NIH Policy and Ethics of Record Linkage Workshop Biographies

June 29-30, 2021

Policy and Ethics of Record Linkage Workshop Biographies

Day One: 6/29

Opening Remarks – Susan Gregurick, Ph.D.

Associate Director for Data Science and Director of the Office of Data Science Strategy, NIH

Dr. Gregurick was previously the Division Director for Biophysics, Biomedical Technology, and Computational Biosciences at the National Institute of General Medical Sciences (NIGMS). Her mission in this role was to advance research in computational biology, biophysics and data sciences, mathematical and biostatistical methods, and biomedical technologies in support of the NIGMS mission to increase our understanding of life processes. In this role Dr. Gregurick led the institutes effort to reimagine the NIGMS technology programs including early stage, concept development, focused technology programs, development and dissemination centers, through National and Regional Resources to support state-of-the-art facilities, equipment, technologies, research tools, software, and service.

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Dr. Gregurick received her undergraduate degree in chemistry and mathematics from the University of Michigan and her Ph.D. in physical chemistry from the University of Maryland. She completed a Lady Davis postdoctoral fellowship at Hebrew University in Israel and a Sloan postdoctoral fellowship at the University of Maryland's Center for Advanced Research in Biotechnology, now the Institute for Bioscience & Biotechnology Research, in Shady Grove, Md.

Overview of the Workshop - Pilar Ossorio, J.D., Ph.D. (Chair)

Professor of Law and Bioethics, University of Wisconsin-Madison Law School

Dr. Ossorio is Professor of Law and Bioethics at the University of Wisconsin-Madison (UW) and the Ethics Scholar-in-Residence and Ethics Program Lead at the UW-affiliated, non-profit Morgridge Institute for Research. She is also a trainer in the Computation and Informatics in Biology and Medicine training program. She directs UW's Research Ethics Consultation Service and led the ethics core of UW's Center for Predictive Computational Phenotyping. Dr. Ossorio has served on numerous national and international policy committees. Her research interests include: governance of emerging technologies; ethics and regulation of machine learning for health care; data sharing; regulation of research with human participants; the use of race in research and health care; and other questions relating to ethics in genomics.

Ongoing NIH Pilots and Considerations of Record Linkage

An Introduction to Privacy Preserving Record Linkage: What It Is and Why It Matters – Alastair Thomson

Chief Information Officer, National Heart, Lung, and Blood Institute, NIH

Originally from the South Island of New Zealand, Alastair received his BSc(Hons) in Psychology from the University of Otago in 1984 where he developed a computer system for temporospatial analysis of EEG

data, followed by a Graduate Diploma in Computer Science in 1992 with a dissertation on the use of temporal neural networks for the composition of music.

After working for Television New Zealand he formed a computer animation business and established partnership between TVNZ and the University of Otago that became Animation Research Limited, which focuses on real-time animation for television broadcasts including the sailing and golf. The then joined the University of Otago as Director of the Computer Science Applied Research Center where he worked to commercialize the research discoveries of the Department of Computer Science.

In 1997 he the move to the United States to work with MCI Telecommunications before joining a small consulting firm where he spent time guiding the construction and management of complex IT systems for insurance, finance, logistics, telecommunications, clinical research lab testing and for several government agencies including the NIH.

As a consultant at the NIH he worked for several research Institutes and Centers providing advice in enterprise architecture and Agile software development. Alastair was appointed Chief Information Security Officer in 2012 and became Chief Information Officer in 2013. He has since led major programs supporting the NHLBI Intramural Research Program including deployment of a multi-petabyte high performance storage system to support research, pilots of cloud services for genomic analysis, bio-physics simulations and real-time image reconstruction for cardiac MRI. He currently serves as the co-lead of the NHLBI BioData Catalyst cloud based eco-system for data driven research. He continues to advance the IT support provided to the Intramural Program while also helping to drive key programs such as the Post Acute Sequlae of SARS-CoV-2 (PASC) and Cure Sickle Cell Initiatives.

Linking TCIA Imaging Data with N3C EHR Data – Sam Michael

Chief, Information Technology Resources Branch, National Center for Advancing Translational Sciences, NIH

I have been the chief of the Information Technology Resources Branch (ITRB) at NCATS for over 5 years now after having spent the previous 10 years as the lead of the Automation and Compound Management group (ACOMM). While working as the lead of ACOMM, the group successfully completed hundreds of high throughput screens (HTS) spanning a multitude of complex assay types that have led to hundreds of probe compounds and several investigational new drugs (IND). These hundreds of HTS campaigns required over 1 million 1536 well assay plates to execute, representing billions of data points

generated. We also helped establish critical platforms such as combination screening, automated tissue culture, and the 3D tissue group which are currently in use at NCATS to help advance our scientific mission. The sheer volume of production and complex systems required to generate and analyze this volume of scientific data led me to realize that laboratory automation was essentially a complex information technology (IT) problem, so when the opportunity arose to become the acting chief information officer (CIO) at NCATS I took it. To ensure that there was no disconnect between the scientific needs of the center and the IT resources required to meet them, the ITRB group was formed to essentially merge the two. The group now has three distinct components, the Research Services Core (RSC), which is responsible for all intramural scientific platforms at NCATS, the Information Technology Services Section (ITSS) , which is responsible for all IT systems across the center; both intramural and extramural, and the Cybersecurity Section (CSS), which is responsible for ensuring the security and privacy of all NCATS systems. ITRB is responsible for the development, operation, maintenance, security, and continuous improvement of multiple automated systems, including several complex cloud environments supporting thousands of users across both NIH and the extramural community. Our responsibility is to build and support these secure scientific collaborative platforms to enable the scientific mission of NCATS, especially in response to the COVID-19 pandemic where we have done extensive work both intra and extramurally.

P3RL Software Landscape and Assessment: Evaluation Process and Lessons Learned – Lynne Penberthy, M.D., M.P.H.

Associate Director, Surveillance Research Program, National Cancer Institute, NIH

Dr. Lynne Penberthy is the Associate Director for the Surveillance Research Program (SRP), which is within the Division of Cancer Control and Population Sciences (DCCPS) at the National Cancer Institute (NCI). Dr. Penberthy obtained her MD from the University of Michigan and her MPH in epidemiology at Johns Hopkins. Dr. Penberthy's career includes a surgical internship in Baltimore, Maryland, at the Sinai Hospital and a preventive medicine residency at Johns Hopkins University. After her residency, she completed her post-doctoral training in epidemiology with the CDC as an epidemic intelligence service (EIS) officer with the Commonwealth of Virginia. She is licensed to practice medicine in the state of Maryland.

Prior to her NCI appointment, Dr. Penberthy was the Director of Cancer Research Informatics and Services and Associate Professor of General Internal Medicine at the Virginia Commonwealth University Massey Cancer Center. She directed a team in the development of innovative software with the objectives of using existing data for clinical trials eligibility screening, automated capture of treatment data from oncology practice claims, and the extraction of clinical characteristics from various electronic medical records (EMR) components. Dr. Penberthy was also involved in biobanking and annotation of specimens using clinical data. She has 20 years of experience in cancer surveillance and automation using secondary data. Dr. Penberthy has worked on more than 20 grants and contracts as well as 31 publications related to using secondary data and/or informatics tools for cancer surveillance and clinical trials assessment.

Privacy and Security of Record Linkage – Anthony Solomonides, D.Phil.

Program Director, Outcomes Research and Biomedical Informatics, NorthShore University Health System

Anthony (Tony) Solomonides is a biomedical informatician, serving as Program Director for Outcomes Research at NorthShore University HealthSystem, Evanston, IL. Trained initially in Mathematics, he switched to Computer Science and almost immediately began working with physicians in the development of clinical trial records in the mid-1980's while also working on other large-scale projects, including a Large Hadron Collider experiment. Since 2002, Biomedical Informatics has been at the heart of all his research. Before transitioning from the UK to the US, he had collaborated on projects in a broad range of clinical topics, including type II diabetes, inflammatory bowel disease, and breast cancer screening, before tackling some methodological issues, such as learning from the use of clinical pathways, and ethical and legal issues in data sharing.

Soon after his appointment to NorthShore in 2011, he engaged with the Chicago-wide PCORnet CRN, CAPriCORN and eventually led a number of local studies and as CAPriCORN PI for the study of the effects of antibiotics in infancy on weight trajectories. For the past three years, he has served as PI for NorthShore in the Chicago-Rush-led Institute for Translational Medicine, a CTSA program. He has led two Working Groups of the American Medical Informatics Association and been an active member of its Public Policy and Ethics Committees. In the policy arena, he is active in aspects of computable biomedical knowledge and clinical decision support, in mapping social determinants of health, and in bias in AI. Tony is a strong advocate for personal health records and meaningful stakeholder

engagement in research, including aspects that might be described as “quantified self” or “citizen science.”

Considerations and Wrap Up - Patricia Flatley Brennan, R.N., Ph.D.

Director, National Library of Medicine, NIH

Patricia Flatley Brennan, RN, PhD, is the Director of the National Library of Medicine (NLM), one of the 27 Institutes and Centers of the National Institutes of Health (NIH). NLM, the center for biomedical and health data science research, is the world’s largest biomedical library and the producer of digital information services used by scientists, health professionals and members of the public worldwide.

Since assuming the directorship in August 2016, Dr. Brennan has positioned the Library to be the hub of data science at NIH and a national and international leader in the field. She spearheaded the development of a new strategic plan that envisions NLM a platform for biomedical discovery and data-powered health. Leveraging NLM’s heavily used data and information resources, intramural research, and extramural research and training programs, Brennan aims for NLM to accelerate data driven discovery and health, engage with new users in new ways, and develop the workforce for a data-driven future.

Her professional accomplishments reflect her background, which unites engineering, information technology, and clinical care to improve the public health and ensure the best possible experience in patient care.

Dr. Brennan came to NIH from the University of Wisconsin-Madison, where she was the Lillian L. Moehlman Bascom Professor at the School of Nursing and College of Engineering. She also led the Living Environments Laboratory at the Wisconsin Institutes for Discovery, which develops new ways for effective visualization of high dimensional data.

She received a master of science in nursing from the University of Pennsylvania and a PhD in industrial engineering from the University of Wisconsin-Madison. Following seven years of clinical practice in critical care nursing and psychiatric nursing, Dr. Brennan held several academic positions at Marquette University, Milwaukee; Case Western Reserve University, Cleveland; and the University of Wisconsin-Madison.

A past president of the American Medical Informatics Association, Dr. Brennan was elected to the Institute of Medicine of the National Academy of Sciences (now the National Academy of Medicine) in 2001. She is a fellow of the American Academy of Nursing, the American College of Medical Informatics, and the New York Academy of Medicine.

In 2020, Dr. Brennan was inducted into the American Institute for Medical and Biological Engineering (AIMBE). The AIMBE College of Fellows is among the highest professional distinctions accorded to a medical and biological engineer.

Day Two: 6/30

Welcome Back Opening - Susan Gregurick, Ph.D.

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Participant Perspectives of Record Linkage – Sharon Terry, M.A.

President and Chief Executive Officer, Genetic Alliance

Sharon F. Terry is President and CEO of Genetic Alliance, an enterprise engaging individuals, families and communities to transform health. Genetic Alliance works to provide programs, products and tools for ordinary people to take charge of their health and to further biomedical research. As 'just a Mom' with a master's degree in theology, she cofounded PXE International, a research advocacy organization for the genetic condition pseudoxanthoma elasticum (PXE), in response to the diagnosis of PXE in her two children in 1994. She is a co-discoverer of the ABCC6 gene, and patented it to ensure ethical stewardship in 2000, assigning her rights to the foundation. She subsequently developed a diagnostic test and conducts clinical trials. She is the author of 150 peer-reviewed papers, of which 30 are clinical PXE studies. Her story is the topic of her TED Talk and TED Radio Hour. In her focus at the forefront of consumer participation in genetic research, services and policy, she serves in a leadership role on many major international and national organizations and projects. Terry is an Ashoka Fellow. She is an avid student and facilitator of Gestalt Awareness Practice, offering workshops and individual facilitation. Her daughter and son, their wives, and her granddaughter ground and enliven her.

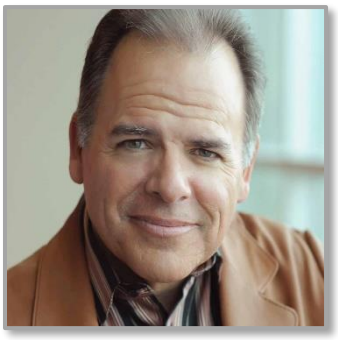
Ethics of Record Linkage - Richard Sharp, Ph.D.

Director, Biomedical Ethics Program, Center for Individualized Medicine Bioethics Program and the Clinical and Translational Research Ethics Program, Mayo Clinic

Dr. Richard Sharp is the Lloyd A. and Barbara A. Amundson Professor of Biomedical Ethics and Professor of Medicine at Mayo Clinic, where he serves as the Director of the Biomedical Ethics Program, the Center for Individualized Medicine Bioethics Program, and the Clinical and Translational Research Ethics

Program. Prior to joining Mayo Clinic in 2013, he was Director of Bioethics Research at Cleveland Clinic and Co-Director of the Center for Genetic Research Ethics and Law at Case Western Reserve University. Dr. Sharp has published widely on topics in biomedical ethics, including the integration of genetic technologies into patient care, best practices for clinical ethics consultation, financial conflicts of interest and ethical dimensions of patient advocacy. His current research is examining how patients and healthcare providers view new forms of personalized medicine and clinical interventions enabled by molecular diagnosis. Dr. Sharp frequently advises healthcare organizations on ethical issues and has served on advisory committees for the National Institutes of Health, Institute of Medicine, American College of Medical Genetics, and US Environmental Protection Agency

Connecting Main Ideas Panel Discussion – Spero Manson, Ph.D. (Moderator)



Professor of Public Health and Psychiatry, Director of Centers for American Indian and Alaska Native Health, and Associate Dean of Research, Colorado School of Public Health, University of Colorado Denver's Anschutz Medical Center

Spero M. Manson, Ph.D. (Pembina Chippewa) is Distinguished Professor of Public Health and Psychiatry, directs the Centers for American Indian and Alaska Native Health, and occupies the Colorado Trust Chair in American Indian Health within the Colorado School of Public Health at the University of Colorado Denver's Anschutz Medical Center. His programs include 10 national centers, which pursue research, program development, training, and collaboration with 225 Native communities, spanning rural, reservation, urban, and village settings across the country. Dr. Manson has acquired $268 million in sponsored research to support this work and published 280 articles on the assessment, epidemiology, treatment, and prevention of physical, alcohol, drug, as well as mental health problems over the developmental life span of Native people. His numerous awards include the APHA's Rema Lapouse Mental Health Epidemiology Award (1998) and Award for Lifetime Contribution to the Field of Mental Health (2019), 4 special recognition awards from the IHS (1985, 1996, 2004, 2011), election to the National Academy of Medicine (2002); 2 Distinguished Mentor Awards from the GSA (2006; 2007), AAMC's Nickens Award (2006); George Foster Award for Excellence (2006) and Career Achievement Award (2020) from the Society for Medical Anthropology, NIH Health Disparities Award for Excellence (2008), Bronislaw Malinowski Award from the Society for Applied Anthropology (2019); and CDC Foundation's Elizabeth Fries Health Education Award (2021). He is widely acknowledged as one of the nation's leading authorities in regard to Indian and Native health.

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