## **SARA GERKE**

Associate Professor of Law & Richard W. & Marie L. Corman Scholar University of Illinois Urbana-Champaign College of Law 504 E Pennsylvania Ave Champaign, IL 61820 gerke@illinois.edu

## PRACTICE EXPERIENCE

#### University of Illinois College of Law

Urbana-Champaign, IL

Associate Professor of Law Richard W. & Marie L. Corman Scholar July 2024-present

## Primary Research Interests:

Health Law (including bioethics, artificial intelligence, digital health, stem cell research, genetics, reproductive technology, and other health law topics), Food and Drug Law, Privacy Law, Law and Medicine, Law and Technology, Torts, and Comparative Law (U.S. and Europe).

## Courses:

- Torts (4 credits)
- Health Law (3 credits)
- Food and Drug Law (3 credits)

## **Current Research Projects:**

## **CLASSICA (Validating AI in Classifying Cancer in Real-Time Surgery)**

European Union, Horizon Europe (Grant Agreement no. 101057321)

Role: Principal Investigator (UIUC); Co-Principal Investigator, WP8 (Legal, Ethical & Liability)

Total project amount awarded: approx. €6 million

Awarded sum: approx. \$595,276 USD

Dates: May 2022 - April 2026 https://classicaproject.eu/

## OperA (Optimising Colorectal Cancer Prevention through Personalised Treatment with Artificial **Intelligence**)

European Union, Horizon Europe (Grant Agreement no. 101057099)

Role: Principal Investigator (UIUC); Co-Principal Investigator, WP4 (Addressing Ethical/Legal Concerns)

Total project amount awarded: approx. €6 million (i.e., €4.7 million from Horizon Europe & the remainder from

a U.K. funding body)

Awarded sum: approx. \$117,220 USD Dates: September 2022 – August 2027

https://www.opera.uio.no/

#### BLAST (Bioethical, Legal, and Anthropological Study of Technologies)

National Institute of Biomedical Imaging and Bioengineering (NIBIB) and the National Institutes of Health Office of the Director (NIH OD) (Grant Agreement no. 1R21EB035474-01)

Role: Multiple Principal Investigator

Total project amount awarded: \$441,100 USD

Dates: September 2023 – August 2025

## Research Fellowship:

Center for Advanced Studies in Bioscience Innovation Law (CeBIL), Faculty of Law, University of Copenhagen

## Inter-CeBIL (International Collaborative Bioscience Innovation & Law Programme)

Novo Nordisk Foundation Grant for a scientifically independent International Collaborative Bioscience Innovation & Law Programme (Inter-CeBIL programme - grant no. NNF23SA0087056)

Total project amount awarded to the University of Copenhagen: DKK 50 million (ca. \$6.7 million USD)

Dates: July 2024 – June 2025

#### PENN STATE DICKINSON LAW

Carlisle, PA

Assistant Professor of Law

July 2021-June 2024

## **Primary Research Interests:**

Health Law (including bioethics, artificial intelligence, digital health, stem cell research, genetics, reproductive technology, and other health law topics), Food and Drug Law, Privacy Law, Law and Medicine, Law and Technology, Torts, and Comparative Law (U.S. and Europe).

#### Courses:

- Torts (4 credits)
- Health Care Law & Policy (3 credits)
- Food and Drug Law (3 credits)
- S.J.D. Research Colloquium (with Prof. William E. Butler, 2 credits)

#### Research Projects:

- CLASSICA (Validating AI in Classifying Cancer in Real-Time Surgery) (see details above)
- OperA (Optimising Colorectal Cancer Prevention through Personalised Treatment with Artificial Intelligence) (see details above)
- BLAST (Bioethical, Legal, and Anthropological Study of Technologies) (see details above).
- PREMIERE: A PREdictive Model Index and Exchange Repository

National Institute of Biomedical Imaging and Bioengineering (NIBIB) and the National Institutes of Health Office of the Director (NIH OD) (Grant Agreement no. 3R01EB027650-03S1)

Role: Co-Investigator (Supplemental Project PSU)

Total project amount awarded to Penn State: \$186,709 USD

Dates: September 2022 – May 2024

## • TCORS: Tobacco Product Composition Effects on Toxicity

National Institute on Drug Abuse (NIDA)/National Institutes of Health (NIH) (Grant Agreement no. 1U54DA058271-01)

Role: Co-Investigator (September 2023 – June 2024)

Total project amount awarded to Penn State: \$19,593,890

Dates: September 2023 – August 2028

# HARVARD LAW SCHOOL, THE PETRIE-FLOM CENTER FOR HEALTH LAW POLICY, BIOTECHNOLOGY AND BIOETHICS Cambridge, MA

Research Fellow, Medicine, Artificial Intelligence, and Law

August 2018–June 2021

Overseeing the day-to-day work of the **Project on Precision Medicine**, **Artificial Intelligence**, **and the Law (PMAIL)**, including conducting law, policy, and ethics research; drafting reports and recommendations; and coordinating the Petrie-Flom Center's efforts with collaborators at the **Center for Advanced Studies in Biomedical Innovation Law (CeBIL)** at the University of Copenhagen as well as other partners.

Visiting Researcher April 2018–June 2018

The ethics and law of in vitro gametogenesis (IVG) in the U.S. and Europe, reproductive and regenerative medicine, U.S. patent and Food and Drug Administration (FDA) law.

# INSTITUTE FOR GERMAN, EUROPEAN AND INTERNATIONAL MEDICAL LAW, PUBLIC HEALTH LAW AND BIOETHICS OF THE UNIVERSITIES OF HEIDELBERG AND MANNHEIM Mannheim, Germany

General Manager October 2016–March 2018

External presentation of the **Institute**, contact person for cooperation requests of national and international scholars and institutions, supervision of 24 student assistants, organization of conferences (e.g., Ethics Symposium), acquiring third-party funded projects, annual and financial reports.

Co-Investigator April 2016–March 2018

Project: ClinhiPS – A Scientific, Ethical and Comparative Legal Analysis of the Clinical Application of Human Induced Pluripotent Stem Cells in Germany and Austria; sponsored by the German Federal Ministry of Education and Research (BMBF); total project amount awarded: €657,678.00.

Research Associate January 2014–June 2015

Conducting various research projects in the areas of medical law, public health law, and bioethics.

School of Law and Economics, University of Mannheim, Germany: teaching of law students; correction of/assessor in examinations; creation of the PowerPoint slides (266 slides) and revision of the Script (163 pages) for the Lecture "Medical Law" & assistance in the drafting of the case and solution to the case for the Exam in Civil Law, Prof. Dr. Jochen Taupitz.

## DR. IUR. BIANKA S. DÖRR BÜHLMANN, LL.M., ATTORNEY-AT-LAW, UNIVERSITY OF ZURICH Zurich, Switzerland

Research Assistant September 2012

Literature review in Medical Law and Human Rights.

#### LAW FIRM BENDER & PHILIPP

Munich, Germany

Research Assistant August–September 2012

Drafting and revising the commentary on sections 1–19, 28–45b SGB XI; Kreikebohm, R., Spellbrink, W. and Waltermann, R. (eds.) (2013) Kommentar zum Sozialrecht [Commentary on Social Law]. 3rd ed. Munich: C. H. Beck.

#### UNIVERSITY OF AUGSBURG, LAW SCHOOL

Augsburg, Germany

December 2009–September 2010

Medical Law, Health Sciences, and Civil Law; guest chair holder: Dr. Bianka S. Dörr

Literature review, reviewing and summarizing articles, drafting teaching materials, developing and compiling arguments on current medical law problems.

#### **LAW FIRM BENDER & PHILIPP**

Student Assistant

Freiburg, Germany

Intern August–September 2009

Health Law (hospital planning and care rates, ambulance service).

Social Law (financing – care rates and public funding, approval and operation of social facilities and services).

Home Law (nursing homes, inpatient facilities for the welfare of people with disabilities and adolescents, senior citizens' residences).

## **PUBLIC PROSECUTOR'S OFFICE**

Lörrach, Germany

Intern August 2009

Criminal Law related to medical law (e.g., death investigations, questions of medical malpractice and violation of the Medicinal Products Act, cases of dangerous bodily harm).

Preparation of documents for court hearings, participation in court hearings, participation in autopsy at the Institute for Forensic Medicine at the University of Freiburg.

LAW FIRM ALTHOFF
Lörrach, Germany

Intern

September-October 2008

Insolvency and corporate law as well as general civil law (process of standard insolvency proceedings, examination of insolvency-specific cases and claims against limited companies' managing directors and partners, preparation of contract negotiations in general corporate and civil law).

## **EDUCATION**

#### KING'S COLLEGE LONDON, UK, M.A. in Medical Ethics and Law

December 2013

#### Modules:

- Medical Law I: Consent, Refusal, and Request
- Law at the End of Life
- Law and Reproduction

- Moral Theory and Medical Ethics
- Ethics at the End of Life
- Topics in Medical Ethics

#### Dissertation:

A Market in Human Organs from the Living or an Opt-Out System? A Legal and Ethical Analysis to Identify a Way to Address the Organ Shortage in the UK (awarded Distinction)

UNIVERSITY OF AUGSBURG, Germany, Dipl.-Jur. Univ. (Juris Doctor (J.D.) equivalent degree)

July 2012

Major field of study: Biolaw, Health Law, and Medical Law (highest possible honors)

Final paper: The Transplantation of Organs – What are the Rights of Organ Donors and Organ Recipients? (highest possible honors)

UNIVERSITY OF PASSAU, Germany, Law Studies

October 2006–March 2009

GYMNASIUM LANDSCHULHEIM SCHLOSS HEESSEN, Hamm, Germany, Allgemeine Hochschulreife (general higher education entrance qualification)

May 2006

Highest possible honors, best student of the year

## **FURTHER EDUCATION (SELECTION)**

UNIVERSITY OF MANNHEIM, Germany, Dr. iur. (Ph.D. equivalent degree in Law)

Present

Thesis: Stem Cell Research – From Laboratory to Clinic in Europe

Supervisor: Prof. Dr. Jochen Taupitz

## HARVARD LAW SCHOOL, Cambridge, MA

Auditor, Bioethics and Health Law, taught by I. Glenn Cohen (Jan. 2021).

Auditor, Health Law, Policy, Bioethics, and Biotechnology Workshop, led by I. Glenn Cohen (Fall 2019).

Auditor, Torts, taught by Daniel Hemel (Fall 2019).

Auditor, Food and Drug Law, taught by Peter Barton Hutt (Jan. 2019).

Auditor, Health Law, Policy, Bioethics, and Biotechnology Workshop, led by Prof. I. Glenn Cohen (Fall 2018).

Course Participant, HLS4X: Bioethics: The Law, Medicine, and Ethics of Reproductive Technologies and Genetics; elearning course taught by I. Glenn Cohen, final grade: 100 % (September–November 2016).

## **PUBLICATIONS**

(Publications during tenure track are marked with an asterisk\*)

#### EDITED BOOK

1. Sara Gerke, Jochen Taupitz, Claudia Wiesemann, Christian Kopetzki & Heiko Zimmermann (eds.), Die klinische Anwendung von humanen induzierten pluripotenten Stammzellen — Ein Stakeholder-Sammelband [The Clinical Application of Human Induced Pluripotent Stem Cells — A Stakeholder Anthology] (Springer 2020).

## **JOURNAL ARTICLES**

- 2. Mindy Duffourc, Sara Gerke & Konrad Kollnig, *Privacy of Personal Data in the Generative AI Data Lifecycle*, 13(2) N.Y.U. JOURNAL OF INTELL. PROP. & ENT. LAW 219 (2024).
- 3. Carmel Shachar, Amy Killelea & Sara Gerke, *AI And Health Insurance Prior Authorization: Regulators Need To Step Up Oversight*, HEALTH AFFAIRS FOREFRONT (2024).
- 4. Ronan A. Cahill, Mindy Duffourc & Sara Gerke, Surgical Video Data "In," "Out," or "Shake It All About" the Medical Record, ANNALS OF SURGERY (2024) (Published Ahead-of-Print).\*
- 5. Sami Elamin, Mindy Duffourc, Tyler M. Berzin, Mark E. Geissler, & Sara Gerke, *Artificial Intelligence and Medical Liability in Gastrointestinal Endoscopy*, 22 CLINICAL GASTROENTEROLOGY AND HEPATOLOGY 1165 (2024).\*
- 6. Sara Gerke & Delaram Rezaeikhonakdar, *Privacy Shield 2.0 A New Trans-Atlantic Data Privacy Framework Between the European Union and the United States*, 45 CARDOZO LAW REVIEW 2 (2023, published February 2024).\*
- 7. Mindy Duffourc & Sara Gerke, Health Care AI and Patient Privacy—Dinerstein v Google, JAMA (2024).\*
- 8. Mindy Duffourc & Sara Gerke, *Decoding U.S. Tort Liability in Healthcare's Black-Box AI Era: Lessons from the European Union*, 27 STANFORD TECHNOLOGY LAW REVIEW 1 (2024).\*
- 9. Eugenia N. Uche-Anya, Sara Gerke & Tyler M. Berzin, *Video Endoscopy as Big Data: Balancing Privacy and Progress in Gastroenterology*, THE AMERICAN JOURNAL OF GASTROENTEROLOGY (2024).\*
- 10. I. Glenn Cohen, Boris Babic, Sara Gerke, Qiong Xia, Theodoros Evgeniou & Klaus Wertenbroch, *How AI Can Learn from the Law: Putting Humans in the Loop Only on Appeal*, 6 NPJ DIGITAL MEDICINE Article number: 160 (2023).\*
- 11. Mindy Duffourc & Sara Gerke, Generative AI in Health Care and Liability Risks for Physicians and Safety Concerns for Patients, 330 JAMA 313 (2023).\*
- 12. Rosh Walsh, Emma C. Kearns, Alice Moynihan, Sara Gerke, Mindy Duffourc, Marcelo Corrales Compagnucci, Timo Minssen & Ronan A Cahill, *Ethical Perspectives on Surgical Video Recording for Patients, Surgeons and Society: Systematic Review*, 7 BJS OPEN zrad063 (2023).\*
- 13. Dennis M. Hedderich, Christian Weisstanner, Sofe Van Cauter, Christian Federau, Myriam Edjlali, Alexander Radbruch, Sara Gerke & Sven Haller, *Artificial Intelligence Tools in Clinical Neuroradiology: Essential Medico-Legal Aspects*, 65 NEURORADIOLOGY 1091 (2023).\*
- 14. Mindy N. Duffourc & Sara Gerke, *The Proposed EU Directives for AI Liability Leave Worrying Gaps Likely to Impact Medical AI*, 6 NPJ DIGITAL MEDICINE Article number: 77 (2023).\*
- 15. Michael Bretthauer, Sara Gerke, Cesare Hassan, Omer F. Ahmad & Yuichi Mori, *The New European Medical Device Regulation: Balancing Innovation and Patient Safety*, ANNALS OF INTERNAL MEDICINE (2023).\*
- 16. Sara Gerke, "Nutrition Facts Labels" for Artificial Intelligence/Machine Learning-Based Medical Devices—The Urgent Need for Labeling Standards, 91 THE GEORGE WASHINGTON LAW REVIEW 79 (2023).\*
- 17. Carmel Shachar & Sara Gerke, *Prevention of Bias and Discrimination in Clinical Practice Algorithms*, 329 JAMA 283 (2023).\*
- 18. Kristin M. Kostick-Quenet & Sara Gerke, *AI in the Hands of Imperfect Users*, 5 NPJ DIGITAL MEDICINE Article number: 197 (2022).\*
- 19. Craig M. Klugman & Sara Gerke, *Rise of the Bioethics AI: Curse or Blessing?*, 22 THE AMERICAN JOURNAL OF BIOETHICS 35 (2022).\*

- 20. Carmel Shachar, Sara Gerke, Walker Morrell, Aaron Kirby, I. Glenn Cohen & Barbara E. Bierer, *When is a Change Significant? The Update Problem of Apps in Medical and Behavioral Research*, 44 ETHICS & HUMAN RESEARCH 2 (2022).\*
- 21. Sara Gerke, *Health AI for Good Rather than Evil? The Need for a New Regulatory Framework for AI-Based Medical Devices*, 20 YALE JOURNAL OF HEALTH POLICY, LAW, AND ETHICS 433 (2021, published April 2022).\*
- 22. Sara Gerke & Delaram Rezaeikhonakdar, *Privacy Aspects of Direct-to-Consumer Artificial Intelligence/Machine Learning Health Apps*, 6 INTELLIGENCE-BASED MEDICINE 100061 (2022).\*
- 23. Georgia R. Goodman, Anna Kikut, Maria J. Bustamante, Lizette Mendez, Yassir Mohamed, Carmel Shachar, I. Glenn Cohen, Sara Gerke, Edward W. Boyer, Rochelle K. Rosen, Kenneth H. Mayer, Conall O'Cleirigh & Peter R. Chai, "I'd Feel Like Someone Was Watchin' Me... Watching for a Good Reason": Perceptions of Data Privacy, Access, and Sharing in the Context of Real-Time PrEP Adherence Monitoring Among HIV-Negative MSM With Substance Use, AIDS AND BEHAVIOR (2022).\*
- 24. Kristin M. Kostick-Quenet, I. Glenn Cohen, Sara Gerke, Bernard Lo, James Antaki, Faezah Movahedi, Hasna Njah, Lauren Schoen, Jerry E. Estep & J.S. Blumenthal-Barby, *Mitigating Racial Bias in Machine Learning*, 50 JOURNAL OF LAW, MEDICINE & ETHICS 92 (2022).\*
- 25. Julia Amann, Dennis Vetter, Stig Nikolaj Blomberg, Helle Collatz Christensen, Megan Coffee, Sara Gerke, Thomas K. Gilbert, Thilo Hagendorff, Sune Holm, Michelle Livne, Andy Spezzatti, Inga Strümke, Roberto V. Zicari & Vince Istvan Madai, *To Explain or Not to Explain?—Artificial Intelligence Explainability in Clinical Decision Support Systems*, 1 PLOS DIGITAL HEALTH e0000016 (2022).\*
- 26. Kelly N. Michelson, Craig M. Klugman, Abel N. Kho & Sara Gerke, *Ethical Considerations Related to Using Machine Learning-Based Prediction of Mortality in the Pediatric Intensive Care Unit*, 247 THE JOURNAL OF PEDIATRICS 125 (2022).\*
- 27. Marc A. Rodwin & Sara Gerke, *German Pharmaceutical Pricing: Lessons for the United States*, 52 INTERNATIONAL JOURNAL OF HEALTH SERVICES 146 (2022).\*
- 28. Boris Babic, Sara Gerke, Theodoros Evgeniou & I. Glenn Cohen, *Beware Explanations From AI in Health Care*, 373 SCIENCE 284 (2021).\*
- 29. Roberto V. Zicari, James Brusseau, Stig N. Blomberg, Helle Collatz Christensen, Megan Coffee, Marianna B Ganapini, Sara Gerke, Thomas Krendl Gilbert, Eleanore Hickman, Elisabeth Hildt, Sune Holm, Ulrich Kühne, Vince I. Madai, Walter Osika, Andy Spezzatti, Eberhard Schnebel, Jesmin J. Tithi, Dennis Vetter, Magnus Westerlund, Renee Wurth, Julia Amann, Antun Vegard, Valentina Beretta, Frédérick Bruneault, Erik Campano, Boris Düdder, Alessio Gallucci, Emmanuel Goffi, Christoffer B. Haase, Thilo Hagendorff, Pedro Kringen, Florian Möslein, Davi Ottenheimer, Matiss Ozols, Laura Palazzani, Martin Petrin, Karin Tafur, Jim Tørresen, Holger Volland & Georgios Kararigas, *On Assessing Trustworthy AI in Healthcare. Machine Learning as a Supportive Tool to Recognize Cardiac Arrest in Emergency Calls*, 3 FRONTIERS IN HUMAN DYNAMICS 673104 (2021).
- 30. Sara Gerke, Gali Katznelson, Dorit Reiss & Carmel Shachar, *COVID-19 Antibody Testing as a Precondition for Employment: Ethical and Legal Considerations*, 49 THE JOURNAL OF LAW, MEDICINE & ETHICS 293 (2021).
- 31. Boris Babic, Sara Gerke, Theodoros Evgeniou & I. Glenn Cohen, *Direct-to-Consumer Medical Machine Learning and Artificial Intelligence Applications*, 3 NATURE MACHINE INTELLIGENCE 283 (2021).
- 32. George Maliha, Sara Gerke, I. Glenn Cohen & Ravi B. Parikh, *Artificial Intelligence and Liability in Medicine: Balancing Safety and Innovation*, 99 MILBANK QUARTERLY 629 (2021).
- 33. Gali Katznelson & Sara Gerke, *The Need for Health AI Ethics in Medical School Education*, 26 ADVANCES IN HEALTH SCIENCES EDUCATION 1447 (2021).
- 34. W. Nicholson Price II, Sara Gerke & I. Glenn Cohen, *How Much Can Potential Jurors Tell Us about Liability for Medical Artificial Intelligence?*, 62 JOURNAL OF NUCLEAR MEDICINE 15 (2021).
- 35. I. Glenn Cohen, Sara Gerke & Daniel B. Kramer, *Ethical and Legal Implications of Remote Monitoring of Medical Devices*, 98 MILBANK Q. 1257 (2020).
- 36. Sara Gerke, Carmel Shachar, Peter R. Chai & I. Glenn Cohen, *Regulatory, Safety, and Privacy Concerns of Home Monitoring Technologies During COVID-19*, 26 NATURE MEDICINE 1176 (2020).
- 37. Hrefna D. Gunnarsdóttir, Michael S. Sinha, Sara Gerke & Timo Minssen, *Applying the Proportionality Principle to COVID-19 Antibody Testing*, JOURNAL OF LAW AND THE BIOSCIENCES Isaa058 (2020).

- 38. Sara Gerke, Ariel D. Stern & Timo Minssen, *Germany's Digital Health Reforms in the COVID-19 Era: Lessons and Opportunities for Other Countries*, 3 NPJ DIGITAL MEDICINE Article number: 94 (2020).
- 39. I. Glenn Cohen, Theodoros Evgeniou, Sara Gerke & Timo Minssen, *The European Artificial Intelligence Strategy: Implications and Challenges for Digital Health*, 2 THE LANCET DIGITAL HEALTH E376 (2020).
- 40. Carmel Shachar, Sara Gerke & Eli Y. Adashi, *AI Surveillance during Pandemics: Ethical Implementation Imperatives*, 50 HASTINGS CENTER REPORT 18 (2020).
- 41. Timo Minssen, Sara Gerke, Mateo Aboy, Nicholson Price & I. Glenn Cohen, *Regulatory Responses to Medical Machine Learning*, JOURNAL OF LAW AND THE BIOSCIENCES Isaa002 (2020).
- 42. Sara Gerke, Boris Babic, Theodoros Evgeniou & I. Glenn Cohen, *The Need for a System View to Regulate Artificial Intelligence/Machine Learning-Based Software as Medical Device*, 3 NPJ DIGITAL MEDICINE Article number: 53 (2020).
- 43. Sara Gerke, Serena Yeung & I. Glenn Cohen, *Ethical and Legal Aspects of Ambient Intelligence in Hospitals*, 323 JAMA 601 (2020).
- 44. I. Glenn Cohen, Eli Y. Adashi, Sara Gerke, César Palacios-González & Vardit Ravitsky, *The Regulation of Mitochondrial Replacement Techniques Around the World*, 21 ANNUAL REVIEW OF GENOMICS AND HUMAN GENETICS 565 (2020).
- 45. Boris Babic, Sara Gerke, Theodoros Evgeniou & I. Glenn Cohen, *Algorithms on Regulatory Lockdown in Medicine: Prioritize Risk Monitoring to Address the "Update Problem"*, 366 SCIENCE 1202 (2019).
- 46. W. Nicholson Price II, Sara Gerke & I. Glenn Cohen, *Potential Liability for Physicians Using Artificial Intelligence* 322 JAMA 1765 (2019).
- 47. Mateo Aboy, Kathleen Liddell, Cristina Crespo, I. Glenn Cohen, Johnathon Liddicoat, Sara Gerke, & Timo Minssen, How Does Emerging Patent Case Law in the US and Europe Affect Precision Medicine?, 37 NATURE BIOTECHNOLOGY 1118 (2019).
- 48. Sara Gerke, Timo Minssen, Helen Yu & I. Glenn Cohen, *Ethical and Legal Issues of Ingestible Electronic Sensors*, 2 NATURE ELECTRONICS 329 (2019).
- 49. Sara Gerke & Shaun Pattinson, *EU Marketing Authorisation of Orphan Medicinal Products and Its Impact on Related Research*, 24 EUROPEAN JOURNAL OF HEALTH LAW 541 (2017).
- 50. Jochen Taupitz, Franz Geisthövel, Dagmar Coester-Waltjen, Helmut Frister, Monika Frommel, Sara Gerke, Benjamin Hermes, Friedhelm Hufen, Alexandra Ochsner, Henning Beier & Christian Thaler, V. Mannheimer Workshop zur Fortpflanzungsmedizin: Ein juristischer Diskurs zur Präimplantationsdiagnostik und Embryonenspende auf der Basis neuerer reproduktionsbiologischer Prämissen [5th Mannheim Workshop on Reproductive Medicine: A Legal Discourse on Preimplantation Diagnosis and Embryo Donation Based on Recent Reproductive Biological Premises], 12 JOURNAL OF REPRODUCTIVE MEDICINE AND ENDOCRINOLOGY 42 (2015).

#### **BOOK CHAPTERS**

- 51. W. Nicholson Price II, Sara Gerke & I. Glenn Cohen, *Liability for Use of Artificial Intelligence in Medicine*, *in* Research Handbook on Health, AI and the Law, 150 (Barry Solaiman & I. Glenn Cohen eds., Edward Elgar Publishing Ltd. 2024).\*
- 52. Sara Gerke, *Labeling of Direct-to-Consumer Medical Artificial Intelligence Applications for "Self-Diagnosis,"* in Digital Health Care outside of Traditional Clinical Settings, 139 (I. Glenn Cohen et al. eds., Cambridge University Press 2024).\*
- 53. I. Glenn Cohen, Andrew Slottje & Sara Gerke, *Medical AI and Tort Liability*, *in* Artificial Intelligence in Medicine, 89 (Joseph J.Y. Sung and Cameron Stewart eds., Academic Press 2024).\*
- 54. Sara Gerke, *Ethical and Legal Issues in Artificial Intelligence-Based Cardiology*, *in* Intelligence-Based Cardiology and Cardiac Surgery, 415 (Anthony C. Chang and Alfonso Limon eds., Elsevier 2024).\*
- 55. Sara Gerke, *Privacy Laws in the USA, Europe, and South Africa*, in AI in Clinical Medicine: A Practical Guide for Healthcare Professionals, 395 (Michael F. Byrne et al. eds., Wiley, 2023).\*
- 56. Timo Minssen & Sara Gerke, *Ethical and Legal Challenges of Digital Medicine in Pandemics*, *in Pandemics* and Ethics 165 (Andreas Reis, Martina Schmidhuber & Andreas Frewer eds., Springer 2023).\*

- 57. Jenna Becker, Sara Gerke & I. Glenn Cohen, *The Development, Implementation, and Oversight of Artificial Intelligence in Health Care: Legal and Ethical Issues*, in Handbook of Bioethical Decisions. Volume I. Decisions at the Bench 441 (Erick Valdés & Juan Alberto Lecaros eds., Springer 2023).\*
- 58. Hrefna D. Gunnarsdóttir, I. Glenn Cohen, Timo Minssen & Sara Gerke, *The Ethics and Laws of Medical Big Data*, *in* The Cambridge Handbook of Information Technology, Life Sciences and Human Rights 48 (M. Ienca, O. Pollicino, L. Liguori, E. Stefanini & R. Andorno eds., Cambridge University Press 2022).\*
- 59. Sara Gerke, *Digital Home Health During the COVID-19 Pandemic: Challenges to Safety, Liability, and Informed Consent, and the Way to Move Forward, in* The Future of Medical Device Regulation: Innovation and Protection 141 (I. Glenn Cohen, Timo Minssen, W. Nicholson Price II, Christopher Robertson & Carmel Shachar eds., Cambridge University Press 2022).\*
- 60. Timo Minssen & Sara Gerke, *Ethische und rechtliche Herausforderungen digitaler Medizin in Pandemien [Ethical and Legal Challenges of Digital Medicine in Pandemics]*, *in* Pandemien und Ethik [Pandemics and Ethics] 179 (Andreas Reis, Martina Schmidhuber & Andreas Frewer eds., Springer 2021).\*
- 61. Sara Gerke, Timo Minssen & I. Glenn Cohen, *Ethical and Legal Challenges of Artificial Intelligence-Driven Healthcare*, *in* Artificial Intelligence in Healthcare 295 (Adam Bohr & Kaveh Memarzadeh eds., Elsevier 2020).
- 62. Sara Gerke, *Die klinische Translation von hiPS-Zellen in Deutschland [The Clinical Translation of hiPSCs in Germany]*, *in* Die klinische Anwendung von humanen induzierten pluripotenten Stammzellen [The Clinical Application of Human Induced Pluripotent Stem Cells] 243 (Sara Gerke et al. eds., Springer 2020).
- 63. Sara Gerke & Solveig Lena Hansen, *Die Klinische Anwendung von hiPS-Zellen: Ein Überblick [The Clinical Application of hiPSCs: An Overview]*, in Die klinische Anwendung von humanen induzierten pluripotenten Stammzellen [The Clinical Application of Human Induced Pluripotent Stem Cells] 1 (Sara Gerke et al. eds., Springer 2020).
- 64. Sara Gerke, Solveig Lena Hansen, Verena Christine Blum, Stephanie Bur, Clemens Heyder, Christian Kopetzki, Ina Meiser, Julia C. Neubauer, Danielle Noe, Claudia Steinböck, Claudia Wiesemann, Heiko Zimmermann & Jochen Taupitz, Naturwissenschaftliche, ethische und rechtliche Empfehlungen zur klinischen Translation der Forschung mit humanen induzierten pluripotenten Stammzellen und davon abgeleiteten Produkten [Scientific, Ethical, and Legal Recommendations for the Clinical Translation of Research Using Human Induced Pluripotent Stem Cells and Derived Products], in Die klinische Anwendung von humanen induzierten pluripotenten Stammzellen [The Clinical Application of Human Induced Pluripotent Stem Cells] 459 (Sara Gerke et al. eds., Springer 2020).
- 65. Sara Gerke, Christian Kopetzki, Verena Christine Blum, Danielle Noe & Claudia Steinböck, Eine rechtsvergleichende Analyse der klinischen Translation von hiPS-Zellen in Deutschland und Österreich [A Comparative Legal Analysis of the Clinical Translation of hiPSCs in Germany and Austria], in Die klinische Anwendung von humanen induzierten pluripotenten Stammzellen [The Clinical Application of Human Induced Pluripotent Stem Cells] 421 (Sara Gerke et al. eds., Springer 2020).
- 66. Sara Gerke & Jochen Taupitz, Rechtliche Aspekte der Stammzellforschung in Deutschland: Grenzen und Möglichkeiten der Forschung mit humanen embryonalen Stammzellen (hES Zellen) und mit humanen induzierten pluripotenten Stammzellen (hiPS Zellen) [Legal Aspects of Stem Cell Research in Germany: Limits and Possibilities of Research Using Human Embryonic Stem Cells (hESCs) and Human Induced Pluripotent Stem Cells (hiPSCs)], in Stammzellforschung: Aktuelle wissenschaftliche und gesellschaftliche Entwicklungen [Stem Cell Research: Current Scientific and Social Developments] 209 (Martin Zenke, Lilian Marx-Stölting & Hannah Schickl eds., Nomos 2018).

#### **BLOGS**

- 67. Sara Gerke, *Ethical and Legal Challenges Posed by the Implementation of AI Applications in the Healthcare Setting*, ELSIHUB COLLECTIONS (2022).\*
- 68. Sara Gerke & Chloe Reichel, Should We Regulate Direct-to-Consumer Health Apps?, BILL OF HEALTH (2021).\*
- 69. Sara Gerke & Chloe Reichel, Mitigating Bias in Direct-to-Consumer Health Apps, BILL OF HEALTH (2021).\*
- 70. Sara Gerke & Chloe Reichel, Who Owns the Data Collected by Direct-to-Consumer Health Apps?, BILL OF HEALTH (2021).\*
- 71. Sara Gerke & Chloe Reichel, Should Users Have Access to Data Collected by Direct-to-Consumer Health Apps?, BILL OF HEALTH (2021).\*
- 72. Sara Gerke & Chloe Reichel, *Perspectives on Data Privacy for Direct-to-Consumer Health Apps*, BILL OF HEALTH (2021).\*

- 73. Boris Babic, Sara Gerke, Theodoros Evgeniou & I. Glenn Cohen, *The Hidden Hazards of Smart Device Medical Advice*, INSEAD.
- 74. Carmel Shachar, Sara Gerke & I. Glenn Cohen, *Maximizing the Use of Claims Data to Address COVID-19: We Need To Revisit Gobeille v. Liberty Mutual*, HEALTH AFFAIRS BLOG (2020).
- 75. Sara Gerke, Germany's Response to the COVID-19 Pandemic, BILL OF HEALTH (2020).
- 76. Sara Gerke & I. Glenn Cohen, *Ethical and Legal Issues of Ingestible Electronic Sensors: Behind the Paper*, NATURE RES. DEVICE & MATER. ENG. Reposted on BILL OF HEALTH (2019).
- 77. Timo Minssen, Sara Gerke & Carmel Shachar, *Is Data Sharing Caring Enough About Patient Privacy? Part II: Potential Impact on US Data Sharing Regulations*, BILL OF HEALTH (2019).
- 78. Timo Minssen, Sara Gerke & Carmel Shachar, *Is Data Sharing Caring Enough About Patient Privacy? Part I: The Background*, BILL OF HEALTH (2019).
- 79. Sara Gerke & Joshua Feldman, *The Tricky Task of Defining AI in the Law*, BILL OF HEALTH (2018).
- 80. Sara Gerke, *The German Stem Cell Network Has Compiled a Sample Text for Informed Consent*, BILL OF HEALTH (2018).
- 81. Sara Gerke, *The EU's GDPR in the Health Care Context*, BILL OF HEALTH (2018).

#### **GUIDELINES**

- 82. Federation of State Medical Boards (FSMB), Navigating the Responsible and Ethical Incorporation of Artificial Intelligence into Clinical Practice (2024) (Subject Matter Expert).
- 83. World Health Organization (WHO), *Ethics & Governance of Artificial Intelligence for Health* (2021) (External Reviewer).
- 84. German Stem Cell Network (GSCN) together with the ELSA working group and the Pluripotent Stem Cell Core Network (PluriCore Network), *Informed Consent Sample Text for the Donation of Somatic Cells for Human Induced Pluripotent Stem Cell (hiPSC) Research* (2018).

## **MAGAZINE ARTICLES/OP-EDS**

- 85. Boris Babic & Sara Gerke, Explaining Medical AI Is Easier Said Than Done, STAT (2021).\*
- 86. George Maliha, Sara Gerke, Ravi B. Parikh & I. Glenn Cohen, *To Spur Growth in AI, We Need a New Approach to Legal Liability*, HARVARD BUSINESS REVIEW (2021).\*
- 87. Boris Babic, I. Glenn Cohen, Theodoros Evgeniou & Sara Gerke, *When Machine Learning Goes Off the Rails*, HARVARD BUSINESS REVIEW (2021).
- 88. Boris Babic, I. Glenn Cohen, Theodoros Evgeniou, Sara Gerke & Nikos Trichakis, *Can AI Fairly Decide Who Gets an Organ Transplant?*, HARVARD BUSINESS REVIEW (2020).
- 89. Sara Gerke, Daniel Kramer & I. Glenn Cohen, *Ethical and Legal Challenges of Artificial Intelligence in Cardiology*, 2 AIMED MAG. 12 (2019).
- 90. Sara Gerke & Tobias Cantz, *ELSA: A New Working Group of the GSCN*, FUTURE OF STEM CELL RESEARCH: ANNUAL MAGAZINE OF THE GERMAN STEM CELL NETWORK 2017/18, 47 (2018).

#### **WORKING PAPER & MISCELLANEOUS**

- 91. Sara Gerke, *Transcript: Presentation on Data Privacy Questions in the Digital Health World*, 35 J.L. & Health 449 (2022).\*
- 92. David Arney, Max Senges, Sara Gerke, Cansu Canca, Laura Haaber Ihle, Nathan Kaiser, Sujay Kakarmath, Annabel Kupke, Ashveena Gajeele, Stephen Lynch & Luis Melendez, *A User-Focused Transdisciplinary Research Agenda for AI-Enabled Health Tech Governance* (2019).

#### MEDIA (FEATURING WORK BY SARA GERKE) (SELECTION)

Fingertip Oxygen Sensors Can Fail on Dark Skin — Now a Physician Is Suing, Anil Oza, NATURE (January 2024).

Research Conversation with CLASSICA Project Members: AI to Help With Cancer Classification, Research Conversation: Digital Legal Lab, Podcast (December 2023).

- Insurers Scrutinized for Bulk Claim Denials, Tara Bannow, STAT, Newsletter Health Care Inc. (July 2023).
- Ethical Problems When Using Artificial Intelligence Assistance During Surgery, Stacey Kusterbeck, MEDICAL ETHICS ADVISOR (June 2023).
- Rooting Out Racial Bias in Health Care AI, Part 1 & Part 2, TRADEOFFS (May & June 2023).
- Researchers Discuss Implications of Using AI to Address Mental Health at Harvard Law School Webinar, Camilla J. Martinez & Nicole Y. Lu, THE HARVARD CRIMSON (March 2023).
- Is Your Phone a Medical Device?, Nabil Shaikh, THE REGULATORY REVIEW (February 2023).
- Google's AI Is Best Yet at Answering Medical and Health Questions, Jeremy Hsu, NEW SCIENTIST (January 2023).
- 'Out of Control': Dozens of Telehealth Startups Sent Sensitive Health Information to Big Tech Companies, Katie Palmer, Todd Feathers & Simon Fondrie-Teitler The Markup, STAT & THE MARKUP (December 2022).
- The Medic Reinvented Can Medical AI on the Battlefield Make Sound Decisions about Who Lives or Dies?, Adam Bluestein, PROTO MASSACHUSETTS GENERAL HOSPITAL (November 2022).
- Artificial Intelligence Soon Could Transform the Field of Clinical Ethics, Stacey Kusterbeck, MEDICAL ETHICS ADVISOR (November 2022).
- Dickinson Law Welcomes Postdoctoral Fellow for CLASSICA Project, PENN STATE UNIVERSITY (November 2022).
- *The AI Health Care Dilemma*, Katie Cohen, Caroline Hackley & Anilya Krishnan, THE REGULATORY REVIEW (October 2022).
- Dickinson Law Professor to Study Ethical, Legal Concerns of AI in Colonoscopy, PENN STATE UNIVERSITY (September 2022).
- Team Including Dickinson Law Professor Sara Gerke Receives €6 Million EU Grant to Research AI and Colorectal Cancer, PENN STATE DICKINSON LAW (September 2022).
- Artificial Intelligence & Machine Learning: Recent Scholarship, Erika Lietzan, OBJECTIVE INTENT (September 2022).
- Team That Includes Dickinson Law Professor Receives 6 Million Euro EU Grant, PENN STATE UNIVERSITY (June 2022).
- Team including Dickinson Law Professor Sara Gerke Receives €6 million EU Grant to Research AI and Cancer Surgery, Penn State Dickinson Law (June 2022).
- *Use Caution if Machine Learning Models Are Used to Predict Mortality*, Stacey Kusterbeck, MEDICAL ETHICS ADVISOR (May 2022).
- New Guidelines Bring Current Developments in Stem Cell Research into Focus, Annual Magazine 2021/2022, GERMAN STEM CELL NETWORK (GSCN) (May 2022).
- Exploring the Ethics of Algorithmic Bias in Artificial Intelligence, Interview, "Making the Rounds" Podcast Series, AMERICAN MEDICAL ASSOCIATION (January 2022).
- United Kingdom to Begin Offering Home-Finger-Prick Tests for Covid-19 Antibodies, Katherine C. Pearson, ELDER LAW PROF BLOG (August 2021).
- Der Nutzen der Künstlichen Intelligenz und ihre Nebenwirkungen, Dr. Thomas Meißner, ÄrzteZeitung (July 2021).
- Dickinson Law Professor Named Health Law Scholar, PENN STATE UNIVERSITY (July 2021).
- Dickinson Law Enhances Resident Faculty with Addition of New Scholars, PENN STATE UNIVERSITY (June 2021).
- Tech Companies Want AI to Fix the Disastrous Vaccine Rollout, Todd Feathers, VICE (February 2021).
- Potential Jurors Favor Use of Artificial Intelligence in Precision Medicine, Rebecca Maxey, SCIENMAG SCIENCEMAGAZINE (January 2021).
- With 'Nutrition Labels' and an Anthropologist's Eye, Duke Pioneers a New Approach to AI in Medicine, Erin Brodwin, STAT (October 2020).
- Remote Monitoring Tech Incites Privacy, Safety Concerns Among Bioethics Activists, Katie Adams, BECKER'S HOSPITAL REVIEW (August 2020).
- European Commission's White Paper on Artificial Intelligence, LANCET DIGITAL HEALTH, Interview Podcast (June 2020).
- Harvard, INSEAD Authors Pitch Systemic Regulatory Approach to AI/ML Devices, Nick Paul Taylor, HEALTHCAREDIVE.COM (April 2020).
- Protecting Rights in a Global Crisis, Jonathan Chernoguz, HARVARD LAW TODAY (March 2020).

When AI is Watching Patient Care: Ethics to Consider, Laurie Flynn, SCOPE (February 2020).

Researchers Call on Regulators to Reduce Risks of AI in Medicine, Greg Slabodkin, HEALTH DATA MANAGEMENT (December 2019).

Chart of the Week, STAT HEALTH TECH NEWSLETTER (October 2019).

How Radiologists Can Avoid Malpractice Lawsuits When Using AI, Marty Stempniak, RADIOLOGY BUSINESS (October 2019).

That Pill Is Watching You - Privacy And Hackability Of Ingestible Electronic Sensors, Elizabeth Fernandez, FORBES (September 2019).

Digital Health Coalition Newsletter (July 2019).

Challenges of Recent Innovations, Digital Health Coalition (May 2019).

Rise of AI in Healthcare Raises Important Questions About Safety, Liability and Privacy, Megan Diamond, HARVARD GLOBAL HEALTH INSTITUTE (October 2018).

## **RESEARCH GRANTS**

#### **ACTIVE RESEARCH GRANTS**

CLASSICA (Validating AI in Classifying Cancer in Real-Time Surgery)

European Union, Horizon Europe (Grant Agreement no. 101057321)

Role: Principal Investigator (UIUC); Co-Principal Investigator, WP8 (Legal, Ethical & Liability)

Total project amount awarded: approx. €6 million

Awarded sum: approx. \$595,276 USD

Dates: May 2022 – April 2026 https://classicaproject.eu/

• OperA (Optimising Colorectal Cancer Prevention through Personalised Treatment with Artificial Intelligence)

European Union, Horizon Europe (Grant Agreement no. 101057099)

Role: Principal Investigator (UIUC); Co-Principal Investigator, WP4 (Addressing Ethical/Legal Concerns)

Total project amount awarded: approx. €6 million (i.e., €4.7 million from Horizon Europe & the remainder from a U.K. funding body)

Awarded sum: approx. \$117,220 USD

Dates: September 2022 – August 2027

https://www.opera.uio.no/

• BLAST (Bioethical, Legal, and Anthropological Study of Technologies)

National Institute of Biomedical Imaging and Bioengineering (NIBIB) and the National Institutes of Health Office of the Director (NIH OD) (Grant Agreement no. 1R21EB035474-01)

Role: Multiple Principal Investigator

Total project amount awarded: \$441,100 USD

Dates: September 2023 – August 2025

## **COMPLETED RESEARCH GRANTS**

• PREMIERE: A PREdictive Model Index and Exchange Repository

National Institute of Biomedical Imaging and Bioengineering (NIBIB) and the National Institutes of Health Office of the Director (NIH OD) (Grant Agreement no. 3R01EB027650-03S1)

Role: Co-Investigator (Supplemental Project PSU)

Total project amount awarded to Penn State: \$186,709 USD

Dates: September 2022 - May 2024

• TCORS: Tobacco Product Composition Effects on Toxicity

National Institute on Drug Abuse (NIDA)/National Institutes of Health (NIH) (Grant Agreement no.

1U54DA058271-01)

Role: Co-Investigator (September 2023 – June 2024)

Total project amount awarded to Penn State: \$19,593,890

Dates: September 2023 – August 2028

## • PMAIL (Project on Precision Medicine, Artificial Intelligence, and the Law)

Novo Nordisk Foundation (Grant Agreement no. NNF17SA027784)

Role: Project Leadership Team Member (July 2021 – June 2023); Research Fellow, Medicine, Artificial Intelligence, and Law, Harvard Law School, Cambridge, MA (August 2018 – June 2021)

## Mapping the Ethics of Synthetic Data

Rock Ethics Institute at Penn State University

Role: Co-Principal Investigator (PSU)

Total project amount awarded: \$13,000 USD

Dates: September 2022 – June 2023

## • Bringing Artificial Intelligence to Medical School Education

Ontario Medical Students Association (OMSA) Open Medical Student Education Research Grant (MSERG)

Role: Co-Investigator

Total amount awarded: \$5,000

Dates: Summer 2019

## Post-Grant-Fund, Open Access Publication

German Federal Ministry of Education and Research (BMBF)

Role: First and Corresponding Author Total amount awarded: €2,427.60

Dates: June 2019

## • ClinhiPS (A Scientific, Ethical and Comparative Legal Analysis of the Clinical Application of Human Induced Pluripotent Stem Cells in Germany and Austria)

German Federal Ministry of Education and Research (BMBF)

Role: Co-Investigator

Total project amount awarded: €657,678.00

Dates: April 2016 – March 2018

## **TEACHING EXPERIENCE**

## UNIVERSITY OF ILLINOIS COLLEGE OF LAW, Urbana-Champaign, IL

Associate Professor of Law

## Courses:

- *Torts* (4-credit hour class) (Spring 2025)
- Health Law (3-credit hour class) (Fall 2024)
- Food and Drug Law (3-credit hour class) (Fall 2024)

## PENN STATE DICKINSON LAW, Carlisle, PA

Assistant Professor of Law

#### Courses:

- *Torts* (4-credit hour class) (Fall 2021, Fall 2022, Fall 2023)
- Health Care Law & Policy (3-credit hour class) (Spring 2022, Spring 2023, Spring 2024)
- Food and Drug Law (3-credit hour class) (Spring 2022, Spring 2023, Spring 2024)
- *S.J.D. Research Colloquium* (with Prof. William E. Butler) (2-credit public, weekly seminar compulsory for S.J.D. students and candidates in residence) (Spring 2023)

#### HARVARD MEDICAL SCHOOL, Boston, MA

Guest Lecturer, "Nutrition Facts Labels" for Artificial Intelligence/Machine Learning-Based Medical Devices (February 2024, virtual)

Course: Bioethics & AI seminar at Harvard Center for Bioethics, instructed by Francis Shen

## UNIVERSITY OF OSLO, FACULTY OF MEDICINE, Oslo, Norway

Guest Lecturer, Legal Considerations Regarding Artificial Intelligence in Medicine (January 2024, virtual)

Course: MED 3065 - Artificial intelligence, Innovation, and Trustworthy Decision Support, organized by Yuichi Mori and Per Olav Vandvik

#### YALE UNIVERSITY, New Haven, CT

Guest Lecturer, AI and Mental Health (April 2023, virtual)

EP&E 318: Healthcare Business Ethics: The Moral Political Economy of Healthcare, instructed by Ximena Benavides

## UNIVERSITY OF NORTH CAROLINA SCHOOL OF LAW, Chapel Hill, NC

Guest Lecturer, The Need for a New Regulatory Framework for AI-Based Medical Devices (February 2023, virtual)
Artificial Intelligence and the Law Seminar, instructed by Andrew Chin

#### VILLANOVA UNIVERSITY, CHARLES WIDGER SCHOOL OF LAW, Villanova, PA

Guest Lecturer, Artificial Intelligence (November 2022, virtual)

Course: Villanova Health Innovation & Equity Speaker Series, instructed by Ana Santos Rutschman

## MASSACHUSETTS INSTITUTE OF TECHNOLOGY, Cambridge, MA

Guest Lecturer, Ethics of Big Data and AI in Healthcare (October 2022, virtual)

Course: Health Sciences and Technology (HST) 590 graduate program: Topics in Biomedical and Research Ethics, primarily attended by MD/PhD and PhD students, instructed by Emily Lindemer

## HARVARD MEDICAL SCHOOL, Boston, MA

Guest Lecturer, Ethical and Legal Considerations for Biomedical AI (March-May 2021, April-May 2022, May 2023, virtual)

Course: BMI 702: Foundations of Biomedical Informatics II, instructed by Marinka Zitnik, Master of Biomedical Informatics Program

## HARVARD T.H. CHAN SCHOOL OF PUBLIC HEALTH, Boston, MA

Guest Lecturer; Artificial Intelligence in Health, Ethics, Privacy, and Bias

Course: Artificial Intelligence in Health, instructed by Deborah DiSanzo, graduate level students from Harvard Medical School and Harvard T.H. Chan School of Public Health (May 2020, July 2021, virtual)

Course: Managing Information in Health, Master in Health Care Management, instructed by Deborah DiSanzo (August 2020, July 2022, August 2023, virtual)

## PENN STATE UNIVERSITY, University Park, PA

Guest Lecturer, Regulation of Artificial Intelligence, Liability & Data Privacy (March 2022, March 2023, virtual)

Course: Biomedical Engineering, Law & Policy, instructed by Jennifer Kristin Wagner

## MCGILL UNIVERSITY, Faculty of Medicine and Health Sciences, Montreal, Quebec, Canada

Guest Lecturer, Ethical and Legal Aspects of Artificial Intelligence in Health Care (September 2021, virtual)

Course: Artificial Intelligence in Medicine, instructed by Jake Barralet & Thomas Fevens, Master of Science

#### MCMASTER UNIVERSITY, Ontario, Canada

Guest Lecturer; Legal, Ethical, and Governance Issues Associated with AI in Health Care (June 2020, virtual)

Course: Social Issues Around AI, instructed by Matthew Jordan

## UNIVERSITY OF MANNHEIM, SCHOOL OF LAW AND ECONOMICS, Germany

Instructor, Civil Law (2014–2015)

Teaching of several courses in Civil Law, and the correction of over 75 exams

Crash Course in Civil Law (January 2015)

Tutorial Civil Law 1.2 (September–December 2014)

Tutorial Civil Law 1.1 (September–December 2014)

Assessor, Oral Exam: Medical and Health Law (March 2015)

Conducted by Prof. Dr. Jochen Taupitz

## **MENTORING**

## UNIVERSITY OF ILLINOIS COLLEGE OF LAW, Urbana-Champaign, IL

Faculty Advisor & Mentor & Supervisor, August 2024-Present

- Actively mentoring and supervising several law students and postdoctoral student/research project team members.
  - ➤ Postdoctoral Fellow, BLAST Project (June 2024–present) (secondary supervisor)
  - ➤ Project Team Member, CLASSICA Project (July 2024–present)

## PENN STATE DICKINSON LAW, Carlisle, PA

Faculty Advisor & Mentor & Supervisor, August 2021–June 2024

- Actively mentoring and supervising several law students (J.D., J.D./M.B.A., J.D./M.P.H., J.D./Doctor of Public Heath, LL.M., S.J.D.) and postdoctoral fellow/research project team members.
  - ➤ Postdoctoral Fellow, BLAST Project (June 2024–July 2024) (secondary supervisor)
  - ➤ Postdoctoral Fellow CLASSICA Project (October 2022—June 2023); Project Team Member CLASSICA Project (July 2023—June 2024)
  - > Two S.J.D. Scholars (topics: Privacy Laws in the U.S. and Europe; Sovereignty and Human Rights in Cyberspace)
  - > J.D./Master of Public Health Student (topic: Can States Ban Access to Specific Medications? Mifepristone and Beyond)
- S.J.D. defenses (chair & committee member)
- Student support (e.g., letters of recommendation, moot court preparation, health certificate introduction, etc.)
- Mentor, Nittany AI Challenge (Spring/Summer 2022)

## HARVARD LAW SCHOOL, Cambridge, MA

Mentor of Graduate Students, Winter 2018, Spring 2019, Summer 2019, Winter 2020

Two students in the J.D. Program, Harvard Law School; one visiting student in the M.D. Program, Schulich School of Medicine and Dentistry, Western University, Canada; one Student Fellow, Petrie-Flom Center, Harvard Law School and Master of Bioethics student at Harvard Medical School

# INSTITUTE FOR GERMAN, EUROPEAN AND INTERNATIONAL MEDICAL LAW, PUBLIC HEALTH LAW AND BIOETHICS OF THE UNIVERSITIES OF HEIDELBERG AND MANNHEIM, Mannheim, Germany

Mentor of Law Students, October 2016-March 2018

Supervision of 24 student assistants

## **SCHOLARSHIPS, AWARDS & RECOGNITION (SELECTION)**

- Sigma Xi Nomination to Full Membership, Sigma Xi, The Scientific Research Honor Society (June 2024).
- Paper Selection, Association of American Law Schools (AALS) Section on Law, Medicine and Health Care's New Voices in Law, Medicine and Health Care Program, 2024 AALS Annual Meeting (August 2023).
- Recognition, cited in the Proposed Rule on Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing by the Office of the National Coordinator for Health Information Technology (ONC), Department of Health and Human Services (HHS) (April 2023).
- Recognition, cited in the FDA's Draft Guidance for Industry and Food and Drug Administration Staff on Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence/Machine Learning (AI/ML)-Enabled Device Software Functions (April 2023).
- Membership in U.S. Cyber Command's Academic Engagement Network, Penn State Dickinson Law, application preparation together with Tonya M. Evans, Amy C. Gaudian & Daryl Lim (December 2022).
- Paper Selection, Association of American Law Schools (AALS) Section on Law, Medicine and Health Care's New Voices Works-in-Progress Workshop, 2023 AALS Annual Meeting (October 2022).
- Paper Selection & Travel Award, 2021 Junior Faculty Forum for Law and STEM organized by Northwestern Pritzker School of Law, Penn Law & Stanford Law; University of Pennsylvania Carey Law School, Philadelphia, PA (October 2021).
- Paper Selection & Award, 2021 Health Law Scholar, American Society for Law, Medicine & Ethics and the Saint Louis University School of Law Center for Health Law Studies (June 2021).
- Recognition, cited in the FDA's Action Plan for Artificial Intelligence/Machine Learning-Based Software as a Medical Device (January 2021).
- Nominee, Shortlist of the AIMed Champion Non-Clinician 2020 Award (December 2020).
- Recognition, PMAIL Project, Tech Spotlight at Harvard Kennedy School's Belfer Center (October 2020).

## **PRESENTATIONS (SELECTION)**

- Labeling & AI, Regulation and Innovation in the Biosciences (RIBS) Workshop, NORTHEASTERN UNIVERSITY SCHOOL OF LAW, Boston, MA (May 2024).
- AI, Its Potential, and Pitfalls in the Light of Health Equity, Annual Health Law Conference, The Future of Health Equity after the End of Affirmative Action, NORTHEASTERN UNIVERSITY SCHOOL OF LAW, Boston, MA (April 2024)
- Labeling Challenges for AI/ML-Based Medical Devices, LOYOLA UNIVERSITY CHICAGO LAW JOURNAL, Chicago, IL (April 2024)
- Legal Issues of Medical AI, THE COMMONWEALTH UNIVERSITY OF PENNSYLVANIA (LOCK HAVEN) ETHICS CENTER, virtual (March 2024).
- *Liability Aspects of Using Artificial Intelligence in Healthcare*, The Future of Law in Technology and Governance, Seminar Series organized and moderated by Michael Madison, UNIVERSITY OF PITTSBURGH LAW SCHOOL & THE CENTER FOR GOVERNANCE AND MARKETS, virtual (March 2024).
- U.S. and EU Tort Liability in Healthcare's Black-Box AI Era, INDIANA LAW REVIEW SYMPOSIUM, virtual (February 2024).
- *Labeling for AI/ML-Based Medical Devices*, The 2024 Randolph W. Thrower Symposium, EMORY UNIVERSITY SCHOOL OF LAW, Atlanta, GA (February 2024).
- *Potential Medical Liability Using AI*, 2024 Symposium on Artificial Intelligence in Health Care and Medical Regulation, FEDERATION OF STATE MEDICAL BOARDS (FSMB), Washington, D.C., virtual (January 2024).
- Decoding US Tort Liability in Healthcare's Black-Box Era: Lessons From the EU, AALS Section on Law, Medicine and Health Care's New Voices in Law, Medicine and Health Care Program, 2024 AALS ANNUAL MEETING, Washington, D.C. (January 2024).
- Policies Protecting Patients, Their Privacy, and Their Data Presentation, Reducing Cancer Care Inequities: Leveraging Technology to Enhance Patient Navigation, PRESIDENT'S CANCER PANEL, Bethesda, Maryland (December 2023).

- Towards Transparency: Creating Labeling Standards for AI/ML-Based Medical Devices, FAIMI Fairness of AI in Medical Imaging, virtual workshop (November 2023).
- Forschung an humanen Embryonen in Deutschland: Die Rechtslage de lege lata und de lege ferenda [Research on Human Embryos in Germany: The Legal Situation de Lege Lata and de Lege Ferenda], Humane Embryonen in der medizinischen Forschung: Tabu? Vertretbar? Chance? [Human Embryos in Medical Research: Taboo? Justifiable? Opportunity?], Interdisciplinary Scientific Conference, hosted by the GERMAN FEDERAL MINISTRY OF EDUCATION AND RESEARCH (BMBF), Berlin, Germany, virtual (October 2023).
- The Urgent Need for "Nutrition Facts Labels" for AI, AMERICAN SOCIETY FOR BIOETHICS AND HUMANITIES (ASBH) AFFINITY GROUP, BIOETHICS & AI SPEAKER SERIES, virtual (August 2023).
- *The Chatbot Doctor: Who is Liable When Patients are Harmed?* Automated Healthcare: ChatGPT, Bing, Bard & the Law of Generative AI, WEILL CORNELL MEDICINE-QATAR, virtual (June 2023).
- Nutrition Facts Labels" for Artificial Intelligence/Machine Learning-Based Medical Device, 2023 Health Law Professors Conference, AMERICAN SOCIETY OF LAW, MEDICINE & ETHICS & UNIVERSITY OF MARYLAND FRANCIS KING CAREY SCHOOL OF LAW, Baltimore, MD (June 2023).
- Legal Implications and Considerations of AI, Fireside Chat, AIMed 2023 Global Summit, San Diego, CA (June 2023).
- *The Issues of Health Apps & Chatbots*, 2023 Tsai Center for Law, Science and Innovation Summit: Food & Drug Scholars Retreat, SMU DEDMAN SCHOOL OF LAW, Vail, CO (May & June 2023).
- "Nutrition Facts Labels" for Artificial Intelligence/Machine Learning-Based Medical Devices—The Urgent Need for Labeling Standards, BioLawLapalooza 5.0, STANFORD LAW SCHOOL, CA (May 2023).
- AI Liability, At the Cutting Edge: Regulating Innovation and the Biosciences, Regulation and Innovation in the Biosciences (RIBS) Workshop, GEORGIA STATE UNIVERSITY COLLEGE OF LAW, Atlanta, GA (May 2023).
- Liability & AI, TEXAS A&M UNIVERSITY SCHOOL OF LAW'S ANNUAL HEALTH LAW CONFERENCE organized by Brendan Maher, virtual (April 2023).
- Legal, Ethical, and Equity Issues Surrounding AI in Healthcare, YALE LAW SCHOOL, virtual (April 2023).
- Fireside Chat Health Law, with Prof. Medha Makhlouf, Student Admission Event, Penn State Dickinson Law, virtual (April 2023).
- New Adventures in Artificial Intelligence, S.J.D. Research Colloquium, PENN STATE DICKINSON LAW (March 2023).
- AI in Mental Health, Artificial Intelligence in Mental Health: Strategies for Avoiding Potential Data Harms, HARVARD LAW SCHOOL, virtual (March 2023).
- *Liability of Medical AI & Data Privacy Aspects*, Medical Ethics Joint Grand Rounds The AI Train Has Left the Station: Can Ethics Catch Up? Ethics Grand Round, NORTHWESTERN UNIVERSITY, virtual (January 2023).
- Ethics, Artificial Intelligence and Big Data in Health Care, Penn State Cancer Institute, Milton S. Hershey Medical Center, PENN STATE COLLEGE OF MEDICINE, virtual (December 2022).
- The World of MedTech: Privacy Laws in the U.S. & Europe, IEEE INTERNATIONAL SYMPOSIUM ON TECHNOLOGY AND SOCIETY 2022, virtual (November 2022).
- Ethics in the Digital Health World, DARPA, ADAPTER / BETR Fall 2022 Program Review, San Diego, CA, virtual (October 2022).
- Bias and Other Challenges in the Ethical Deployment of AI in Healthcare, Symposium of the Cordell Institute for Policy in Medicine & Law, WASHINGTON UNIVERSITY, St. Louis, virtual (October 2022).
- "Nutrition Facts Labels" for Artificial Intelligence/Machine Learning-Based Medical Devices—The Urgent Need for Labeling Standards, Health Law Workshop, HARVARD LAW SCHOOL, Cambridge, MA (September 2022).
- Labeling of Direct-To-Consumer Medical Artificial Intelligence Applications for "Self-Diagnosis," 2022 Petrie-Flom Center Annual Conference: Diagnosing in the Home: The Ethical, Legal, and Regulatory Challenges and Opportunities of Digital Diagnostics and Therapeutics Outside of Traditional Clinical Settings, HARVARD LAW SCHOOL, Cambridge, MA (June 2022).
- Health AI for Good Rather than Evil? The Need for a New Regulatory Framework for AI-Based Medical Devices, 45<sup>th</sup> Annual Health Law Professors Conference, SANDRA DAY O'CONNOR COLLEGE OF LAW, ARIZONA STATE UNIVERSITY, Phoenix, AZ (June 2022).
- Key Issues in AI: Regulation & Legal, AIMED GLOBAL SUMMIT 2022, San Francisco, CA (May 2022).
- Key Issues in AI: Ethics & Equity, AIMED GLOBAL SUMMIT 2022, San Francisco, CA (May 2022).

- Ethical and Legal Aspects of Artificial Intelligence in Health Care, AFRICAN INSTITUTE OF BUSINESS & TECHNOLOGY, virtual (May 2022).
- *Issues of Data Sharing in the World of Medical AI*, At the Cutting Edge: Regulating Innovation and the Biosciences, Regulation and Innovation in the Biosciences (RIBS) Workshop, Innovation, Business, and Law Center, The UNIVERSITY OF IOWA, COLLEGE OF LAW, Iowa City, IA (May 2022).
- Health AI for Good Rather than Evil? The Need for a New Regulatory Framework for AI-Based Medical Devices, BioLawLapalooza 4.2, STANFORD LAW SCHOOL, Stanford, CA (May 2022).
- The Unique Challenges of Labeling for Artificial Intelligence/Machine Learning-Based Medical Devices, Texas A&M University School of Law's Annual Health Law Conference organized by Brendan Maher, virtual (May 2022).
- Ethical, Legal, and Social Issues (ELSI) Workshop, DARPA BTO ELSI group, together with Maxwell Mehlman, Katina Michael & Matthew Wynia, ADAPTER / BETR / POCUS AI Spring 2022 Program Review, DARPA (May 2022).
- Data Privacy Questions in the Digital Health World, Journal of Law & Health, Digital Health & Technology Symposium, CLEVELAND-MARSHALL COLLEGE OF LAW, virtual (April 2022).
- Artificial Intelligence in Health Care, MBI Training Program: Smart Digitalization Decisions in Bioprocess Development and Manufacturing, UNIVERSITY COLLEGE LONDON, DEPARTMENT OF BIOCHEMICAL ENGINEERING, virtual (April 2022).
- Data Privacy Laws in the Research Context, Data Sharing and Data Privacy in the Age of GDPR: Current Challenges and Potential Solutions for Moving Our Clinical Research Forward, DIVISION OF AIDS, NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES, NATIONAL INSTITUTES OF HEALTH, virtual (January 2022).
- Opportunities for Collaboration to Improve Health Equity, Summit on Health Justice, PENN STATE DICKINSON LAW & PENN STATE COLLEGE OF MEDICINE, Hershey, PA (December 2021).
- *ELSI Group*, panel discussion, DARPA's Advanced Acclimation and Protection Tool for Environmental Readiness (ADAPTER) program, DARPA, virtual (November 2021).
- Health AI for Good Rather Than Evil? The Need for a New Regulatory Framework for AI-Based Medical Devices, 2021 Junior Faculty Forum for Law and STEM, UNIVERSITY OF PENNSYLVANIA CAREY LAW SCHOOL, Philadelphia, PA (October 2021).
- The Unique Challenges of Labeling for Artificial Intelligence/Machine Learning-Based Medical Devices, 2021 Health Law Scholars Workshop, AMERICAN SOCIETY FOR LAW, MEDICINE & ETHICS AND SAINT LOUIS UNIVERSITY SCHOOL OF LAW CENTER FOR HEALTH LAW STUDIES, St. Louis, MO (October 2021).
- Ethical and Legal Considerations and Dilemmas Raised by AI in Health Care and Reproductive Health, Use of Artificial Intelligence/Machine Learning to Develop Personalized Approaches to Improve Reproductive Health Outcomes, NICHD/ASRM WORKSHOP, virtual (October 2021).
- Ethical and Legal Aspects of Artificial Intelligence in Health Care, California Artificial Intelligence Summit, GIRLS COMPUTING LEAGUE, virtual (September 2021).
- Artificial Intelligence in Medicine Potential Liability for Physicians, INDIANA ARTIFICIAL INTELLIGENCE WEEK, virtual (September 2021).
- *Culture, Inclusion & Equity and Digital Health Action Collaboratives*, NATIONAL ACADEMY OF MEDICINE LEADERSHIP CONSORTIUM, virtual (August 2021).
- Artificial Intelligence/Machine Learning-Based Software as a Medical Device: The Update Problem & System View, 44<sup>TH</sup> ANNUAL HEALTH LAW PROFESSORS CONFERENCE, virtual (June 2021).
- AI & Health Law, THE EUROPEAN LAW STUDENTS' ASSOCIATION (ELSA) WEBINARS ACADEMY ON LAW AND TECHNOLOGY, virtual (May 2021).
- *Legal Issues of Artificial Intelligence in Health Care*, UNIVERSITY OF OXFORD, FACULTY OF LAW, virtual (May 2021). *Artificial Intelligence*, RIBS WORKSHOP 2021, virtual (May 2021).
- Health AI Ethics, THE AMERICAN BOARD OF ARTIFICIAL INTELLIGENCE IN MEDICINE (ABAIM) REVIEW COURSE, virtual (April 2021).
- Ethical and Legal Aspects of Artificial Intelligence in Health Care and Clinical Research, WIRB-COPERNICUS GROUP, virtual (April 2021).
- *ELSI Group*, panel discussion, DARPA's Advanced Acclimation and Protection Tool for Environmental Readiness (ADAPTER) program, DARPA, virtual (April 2021).

- Artificial Intelligence in Emergency Medicine: The Issue of Bias, StEMi X STANFORD EMERGENCY MEDICINE INNOVATION SYMPOSIUM, virtual (April 2021).
- Ethical & Legal Challenges of Artificial-Intelligence Driven Healthcare, Promoting Equitable Access and Innovations, THE OFFICE OF THE NATIONAL COORDINATOR FOR HEALTH INFORMATION TECHNOLOGY, DEPARTMENT OF HEALTH & HUMAN SERVICES, Annual Meeting, virtual (March 2021).
- Regulating Complexity: Safety Requirements and Cybersecurity of AI-Driven Technology in the Healthcare Sector in the U.S., LEUVEN AI LAW & ETHICS CONFERENCE 2021, virtual (March 2021).

Legal Aspects of AI in Radiology, NORTHWESTERN UNIVERSITY, virtual (March 2021).

Regulation, Ethics & Law, AIMED CLINICIAN SERIES 2021, virtual (March 2021).

When Something Goes Wrong Who Is to Blame: Man, Machine or Both?, 27<sup>th</sup> Annual Thomas Pitts Lectureship in Medical Ethics: Artificial Intelligence in Health Care: Ethical Implications, MEDICAL UNIVERSITY OF SOUTH CAROLINA, virtual (February 2021).

*Misinformation/Disinformation & Medical AI*, Misinformation/ Disinformation & the Law, SAINT LOUIS UNIVERSITY SCHOOL OF LAW, virtual (February 2021).

*The Gene: An Intimate History*, panel discussion, WITF, virtual (February 2021).

Technology and the Law: Examining and Addressing Bias in Healthcare, panel discussion, BOSTON UNIVERSITY JOURNAL OF SCIENCE & TECHNOLOGY LAW (JOSTL) 2021 SYMPOSIUM, virtual (February 2021).

Ethics and AI in Children, AIMED PEDIATRICS, virtual (November 2020).

Data Access and Privacy Issues of Remote Monitoring Devices in the U.S. and Europe, SETON HALL LAW SCHOOL SYMPOSIUM, virtual (November 2020).

Artificial Intelligence and Bias, UNIVERSITY OF DENVER STURM COLLEGE OF LAW, virtual (November 2020).

Al and Healthcare – Mind the Regulation Gap!, organized by Jelena Madir, General Counsel, GAVI, THE VACCINE ALLIANCE, virtual (November 2020).

*Big Data and Artificial Intelligence: Present and Emerging Challenges*, together with Kelly Michelson, Abel Kho, and Craig Klugman, 22<sup>ND</sup> ANNUAL MEETING OF THE AMERICAN SOCIETY FOR BIOETHICS & HUMANITIES, virtual (October 2020).

The Promises and Perils of AI and Digital Health, Annual CLIC Conference, NORTHEASTERN UNIVERSITY, virtual (October 2020).

*Regulatory Issues of AI-Based Medical Devices*, Health & Technology Policy 2020, Center for Law, Ethics & Commerce, GONZAGA UNIVERSITY SCHOOL OF LAW, virtual (October 2020).

*Germany's Digital Health Reforms in the COVID-19 Era: Lessons and Opportunities for Other Countries*, together with Timo Minssen, DIGITAL MEDICINE SOCIETY, virtual (August 2020).

**Population Health and Social Inequities**, AIMED, virtual (July 2020).

Ethical and Legal Issues of Health AI and COVID-19, TECHNIS, virtual (May 2020).

Artificial Intelligence in Health Care – Safety, Effectiveness, and Liability, Symposium Machine Learning, SANTA CLARA UNIVERSITY SCHOOL OF LAW, Santa Clara, CA (March 2020).

Data Rights in the Age of Machine Learning, AIMed, virtual (January 2020).

(Coming) Developments in Health IT, 8th Annual Health Law Year in P/Review, HARVARD LAW SCHOOL, Cambridge, MA (December 2019).

AI in Health, HARVARD TECHNOLOGY REVIEW, Cambridge, MA (October 2019).

Ethical and Legal Challenges of AI in Cardiology, AIMED CARDIOLOGY, Chicago, Illinois, IL (June 2019).

Open Forum: AI in Medicine for Cardiology – Current State of the Art and How to Get Started and Future, AIMED CARDIOLOGY, Chicago, IL (June 2019).

Ethical and Legal Challenges of AI-Driven Health Care in the U.S. and Europe, U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES, virtual (June 2019).

Ethical and Legal Issues of Stem Cell-Based Gametes for Reproductive Purposes, RIBS Symposium, UNIVERSITY OF COPENHAGEN, Denmark (June 2019).

AI and Big Data – Data Protection and Privacy in the US and the EU, Governing Health 4.0: Legal and Ethical Considerations – US-European Perspectives, UNIVERSITY OF COPENHAGEN, Denmark (May 2019).

- Health Care and Life Sciences: Digital Health & Connected Devices, Boston Bar Privacy & Cybersecurity Conference: Managing Digital Risk, BOSTON BAR ASSOCIATION, Boston, MA (May 2019).
- A Smart Pill to Swallow: Legal and Ethical Issues of Ingestible Electronic Sensors, together with Timo Minssen, The 2019 Digital Medicine Symposium, HARVARD BUSINESS SCHOOL AND THE HARVARD MIT CENTER FOR REGULATORY SCIENCES, Boston, MA (May 2019).
- Ethics in Digital Health: The Patient/Consumer Experience, Digital Health Coalition Northeast Summit, AMAG PHARMACEUTICALS, Waltham, MA (May 2019).
- *The Customer Experience Paradigm*, Digital Health Coalition Northeast Summit, AMAG PHARMACEUTICALS, Waltham, MA (May 2019).
- *Precision Medicine: Future Trends & Challenges*, Promises and Perils of Emerging Health Innovations, 2019 Annual Health Law Conference, Center for Health Policy and Law, NORTHEASTERN UNIVERSITY, School of Law, Boston, MA (April 2019).
- Experience the Future of AI in Radiology, AIMed, Boston, MA (April 2019).
- *Ingestible Electronic Sensors: Cutting Edge Medicine, and Their Ethical & Legal Issues*, together with Timo Minssen, BioLawLapalooza, Center for Law and the Biosciences, STANFORD LAW SCHOOL, CA (March 2019).
- How Will AI Transform Healthcare? CELLS (Center for Ethics and Law in the Life Sciences) 10 Year Anniversary Celebration, LEIBNIZ UNIVERSITY HANNOVER, Germany (November 2018).
- *AI in Drug Discovery and Clinical Trials*, Panel IV: Innovations in Drug Discovery and Policy, Drug Pricing Policies in the United States and Globally: From Development to Delivery, HARVARD LAW SCHOOL, Cambridge, MA (October 2018).
- Artificial Intelligence and the Explosion of Health Data: Global Ethical & Legal Issues, together with I. Glenn Cohen, Technology & Health Seminar Series, HARVARD GLOBAL HEALTH INSTITUTE, Cambridge, MA (October 2018).
- *Precision Medicine, Artificial Intelligence, and the Law*, together with I. Glenn Cohen, CeBIL Annual Symposium 2018, UNIVERSITY OF CAMBRIDGE, England (September 2018).
- The Clinical Translation of Human Induced Pluripotent Stem Cells: Legal Challenges and Hurdles? The Clinical Translation of Human Induced Pluripotent Stem Cells: A Stakeholder Conference on the Evaluation of Innovative Risk Research, GOETTINGEN UNIVERSITY MEDICAL CENTER, Germany (October 2017).
- *ELSA Proposal of a New Strategic Working Group*, together with Tobias Cantz, 5<sup>th</sup> Annual GSCN (German Stem Cell Network) Conference, Jena, Germany (September 2017).
- Poster Presentation of the "ClinhiPS" Project, ISSCR (International Society for Stem Cell Research) 2017 Annual Meeting, Boston, MA (June 2017).
- Research in Europe: An Experience Report, Information Seminar on National and European Research Grants, UNIVERSITY OF MANNHEIM, Germany (January 2017).
- CRISPR/Cas9 Genome Editing: The Ethical and Legal Situation in the United Kingdom, Federal Association of the German Centers for Reproductive Medicine (BRZ), Berlin, Germany (April 2016).
- Regulatory Hurdles for Bringing Limbal Stem Cell Research to Clinical Application in Germany and the UK, Durham CELLS (Center for Ethics and Law in the Life Sciences), Durham Law School, Durham, United Kingdom (March 2016).

## ORGANIZATION & MODERATION OF CONFERENCES, WORKSHOPS, ETC. (SELECTION)

- Regulation and Innovation in the Biosciences (RIBS) Workshop, Co-Organizer, Regulation and Innovation in the Biosciences (RIBS) Workshop, NORTHEASTERN UNIVERSITY SCHOOL OF LAW, Boston, MA (May 2024).
- A Symposium Towards Responsible Biomedical AI, Co-Organizer, in person and via webinar, PENN STATE COLLEGE OF ENGINEERING, University Park, PA (October 2023).
- Regulation and Innovation in the Biosciences (RIBS) Workshop, Co-Organizer, GEORGIA STATE UNIVERSITY COLLEGE OF LAW, Atlanta, GA (May 2023).
- 2023 Cyberspace Law & Policy Simulation, Faculty Facilitator, PENN STATE DICKINSON LAW, Carlisle, PA (April 2023).
- Roundtable Discussion on Issues at the Intersection of Artificial Intelligence, Intellectual Property and Healthcare, Moderator & Coordinator, together with Dickinson Intellectual Property Law Society (DIPLS), PENN STATE DICKINSON LAW, virtual (March 2023).

- *ELSA Ethical, Legal and Social Aspects of Stem Cell Research Symposium*, Organization, together with Tobias Cantz & Aljoscha Berve, as part of the 10<sup>th</sup> German Stem Cell Network (GSCN) Annual Conference & 20 Years Stem Cell Network NRW, Münster, Germany (September 2022).
- *War in Ukraine Some Legal and Policy Aspects*, Moderator & Coordinator, together with Dickinson Law's International Law Society, PENN STATE DICKINSON LAW, virtual (April 2022).
- 2022 Cyberspace Law & Policy Simulation, Faculty Facilitator, PENN STATE DICKINSON LAW, Carlisle, PA (February 2022).
- *Machine Learning and Medicine*, Moderator, Annual Bioethics Conference, HARVARD MEDICAL SCHOOL CENTER FOR BIOETHICS, virtual (June 2021).
- AI in Medicine and Healthcare: A Transatlantic Conversation, Moderator, DWIH NEW YORK, GERMAN EMBASSY OTTAWA, GERMAN CONSULATE GENERAL BOSTON, HASSO PLATTNER INSTITUTE, UNIVERSITY ALLIANCE RUHR, virtual (December 2020).
- *ELSA Ethical, Legal and Social Aspects of Stem Cell Research Symposium*, Organization and Moderation, together with Tobias Cantz, as part of the 8<sup>th</sup> German Stem Cell Network (GSCN) Annual Conference, virtual (September 2020).
- Artificial Intelligence and Disability/Dependency: Equity, Access, and Interdependence, Steering Core Committee, together with Danielle Allen, I. Glenn Cohen, Sonoo Thadaney Israni, Eneida A. Mendonca, Carmel Shachar, Michael Stein, HARVARD LAW SCHOOL, Cambridge, MA, virtual (March 2020).
- *ELSA Ethical, Legal and Social Aspects of Stem Cell Research Symposium*, including the workshop *Ethical Aspects of Human-Animal Chimera Research*, Organization and Moderation, together with Tobias Cantz, as part of the 7<sup>th</sup> German Stem Cell Network (GSCN) Annual Conference, MAX DELBRÜCK CENTER (MDC), Berlin, Germany (September 2019).
- Black-Box Medicine: Legal and Ethical Issues, A Health Policy and Bioethics Consortium, Organization, together with the team at Harvard Law School's Petrie-Flom Center, Harvard Medical School Center for Bioethics, and the Program on Regulation, Therapeutics, and Law (PORTAL) at Brigham and Women's Hospital, HARVARD LAW SCHOOL, Cambridge, MA (February 2019).
- Seventh Annual Health Law Year in P/Review, Moderation of the Panel Discussion: AI in Health Care, HARVARD LAW SCHOOL, Cambridge, MA (December 2018).
- ELSA Ethical, Legal and Social Aspects of Stem Cell Research Symposium, including the workshops Cell Therapy and Genome Editing, Organoids, & Gametes, Organization and Moderation, together with Tobias Cantz, as part of the 6<sup>th</sup> German Stem Cell Network (GSCN) Annual Conference, GERMAN CANCER RESEARCH CENTER (DKFZ), Heidelberg, Germany (September 2018).
- *Nudging and AI Governance*, Working Sessions, Organization and Moderation, as part of the AI-Health Working Group, Berkman Klein Center for Internet & Society at Harvard University and Petrie-Flom Center, HARVARD LAW SCHOOL, Cambridge, MA (June 2018–August 2018).
- Requirements for Securing Donor Rights Workshop, Organization & Moderation, together with Solveig Lena Hansen, The Clinical Translation of Human Induced Pluripotent Stem Cells: A Stakeholder Conference on the Evaluation of Innovative Risk Research, GOETTINGEN UNIVERSITY MEDICAL CENTER, Germany (October 2017).

## **INVITED ROUNDTABLES/SUMMITS (SELECTION)**

- Innovation Forum on Capitol Hill, PENN STATE DICKINSON LAW, U.S. Capitol Visitor Center, Washington, D.C. (October 2023).
- Collaboratively Envisioning AI and Ethics in Biomedical Research Microlab 1, NIH OFFICE OF DATA SCIENCE STRATEGY, virtual (December 2021).
- Ethical Challenges Posed by Big Data for AI in Healthcare, THE HASTINGS CENTER, HASSO PLATTNER INSTITUTE, UNIVERSITY COLOGNE, NYU LANGONE HEALTH, virtual (December 2020).
- Data and COVID-19, Roundtable with the Berkman Klein Center for Internet & Society and the Petrie-Flom Center, HARVARD LAW SCHOOL, virtual (June 2020).
- Roundtable on Balancing Privacy with Health Data Access, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, Washington, D.C. (July 2019).
- Roundtable: Mitochondrial Replacement Therapy: Considering the Future of U.S. Policy "Three-Parent IVF", HARVARD LAW SCHOOL, Cambridge, MA (April 2019).

Roundtable on Sharing and Utilizing Health Data for AI Applications, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, Washington, D.C. (April 2019).

Harvard AI for Global Health Summit, Hype vs. Reality: The Role of Artificial Intelligence in Global Health, HARVARD GLOBAL HEALTH INSTITUTE, Cambridge, MA (February 2019).

## **AFFILIATIONS & SERVICE TO THE COMMUNITY**

#### ACTIVE

Member, Lectures Committee, UNIVERSITY OF ILLINOIS COLLEGE OF LAW, Urbana-Champaign, IL (July 2024–Present).

Member, SIGMA XI, THE SCIENTIFIC RESEARCH HONOR SOCIETY (June 2024–Present)

Member, AMERICAN BAR ASSOCIATION (ABA) (August 2023–Present)

#### Sections:

- Health Law
- Science & Technology Law
- Legal Education and Admissions to the Bar

*Member*, AMERICAN TELEMEDICINE ASSOCIATION (ATA), Data Privacy & AI Committees, Arlington, VA (March 2023–Present).

Member, Editorial Board, NPJ DIGITAL MEDICINE (November 2022–Present).

Member, Regulation and Innovation in the Biosciences (RIBS) Steering Committee (July 2022–Present).

Member, American Health Law Association (January 2022–Present).

Member, THE ASSOCIATION OF AMERICAN LAW SCHOOLS (AALS) (November 2021–Present).

#### Sections:

- Comparative Law (October 2023–Present)
- European Law (October 2023–Present)
- Internet and Computer Law (October 2023–Present)
- Law, Medicine, and Health Care (November 2021–Present)
- Biolaw (November 2021–Present)

*Member*, Ethical, Legal, and Social Issues (ELSI) Group, **DARPA'S ADVANCED ACCLIMATION AND PROTECTION TOOL** FOR ENVIRONMENTAL READINESS (**ADAPTER**) PROGRAM (April 2021–Present).

Member, Advisory Group – Academic, AMERICAN BOARD OF AI IN MEDICINE (ABAIM) (May 2020–Present).

*Initiator*, ELSI Strategic Working Group, together with Tobias Cantz, GERMAN STEM CELL NETWORK (GSCN) (September 2017–Present).

*Member*, ASSOCIATION FOR THE PROMOTION OF GERMAN, EUROPEAN AND INTERNATIONAL MEDICAL LAW, HEALTH LAW AND BIOETHICS IN MANNHEIM AND HEIDELBERG, Germany (March 2014—Present).

#### **COMPLETED**

*Member*, **AMERICAN SOCIETY FOR BIOETHICS AND HUMANITIES (ASBH)**, Bioethics and Artificial Intelligence Affinity Group (April 2023–May 2024).

*Member*, FEDERATION OF STATE MEDICAL BOARDS OF THE UNITED STATES, INC. (FSMB) Ethics and Professionalism Committee, Washington, DC (June 2023–April 2024).

*Member*, **PENN STATE CANCER INSTITUTE**, Milton S. Hershey Medical Center, Penn State College of Medicine, Hershey, PA (September 2022–June 2024).

*Member*, Faculty Rights and Responsibilities Committee, PENN STATE DICKINSON LAW, Carlisle, PA (August 2022–June 2024).

*Member*, International Programs and Graduate Education Committee, PENN STATE DICKINSON LAW, Carlisle, PA (August 2022–June 2024).

Member, S.J.D. Program, Core Faculty, PENN STATE DICKINSON LAW, Carlisle, PA (April 2022–June 2024).

Member, 1L Faculty Working Group, PENN STATE DICKINSON LAW, Carlisle, PA (August 2021–June 2024).

Member, Stem Cell Research Oversight (SCRO) committee, SANA BIOTECHNOLOGY (February 2021–June 2024).

Research Member (Health Law), Z-INSPECTION® INITIATIVE (November 2020–February 2022).

*Member*, Advisory Committee, Understanding the Evolving Regulation of AI in Health Care, AIMED GLOBAL SUMMIT 2023 (July 2022–June 2023).

*Member*, Health Justice Advisory Team, PENN STATE COLLEGE OF MEDICINE & PENN STATE DICKINSON LAW (June 2022–August 2023).

Member, Law Review Committee, PENN STATE DICKINSON LAW, Carlisle, PA (August 2021–July 2022).

*Member*, International & Non-J.D. Programs Committee, PENN STATE DICKINSON LAW, Carlisle, PA (August 2021–July 2022).

Member, Library Committee, PENN STATE DICKINSON LAW, Carlisle, PA (August 2021–July 2022).

*Member*, Working Group: The Ethics of Big Data for AI in Health Research and Healthcare, NYU GROSSMAN SCHOOL OF MEDICINE, DIVISION OF MEDICAL ETHICS (May 2021–January 2022).

Member, AMERICAN SOCIETY OF BIOETHICS AND HUMANITIES (September 2020–August 2021).

Member, DURHAM CELLS (CENTER FOR ETHICS AND LAW IN THE LIFE SCIENCES), UK (August 2015–March 2016).

Member, International Society for Stem Cell Research (February 2015–December 2022).

Jury Member, Negotiation Competition 2014, ELSA (EUROPEAN LAW STUDENTS' ASSOCIATION) MANNHEIM E.V., Germany (November 2014).

Probation Officer, NEUSTART, a non-profit private limited company, Mannheim, Germany (July 2014–October 2016).

## PEER REVIEWER (SELECTION)

- Science
- New England Journal of Medicine (NEJM)
- Nature Medicine
- Nature Machine Intelligence
- Npj Digital Medicine
- NEJM AI
- Cambridge University Press
- Oxford Journal of Legal Studies
- American Journal of Law & Medicine
- *Journal of Law and the Biosciences*
- American Journal of Public Health
- Annals of Internal Medicine

- PLOS Global Public Health
- *Health Affairs*
- The American Journal of Bioethics
- The AMA Journal of Ethics
- Journal of Medical Ethics
- Bioethics
- BMC Medical Education
- Ethics & Human Research
- Health Policy & Technology
- Lancet Digital Health
- Annals of Internal Medicine
- International Journal of Law and Psychiatry

## RESEARCH STAYS

Center for Advanced Studies in Biomedical Innovation Law (CeBIL), University of Copenhagen, Denmark (May–June 2019)

Projects on ethical and legal issues with AI and medicine, including working on comparative approaches, cardiac devices as well as data protection and privacy.

The Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School, Cambridge, MA (April–June 2018)

The ethics and law of in vitro gametogenesis (IVG) in the U.S. and Europe, reproductive and regenerative medicine, U.S. patent and Food and Drug Administration (FDA) law.

Durham Law School, Durham University, United Kingdom (June 2015–March 2016)

Field of study: Legal framework for bringing stem cell research to clinical application in the EU, Germany and the UK Supervisor: Prof. Shaun D. Pattinson

## LANGUAGES

German: Native languageEnglish: Business fluent

French: Basic knowledgeSpanish: Basic knowledge