).

10. David J. Echevarria, **Catherine M. Hammack,** Drew W. Pratt, & John David Hosemann, *A Novel Behavioral Test Battery to Assess Global Drug Effects Using the Zebrafish*, 21 International Journal of Comparative Psychology 1, 19-34 (2008).

11. David J. Echevarria, **Catherine M. Hammack,** D.J. Jouandot, & Christina N. Toms, *Does Acute Alcohol Exposure Modulate Aggressive Behaviors in the Zebrafish (Danio Rerio), or is the Bark Worse than the Bite?*, 23 International Journal of Comparative Psychology 1, 62-69 (2010).

Book chapters:

1. **Catherine M. Hammack**, *Research on the Newly Dead, in* Oxford Handbook of Research Ethics (Ana Iltis & Douglas Mackay eds., Oxford University Press) (forthcoming, 2021).
2. Laura M. Beskow, **Catherine M. Hammack**, Kathleen M. Brelsford, & Kevin McKenna, *Thought Leader Perspectives on Risks in Precision Medicine Research, in* Big Data, Health Law, and Bioethics 161-74 (Glenn Cohen, Holly Lynch, & Effy Vayena eds., Cambridge University Press, 2018).

Submitted, under review:

1. **Catherine M. Hammack**, Kathleen M. Brelsford, Kevin C. McKenna, Ross D. Graham, Zachary M. Lampron, & Laura M. Beskow, *Research Use of Electronic Health Records: Patients' Views on Alternative Approaches to Permission* (submitted; under review).

2. Margaret B. Mitchell, **Catherine M. Hammack**, Ellen W. Clayton, & Alexander Langerman, *Overlapping Surgery Policies and "Critical Portion" Definitions at Top U.S. Hospitals* (submitted; under review).

3. Kathleen M. Brelsford, **Catherine M. Hammack**, Ross D. Graham, Kevin C. McKenna, & Laura M. Beskow, *Research Use of Electronic Health Records: Patients' Willingness to Share Information* (submitted; under review).

In process:

1. **Catherine M. Hammack**, Kathleen M. Brelsford, & Laura M. Beskow, Thought Leader Comparisons of Risks in Precision Medicine Research (in process).

2. Laura M. Beskow & **Catherine M. Hammack**, *Development of Model Consent Language for Precision Medicine Research* (in process).

3. Laura M. Beskow, **Catherine M. Hammack**, & Kathleen M. Brelsford, *Prospective Participants' Perceptions of Model Consent Language for Precision Medicine Research* (in process).

4. Laura M. Beskow & **Catherine M. Hammack**, *Non-Traditional Approaches to Informed Consent for Precision Medicine Research: Thought Leader Perspectives* (in process).

5. Leslie E. Wolf, **Catherine M. Hammack**, Erin Fuse Brown, Kathleen M. Brelsford, & Laura M. Beskow, *The Strengths and Limitations of the 'Web' of Protections in Precision Medicine Research* (in process).

6. Kathleen M. Brelsford, **Catherine M. Hammack**, Kemberlee R. Bonnet, & Laura M. Beskow, *Research Use of Electronic Health Records: Researcher, IRB, and Provider Perspectives* (in process).

7. Kathleen M. Brelsford, **Catherine M. Hammack**, Zachary M. Lampron, Kevin C. McKenna, & Laura M. Beskow, *Community Perspectives on Research Use of Electronic Health Records* (in process).

Presentations, workshops (Π indicates presenter)**:**

1. **Catherine M. Hammack**[Π], Kathleen M. Brelsford, & Laura M. Beskow, *EHR Discrepancies: Key Stakeholders' Perspectives on Researchers' Obligations.* American Society for Bioethics and Humanities Annual Conference. Pittsburgh, PA (Oct. 2019). Competitively-selected presentation.

2. **Catherine M. Hammack**[Π], Kathleen M. Brelsford, & Laura M. Beskow, *mHealth Research and Citizen Science: Navigating ELSI Issues in Unregulated Health Research Using Mobile Devices.* American Society for Bioethics and Humanities Annual Conference. Anaheim, CA (Oct. 2018). Competitively-selected presentation.

3. **Catherine M. Hammack**[Π], Kevin McKenna, Kathleen M. Brelsford[Π], & Laura M. Beskow, *Communicating Risks and Protections in the Digital Age: Thought-leader Perspectives on Informed Consent*. Quorum IRB and the Northwest Association for Biomedical Research (NWABR), Ethics and the Digital Age Conference. Seattle, WA (July, 2016). Invited speaker.

4. Laura M. Beskow, Leslie E. Wolf[Π], Erin Fuse Brown[Π], **Catherine M. Hammack**[Π], & Kathleen M. Brelsford, *Risks, Harms, and Legal Protections in Large-Scale Gene-Environment Interaction Studies*. The 4th ELSI Congress: Expanding the ELSI Universe. Farmington, CT (June, 2017). Competitively-selected workshop.

5. **Catherine M. Hammack**[Π], Kevin McKenna, Kathleen M. Brelsford, & Laura M. Beskow, *Identifying and Communicating Risks in Gene Environment Interaction Research: Thought-leader Perspectives on Informed Consent*. International Congress on Personalized Health Care. Montréal, Quebec**,** Canada (June, 2016). Competitively-selected presentation.

6. **Catherine M. Hammack**[Π], Kevin McKenna, Kathleen M. Brelsford, & Laura M. Beskow, *Thought Leader Perspectives on Risks and Protections in Precision Medicine Research*. The Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School, Big Data, Health Law, and Bioethics. Cambridge, MA (May, 2016). Competitively-selected presentation.

7. **Catherine M. Hammack**[Π]**,** D.J. Jouandot, Christina N. Toms, & David J. Echevarria[Π], *Does Acute Alcohol Exposure Disrupt Zebrafish Shoaling by Increasing Aggressive Behaviors?*. Society for Neuroscience Annual Meeting. Washington, D.C. (Nov., 2009). Competitively-selected presentation.

8. **Catherine M. Hammack**[Π] & David K. Marcus, *Somatization, Health-anxiety, and the Two-factor Model of Psychopathy*, American Psychological-Law Society Annual Meeting. San Antonio, TX. (March, 2009). Competitively-selected presentation.

9. David J. Echevarria[Π], **Catherine M. Hammack**[Π]**,** Andrew J. Wooton[Π], Amanda M. Welch, & Mary P. Rosenblatt, *The Effects of Varying Doses of Ethanol on Shoaling Behavior in the Zebrafish (Danio Rerio)*, Society for Neuroscience Annual Meeting. Washington, D.C. (Nov., 2008). Competitively-selected presentation.

10. **Catherine M. Hammack**[Π]**,** John David Hosemann, Drew W. Pratt[Π], & David J. Echevarria[Π], *The Effects of MK-801, SKF 38393, and Ethanol on Shoaling Behaviors in the Zebrafish (Danio Rerio)*. Society for Neuroscience Annual Meeting. Washington, D.C. (Nov., 2008). Competitively-selected presentation.

11. Katie T. Payne[Π], David K. Marcus, Toni Merkey, **Catherine M. Hammack,** & Paul Saputo, *Group Psychotherapy for Older Adults: A Meta-analysis*. American Psychological Association Annual Meeting. Boston, MA (Aug., 2008). Competitively-selected presentation.

12. Drew W. Pratt[Π], **Catherine M. Hammack[Π],** John David Hosemann[Π], Tia Egglestone, & David J. Echevarria[Π], *Developing New Animal Models Using the Zebrafish (Danio Rerio)*. Society for Neuroscience Annual Meeting. San Diego, CA (Nov., 2007). Competitively-selected presentation.

13. David K. Marcus, Katie T. Hughes[Π], Paul Saputo, **Catherine M. Hammack,** Timothy B. Robbins, Toni Merkey, & Randy C. Arnau, *Rumination and Health Anxiety.* American Psychological Association Annual Meeting. San Francisco, CA (Aug., 2007). Competitively-selected presentation.

Other reports, publications, and media:

1. **Catherine M. Hammack**, *The Law and Ethics of Using the Dead in Research* (MA Bioethics thesis, Wake Forest University Graduate School) (on file with the Wake Forest University Z. Smith Reynolds Library) (Dec., 2014).

2. **Catherine M. Hammack**, *Vandalism or Voodoo?: The Mausoleum of Marie Laveau*, The Funeral Law Blog (April 27, 2014).

3. **Catherine M. Hammack**, *Paying Your (Dis)Respects: Memorials That Offend*, The Funeral Law Blog (April 2, 2014).

4. **Catherine M. Hammack**, *Who is Bredo Morstoel?: Colorado's Coolest Grandpa*, The Funeral Law Blog (March 23, 2014).

5. **Catherine M. Hammack**, *Practice Makes Problems: Practicing Medical Procedures on the "Newly-Dead"*, The Funeral Law Blog (March 13, 2014).

6. **Catherine M. Hammack**, *Secrets of the Dead: To Tell or Not to Tell?*, The Funeral Law Blog (Feb. 21, 2014).

Non-authored publications (selected examples of formal acknowledgement in publication)**:**

1. Leslie E. Wolf *et al.*, *The Web of Protections for Participants in Large-Scale Genomic Research*, 29 Health Matrix: Journal of Law-Medicine 1 (2019).

2. Kathleen M. Brelsford, Ernesto Ruiz, & Laura M. Beskow, *Developing Informed Consent Materials for Non-English-Speaking Participants: An Analysis of Four Professional Firm Translations from English to Spanish*, 15 Clinical Trials 6, 557-66 (2018).

3. Kathleen M. Brelsford, Susan E. Spratt, & Laura M. Beskow, *Research Use of Electronic Health Records: Patients' Perspectives on Contact by Researchers*, 25 Journal of the American Medical Informatics Association 9, 1122-9 (2018).

4. Nancy M. P. King, *The Reasonable Patient and the Healer*, 50 Wake Forest Law Review 343 (2015).

5. Suzanne Reynolds & Ralph Peeples, *When Petitioners Seek Custody in Domestic Violence Court and Why We Should Take Them Seriously*, 47 Wake Forest Law Review 5 (2012).

6. David K. Marcus, Kathleen T. Hughes, & Randolph C. Arnau, *Health Anxiety, Rumination, and Negative Affect: A Mediational Analysis*, 64 Journal of Psychosomatic Research 5, 495-501 (2008).

7. Kathleen T. Payne & David K. Marcus, *The Efficacy of Group Psychotherapy for Older Adult Clients: A Meta-Analysis*, 12 Group Dynamics: Theory, Research, and Practice 4, 268-78 (2008).

RESEARCH SUPPORT

Amount is approximate total award amount (directs and indirects) for all years; Duration does not include no-cost extensions

Ongoing:

Surgery for Cancer With Option of Palliative Care Expert (SCOPE) Trial

National Institute On Aging (R03-AG-060085)

Shinall, Ricky (Vanderbilt University)

2018 - 2023

Objective: To compare two types of care -usual surgery and cancer care and usual surgery and cancer care with comprehensive palliative care services to see which is better for improving the experience of patients and families with cancer.

Role: Investigator; Currently collaborating in the development of the Aim 3 semi-structured interview guide, and will conduct interviews with a subset of approximately 64 patients within the SCOPE Trial and assist in the coding and analysis of qualitative interview data.

10-year Comparative Effectiveness and Harms of Treatments for Prostate Cancer

National Cancer Institute (R01-CA-230352)

Barocas, Daniel (Vanderbilt University)

2019 - 2022

Objective: To expand upon an established population-based cohort of men diagnosed with localized prostate cancer by collecting 10-year clinical and patient-reported information that will enable comparisons of oncologic and quality of life outcomes among the treatment options.

Role: Investigator; I am collaborating in the development of interview instruments and will conduct half of all qualitative interviews, serve as secondary coder of data, and collaborate in the analysis of interview data.

Regulation of International Direct-to-Participant Genomic Research

National Human Genome Research Institute (NHGRI) (R01-HG-009914-01)

Rothstein, Mark (University of Louisville); Knoppers, Bartha (McGill University)

2018 - 2021

Objective: To investigate whether international direct-to-participant genomic research is lawful in a sample of 32 countries and what is necessary to facilitate such research while still protecting research participants.

Role: Investigator; I have collaborated in leading the aggregation and synthesis of the initial set of generated ideas from expert stakeholders, instrument design and development, designing several nominal group technique workshops with experts, and developing and fielding a survey of legal experts in 32 countries.

***All of Us* Research Program Participant Engagement Core**

Office of The Director, National Institutes of Health (5-U2C-OD023196-02)

Denny, Joshua (Vanderbilt University)

2016 - 2021

Objective: To facilitate meaningful involvement of diverse participant communities in governance and oversight of the *All of Us* Research Program.

Role: Investigator; I hold a key role in developing instruments and materials to assist in policy guidance and participant outreach. I work closely with other Engagement Core members in the development and simplification of respectful and culturally-sensitive materials as well as other resources and information for *All of Us* Program leaders, participants, and researchers in order to support meaningful engagement and effective communication. I collaborate in developing methods to elicit participant representative perspectives on a range of issues, including the development of interview guides, questionnaires, assessments, and evaluations.

Addressing ELSI Issues in Unregulated Health Research Using Mobile Devices

National Cancer Institute (R01-CA-207538-02)

Rothstein, Mark (University of Louisville); Wilbanks, John (Sage Bionetworks)

2017 - 2020

Objective: To systematically investigate ELSI issues in unregulated research to develop policies on external oversight of research, recruitment and inducements, inclusion and exclusion criteria, informed consent, confidentiality and security, vulnerable populations, return of incidental findings, publication, and data sharing.

Role: Investigator; I collaborated in the development of an in-depth, semi-structured interview guide to assess national thought leaders' perspectives on unregulated mHealth research. I led coordination, recruitment, and data management activities and conducted half of all interviews. I am currently leading the in-depth analysis of interview data and collaborating in the development of policy recommendations.

The Genetic Privacy and Identity in Community Settings (GetPreCiSe) NIH Center of Excellence in Ethics Research

National Human Genome Research Institute (NHGRI) (RM1-HG-009034)

Clayton, Ellen (Vanderbilt University); Malin, Brad (Vanderbilt University)

2016 - 2020

Objective: To use broadly interdisciplinary approaches to develop a more complete understanding of concerns about privacy and identity, which when used to inform modeling, will allow development of evidence-based methods to allay concerns, thereby facilitating the use of genomics to improve health.

Role: Investigator; Currently collaborating in the development of educational materials and data collection instruments for focus groups. I will assist in facilitating focus groups, contribute to the coding and analysis of focus group data, and collaborate in dissemination of results.

VGER, the Vanderbilt Genome-Electronic Records Project

National Human Genome Research Institute (NHGRI) (U01-HG-008672)

Roden, Dan (Vanderbilt University)

2018 - 2019

Objective: To expand the impact of genomic medicine by leveraging the eMERGE network to define the requirements for family health history (FHH) collection, risk assessment, and clinical decision support of electronic health records of diverse national and international medical systems with the goal of integrating a medical system patient portal with a FHH risk assessment platform using biomedical informatics technology.

Role: Investigator; I am assisting in the design, conduct, and analysis of in-depth qualitative interviews with key leaders in various stakeholder groups throughout Vanderbilt University Medical Center.

Pediatric Oncologists' Experiences with Treatment Refusal

Internal funding

Benedetti, Dan (Vanderbilt University)

2019 - 2020

Objective: To develop evidence-based interventions and resources for Pediatric Oncologists and patients/families, aimed at reducing refusal, non-adherence, and abandonment; mediating conflict; and supporting oncology patients/families and providers through the stressful and emotionally challenging time surrounding a cancer diagnosis.

Role: Investigator; Currently collaborating in primary qualitative data collection via in-depth interviews with ~30 Pediatric Oncologists regarding their experience as the attending physician in a case of refusal, non-adherence, or abandonment of recommended cancer treatment.

Submitted, in process:

Exploring Choice of Law Challenges in Multi-Site Precision Medicine Research

R21, Under review

Beskow, Laura (Vanderbilt University); Wolf, Leslie (Georgia State University School of Law)

Submitted Feb. 2019

Objective: To explore stakeholders' experiences and opinions regarding choice of law questions in the research context, as well as whether and how existing choice of law frameworks might be applied in resolving them.

Role: Investigator; I will collaborate in the design and development of research protocol and instruments for various primary data collection activities with national experts in choice of law, research law, and ethics.

Defining the Scope of Broad Consent for Biomedical Research: Mapping the Meaning of Health and Disease

R01, Under review

Beskow, Laura (Vanderbilt University)

Submitted Feb. 2019

Objective: To define, based on public understanding and expectations, the scope of broad consent to research on "health and disease" by using concept mapping, a rigorous participatory technique designed to identify and organize differing ideas, values, and opinions into a common framework.

Role: Investigator; I will collaborate in the design and development research protocols and instruments, and oversee all activities to ensure regulatory compliance. I will collaborate in all data collection with diverse patient populations in 12 study locations throughout the U.S. (e.g., co-facilitating card sorting sessions and moderating focus groups). I will play a key role in developing all educational and other materials.

Genetic Privacy and Identity in Sexual and Gender Minorities: GetPrISM

R21, Under review

Clayton, Ellen (Vanderbilt University)

Submitted Oct. 2018; Nominated for co-funding May 2019

Objective: To investigate perspectives on research using genetic and sexual orientation and gender identity (SOGI) data among a diverse group of self-identifying members of the sexual oritentation and gender identity minority (SGM) community.

Role: Investigator; I will lead development of educational materials, supervise participant recruitment, conduct half of the cognitive interviews, and collaborate in the development of all other focus group instruments and materials. I will assist in facilitating focus groups, serve as secondary coder of focus group data, contribute to the analysis of focus group data, and assist in dissemination of results.

Surgery for Cancer With Option of Palliative Care Expert (SCOPE) Trial – Administrative Supplement for Research on Bioethical Issues

Supplement to R03-AG-060085, Under review

Shinall, Ricky (Vanderbilt University)

Submitted May 2019

Objective: To explore public perceptions and reactions to palliative care and the concept of studying palliative care interventions and develop the first evidence-based model consent language that simply, accurately, and flexibly addresses misunderstandings, concerns, and questions that prospective patients have regarding palliative care studies.

Role: Investigator; I will collaborate in all aspects of the project. Specifically, I will contribute to the development of data collection instruments, play a key role in drafting and revising model consent materials, co-facilitate focus group discussions, assist in the coding and analysis of focus group data, conduct approximately half of cognitive interviews, and lead the qualitative coding and analysis process of cognitive interview data.

Learning about APOL1 Risk and Kidney Disease: Placing Genetics in Context

Blacksher, Erika (University of Washington); Young, Bessie (University of Washington)

Competitive renewal to R01HG007879-03, In process

To be submitted Oct. 2019

Objective: To develop comprehensive communication procedures and resources to support the effective and responsible return of APOL1 results

Role: Investigator; I will collaborate in qualitative data collection from clinicians and patients.

Completed:

Beyond Data Security: Promoting Confidentiality and Advancing Science

National Human Genome Research Institute (R01-HG-007733)

Beskow, Laura (Vanderbilt University)

2014 - 2018

Objective: To gather empirical data regarding the actual scope of the confidentiality protections applicable to genome research, as well as how these are and should be described to prospective participants.

Role: Social Scientist; I conducted one third of 60 semi-structured, in-depth interviews with thought leaders in genomic research and led analysis efforts resulting in the development of several manuscripts. I also collaborated in the analysis of 30 cognitive interviews with lay participants regarding consent language. I played a key role in the systematic development of informed consent language and supplemental materials, as well as the application of all qualitative, quantitative, and legal analyses to real-world research scenarios for use in education, research design, and policy-making. I also collaborated in the design, conduct, and analysis of interviews assessing model consent language.

Ethical Approaches to Research Use of Clinical Records and Data

National Library of Medicine (R01-LM-012178)

Beskow, Laura (Vanderbilt University)

2014 - 2018

Objective: To gather empirical data regarding patients' willingness to share their clinical data for research use, and their reactions to researcher contact based on the results of EHR phenotyping, and to systematically develop recommendations regarding the ethical use of clinical data for research.

Role: Social Scientist; I held a key role in implementing an innovative research methodology that included 120 semi-structured interviews, 15 focus groups, and 4 deliberative dialogue events held at 4 study sites across the southeastern U.S. I collaborated in the development of empirically-based visual aids, educational videos, and other informational materials explaining complex research and ethics concepts specifically designed for low-literacy populations. I conducted one-third of all in-depth interviews and card-sorting activities, assisted with focus group discussions, moderated breakout groups during deliberative dialogue sessions, coordinated recruitment of community leaders and members, and conducted participant observation at research sites.

Enhancing the Biobanking Informed Consent Process to Improve Comprehension

National Human Genome Research Institute (R01-HG-006621)

Beskow, Laura (Vanderbilt University); Weinfurt, Kevin (Duke University)

2012 - 2017

Objective: To develop a simplified consent process for biobanking research by determining the information needed to make informed decisions and testing its efficacy through a national, randomized controlled trial.

Role: Social Scientist; I led the systematic development of a consent form comprehension quiz and supplemental materials. After the development of a simplified consent form which is currently implemented at the Duke Clinical and Translational Science Institute biobank, I led the conduct and analysis of over 20 in-depth, semi-structured interviews to assess the usability thereof with biobank employees and members of various patient advisory committees.

Health Care Systems Research Collaboratory - Coordinating Center

National Center for Complementary & Alternative Medicine (U54-AT-007748)

Hernandez, Adrian (Duke University)

2012 - 2017

Objective: To improve understanding of when and how stakeholders believe research testing interventions that are considered standard of care are acceptable and when consent for it should be sought.

Role: Social Scientist; I coordinated and facilitated numerous meetings with leadership from the Office for Human Research Protections, the National Institutes of Health, and the NIH Collaboratory's Ethics and Regulatory Working Group, principal investigators, and other key experts, to discuss various ethics and regulatory issues related to ongoing national demonstration projects. I managed the Ethics and Regulatory Core Working Group and facilitated the PCORI's Ethics and Regulatory Task Force. I researched, interpreted, and reported on various regulatory guidances to inform Core leadership and collaborated in the development of protocols and standard operating procedures.

Duke Translational Medicine Institute

National Center For Advancing Translational Sciences (UL1-TR-001117)

Boulware, Ebony (Duke University)

2012 - 2017

Objective: To create an Integrated Home for clinical and translational research at Duke by providing infrastructure and resources to serve investigators and trainees across the research spectrum.

Role: Social Scientist; I worked to develop legal, regulatory, policy, and bioethics expertise and resources within the Program for Empirical Bioethics to serve the larger Duke University community.

Aspirin Dosing: A Patient-Centric Trial Assessing Benefits and Long-term Effectiveness (ADAPTABLE)

Patient-Centered Outcomes Research Network (PCORnet) (AS-1502-27081)

Roe, Matthew (Duke University)

2015 - 2016

Objective: To assess whether low- or higher-dose aspirin is better for the prevention of heart attack and stroke in patients with coronary artery disease.

Role: Social Scientist; I collaborated in the systematic development of a unified consent form, accompanying comprehension quiz, and supplemental materials, which are currently implemented in whole or in part at study sites throughout the United States.

Health Care Systems Research Collaboratory – Empirical Ethics Supplement

National Center for Complementary & Alternative Medicine (supplement to U54-AT-007748; A. Hernandez, PI)

Weinfurt, Kevin (Duke University); Sugarman, Jeremy (Johns Hopkins)

2012 - 2017

Objective: To improve the way clinical trials are conducted by creating a new infrastructure for collaborative research with healthcare systems.

Role: Social Scientist; I assisted in developing language for study-specific instruments as well as the conduct and analysis of cognitive interviews for testing and assessment thereof.

RESEARCH INTERESTS

Bioethics	Law, regulation, policy	Qualitative research	Death, dying, the dead
Empirical bioethics	Health law	Informed consent	Morbidity, mortality
Research ethics	Medical law	End-of-life care, planning	Funeral, cemetary law