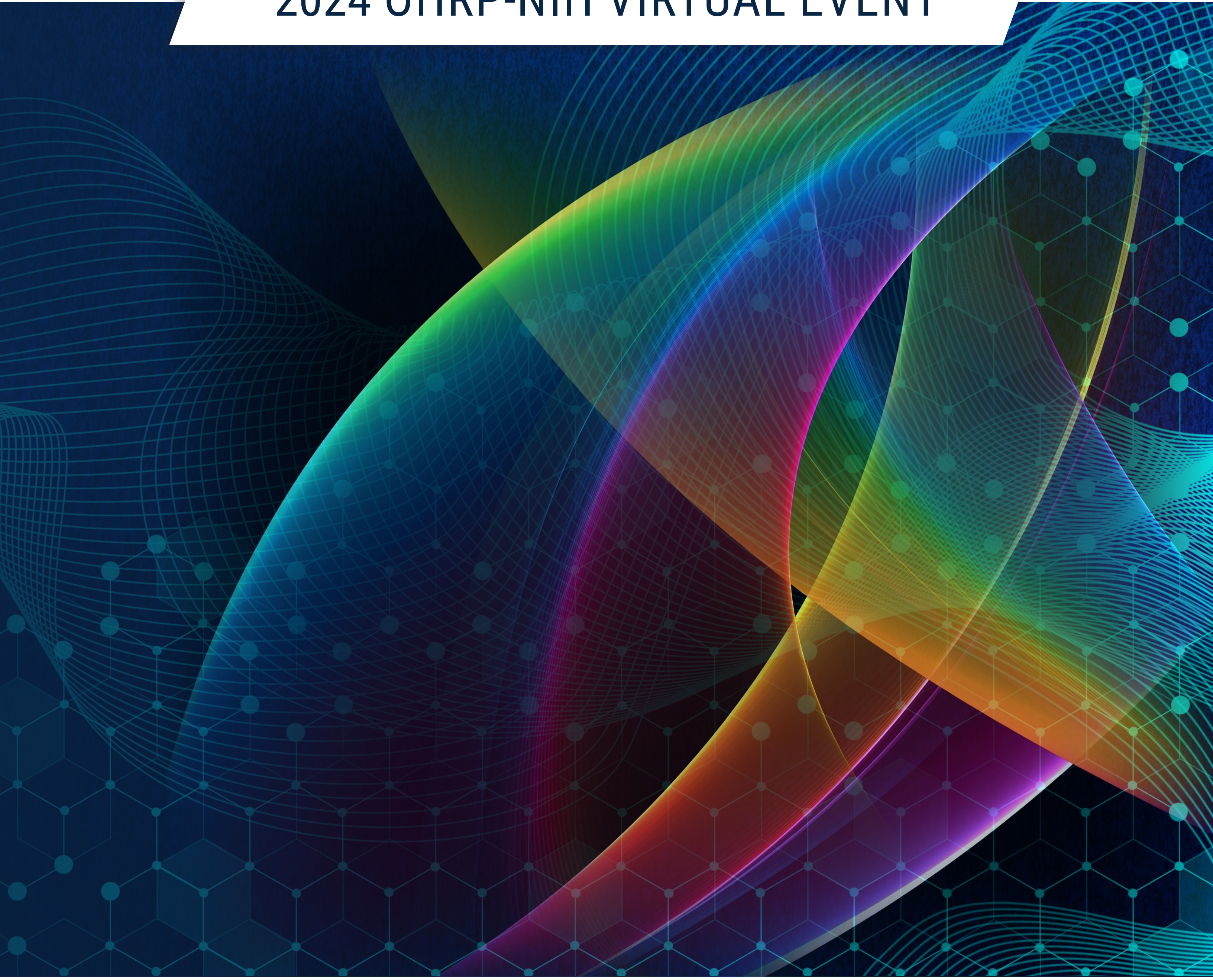
ADVANCING RESEARCH PARTICPATION FOR LGBTQI+ INDIVIDUALS

2024 OHRP-NIH VIRTUAL EVENT



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INTRODUCTION

This webinar, sponsored jointly by the Department of Health and Human Services' Office for Human Research Protections (OHRP) and the Sexual & Gender Minority Research Office (SGMRO) at the National Institutes of Health, supported the goal of promoting diversity, inclusivity, and appropriate representation in biomedical and socio-behavioral research to improve health for everyone.

Promoting diversity, inclusivity, and appropriate representation in biomedical and socio-behavioral research is important to improve health outcomes for everyone in the nation. This webinar focused on advancing this endeavor for LGBTQI+ individuals.

AGENDA

Time	Sessions
Session Title	**Opening Remarks**
12:00 p.m.– 12:10 p.m.	**Rachel L. Levine, MD (she, her)** *Admiral, U.S. Public Health Service, Assistant Secretary for Health, U.S. Department of Health and Human Services*
Session Title	**Review of the SACHRP Recommendations for the Ethical Review and Inclusion of LGBTQI+ Participants in Human Subjects Research**
12:10 p.m.– 12:25 p.m.	**Linda Coleman, JD, CIP, CHC, CHRC, CCEP-I (she, her)** *Associate Vice Provost, Research Policy & Integrity, Office of the Vice Provost and Dean of Research, Stanford University*
Session Title	**The Complex and Evolving Concepts of Sex and Gender**
12:25 p.m.–12:40 p.m.	**Catherine Clune-Taylor, PhD, BMSc (she, her)** *Assistant Professor, Program in Gender and Sexuality Studies, Princeton University*
Session Title	**Ethical Engagement of Minority and Underserved Populations in Research**
12:40 p.m.–12:55 p.m.	**Jennafer (Jenn) Kwait, MHS, PhD (she, her)** *Research Scientist, Whitman-Walker Institute*
Session Title	**The Importance of SOGI Data Collection in Research**
12:55 p.m.–1:10 p.m.	**Christina N. Dragon, MSPH, CHES (she, her)** *Measurement & Data Lead, SGMRO, NIH*
Session Title	**Ethical Challenges of Research with LGBTQIA+ Populations**
1:10 p.m.–1:25 p.m.	**Katharine B. Dalke, MD, MBE (she/her, they/them)** *Vice Chair for Clinical Operations, Department of Psychiatry, Penn Medicine, Benjamin Rush Associate Professor of Clinical Psychiatry, Perelman School of Medicine at the University of Pennsylvania, Affiliated Faculty Member, Eidos LGBTQ+ Health Initiative at the University of Pennsylvania*
Session Title	**Panel Discussion and Audience Questions**
1:25 p.m.–1:58 p.m.	**Moderator: Karen Parker, PhD, MSW (she, her)** *Director, Sexual & Gender Minority Research Office, National Institutes of Health*
Session Title	**Closing Comments**
1:58 p.m.–2:00 p.m.	

SPEAKER BIOGRAPHIES

Rachel L. Levine, MD (she, her)
Admiral, U.S. Public Health Service, Assistant Secretary for Health, U.S. Department of Health and Human Services

Admiral Rachel L. Levine serves as the 17th Assistant Secretary for Health for the U.S. Department of Health and Human Services (HHS) and the head of the U.S. Public Health Service Commissioned Corps. She fights every day to improve the health and well-being of all Americans. She's working to ensure health equity is front and center to build a stronger foundation for a healthier future—one in which all people and places in our nation can thrive. During Admiral Levine's storied career, first as a pediatrician and adolescent medicine specialist in academic medicine focused on the intersection between mental and physical health, treating children, adolescents, and young adults, then as Pennsylvania's Physician General, and later as Pennsylvania's Secretary of Health, she addressed COVID-19, the opioid crisis, behavioral health, and other public health challenges.

Linda Coleman, JD, CIP, CHC, CHRC, CCEP-I (she, her)
Associate Vice Provost, Research Policy & Integrity, Office of the Vice Provost and Dean of Research, Stanford University

Linda Coleman is the Associate Vice Provost, Research Policy & Integrity at Stanford University, where she oversees research security, conflict of interest, data governance and privacy, and the responsible and ethical conduct of research. Before joining Stanford, she was the Director of the Human Research Protection Program at Yale University, which included oversight of its Institutional Review Board and various non-IRB committees. Prior to Yale, Ms. Coleman held progressive roles at Quorum Review (now part of Advarra), an independent IRB and consulting organization serving institutional, independent, and international research sites, including Vice President of Legal & Regulatory Affairs and Director of Regulatory Affairs & General Counsel. Earlier in her career, she worked as an attorney at Bennett, Bigelow & Leedom, focusing on health law, Medicare and Medicaid reimbursement, litigation, behavioral health, and employment law.

Ms. Coleman is actively involved in the research ethics community, serving on various advisory committees and boards. Her interests include ethical integrity in human subjects research and emerging research domains, decentralized trials, data protection, research capacity building, bioethics, global research issues, and improving access to health care and research participation.

Catherine Clune-Taylor, PhD, BMSc (she, her)
Assistant Professor, Program in Gender and Sexuality Studies, Princeton University

Catherine Clune-Taylor is an Assistant Professor in the Program in Gender and Sexuality Studies at Princeton University. She is known for her in-depth, critical feminist analysis of the science of sex, gender, and sexual difference drawing on her training in feminist theory, philosophy of science, and bioethics, and in the biomedical sciences. Dr. Clune-Taylor has published articles on the medical management of intersex conditions in children in *Hypatia* and *Bioethics*, and on the limits of conscientious objection in *The American Journal of Public Health*. She is the author of the chapter "Is Sex Socially Constructed?" in the *Routledge Handbook on Feminist Philosophy of Science* published in 2020. Her book *Securing Autonomously Gendered Futures: A Feminist Philosophical Defense of Intersex and Trans Kids* is currently under review.

Jennafer (Jenn) Kwait, MHS, PhD (she, her)
Research Scientist, Whitman-Walker Institute

Jenn Kwait has worked in public health for over thirty years, beginning as a counselor and health educator at a women's health care clinic in Philadelphia. She came to Whitman-Walker in D.C. via Metro TeenAIDS, bringing with her a research project exploring wellness for LGBTQ+ youth. Currently, Dr. Kwait is the Whitman-Walker site (sub-site of Johns Hopkins) Principal Investigator for the Multicenter AIDS Cohort Stud/Women's HIV Interagency Study Combined Cohort Study focusing on psychosocial and behavioral-related factors, with special interests in stigma and engagement and retention in the cohort. Among other projects focused on LGBTQ+ community engagement, she also co-leads a PCORI-funded community engagement award to build capacity of LGBTQ+ people assigned female sex at birth to be full partners in future sexual and reproductive health care-focused research.

Christina N. Dragon, MSPH, CHES (she, her)
Measurement & Data Lead, SGMRO, NIH

Christina Dragon serves as the Measurement and Data Lead in the NIH Sexual and Gender Minority Research Office and works part time supporting the HHS Office of the Assistant Secretary for Health as the SOGI Data Implementation Specialist. Previously, she served as the Sexual and Gender Minority Data Lead in Medicare's Office of Minority Health and as the data analyst for the Health People 2020 LGBT Health topic area at the National Center for Health Statistics, CDC. She serves on the Sexual Orientation, Gender Identity, and Sex Characteristics Subcommittee of the Federal Committee on Statistical Methodology and in 2022 led the subgroup on SOGI data for administrative forms for the interagency working group on the *Federal Evidence Agenda on LGBTQI+ Equity*, published in January 2023. Besides SGM data, Ms. Dragon worked on two public health emergencies, the Ebola Response 2015 with the CDC and the COVID-19 Response (2020-2021) while working to protect worker safety and health with OSHA. She holds a masters' degree from Johns Hopkins Bloomberg School of Public Health, and a double major from Smith College in Neuroscience and Woman and Gender Studies. Outside of work, she rows with an LGBTQ rowing team, trains for the next marathon, and gardens.

Katharine B. Dalke, MD, MBE (she/her, they/them)
Vice Chair for Clinical Operations, Department of Psychiatry, Penn Medicine, Benjamin Rush Associate Professor of Clinical Psychiatry, Perelman School of Medicine at the University of Pennsylvania, Affiliated Faculty Member, Eidos LGBTQ+ Health Initiative at the University of Pennsylvania

Katharine Dalke is the Vice Chair for Clinical Operations and Benjamin Rush Associate Professor in the Department of Psychiatry at the University of Pennsylvania. Dr. Dalke is a content expert in the mental health of patients who are LGBTQI+ and is passionate about aligning health policy, research, and clinical care to promote resilience among LGBTQI+ populations. Her clinical, scholarly, and advocacy work has been recognized with current appointment as Chair of the Pennsylvania Governor's Commission on LGBTQ Affairs, and past service on the Working Group to the National Institutes of Health Sexual and Gender Minority Research Office and consensus committee member on two LGBTQI+ health publications by the National Academies of Sciences, Engineering, and Medicine. Dr. Dalke graduated from Haverford College, then completed a dual degree program in medicine and bioethics at the University of Pennsylvania. She pursued specialized training in LGBTQI+ mental health during psychiatry residency at Penn. She has previously held faculty appointments in the Departments of Humanities and Psychiatry at the Penn State College of Medicine, where she developed LGBTQI+ mental health programming and served as Vice Chair for Diversity, Equity, and Inclusion.

Karen Parker, PhD, MSW (she, her)

Director, Sexual & Gender Minority Research Office, National Institutes of Health

Karen L. Parker currently serves as Director of the Sexual & Gender Minority Research Office at the National Institutes of Health (NIH). Dr. Parker was instrumental in the formation of the office in the fall of 2015 and was appointed Director in June 2016. In her role as director, Dr. Parker is co-chair of the trans-NIH Sexual and Gender Minority (SGM) Research Coordinating Committee, a committee on which she has served since its inception in 2011, and co-chair of the NIH SGM Research Working Group of the Council of Councils. Dr. Parker is also a member of the NIH Anti-Harassment Steering Committee and serves as the co-chair of the NIH Office of the Director Equity Council. Additionally, she sits as an ad hoc member on the Advisory Committee to the NIH Director Working Group on Diversity. In 2021, Dr. Parker received the LGBTQ Health Achievement Award from GLMA: Health Professionals Advancing LGBTQ Equality, for her contributions in advancing the field of SGM health research and equity.

Dr. Parker is involved in several SGM-related initiatives beyond NIH. She serves as co-chair of the Sexual Orientation, Gender Identity, and Sex Characteristics Subcommittee of the Federal Committee on Statistical Methodology, as well as an Executive Director of Department of Health and Human Services LGBTQI+ Coordinating Committee. Dr. Parker began her NIH career in 2001 as a Presidential Management Fellow at the National Cancer Institute (NCI). She spent several years at NCI, serving in various roles in the NCI Office of the Director.

Dr. Parker received her Bachelor of Arts in English from Indiana University and her Master of Social Work from the University of Michigan, where she studied community organization, social policy, and evaluation. She subsequently completed her PhD at the University of Maryland, School of Social Work.

CONTENTS

OPENING REMARKS

- *Rachel L. Levine, M.D. Admiral, U.S. Public Health Service, Assistant Secretary for Health (ASH), U.S. Department of Health and Human Services (HHS)*
- *Yvonne Lau, M.B.B.S., M.B.H.L., Ph.D., Director, Division of Education and Development (DED), Office of Human Research Protections (OHRP)*
- *Karen L. Parker, Ph.D., M.S.W., Director of the Sexual & Gender Minority Research Office (SGMRO), National Institutes of Health (NIH)*

Dr. Lau welcomed everyone to the workshop and expressed appreciation for its sponsors and distinguished speakers. This webinar, sponsored jointly by OHRP and the NIH SGMRO, supports the goal of promoting diversity, inclusivity, and appropriate representation in biomedical and socio-behavioral research to improve health for everyone. The webinar focuses on ways to achieve this goal specifically for LGBTQI+ individuals. She welcomed Admiral Levine, noting that "nobody in HHS is more suitable than the ASH" to introduce the webinar.

Admiral Levine welcomed attendees and the distinguished panel. She stressed the importance of addressing the significant gaps in research participation among LGBTQI+ individuals, who historically have been underrepresented or misrepresented in research. These individuals should be welcomed and supported by research designs and methods that are sensitive to their needs. She stressed the need for effective strategies to build trust and reduce barriers to study participation.

She hoped the discussion to follow would elucidate what is needed to ensure meaningful engagement of LGBTQI+ individuals and communities throughout the research process, from conception to dissemination of findings. She urged researchers to codesign studies with attention to their voices. She called for systemic changes, including funding opportunities dedicated to research designed to meet this population's needs. Increased participation by subjects and their communities can ensure outcomes that lead to tangible improvements in the lives of LGBTQI+ individuals.

Dr. Parker reported that NIH is deeply interested in increasing participation by LGBTQI+ individuals in research. The Secretary's Advisory Committee on Human Research Protections (SACHRP) has recently released recommendations aimed at supporting this goal. She introduced Ms. Coleman, who summarized these recommendations.

REVIEW OF THE SACHRP RECOMMENDATIONS FOR THE ETHICAL REVIEW AND INCLUSION OF LGBTQI+ PARTICIPANTS IN HUMAN SUBJECTS RESEARCH

- *Linda Coleman, J.D., CIP, CHC, CHRC, CCEP-I, Associate Vice Provost, Research Policy & Integrity, Office of the Vice Provost and Dean of Research, Stanford University*

Ms. Coleman summarized the recommendations SACHRP finalized July 24, 2024. She noted that these recommendations are the culmination of work done by the SACHRP subcommittee and approved by the parent committee.

OHRP's charge to SACHRP was motivated by three objectives:

- Ensuring the ethical protection of LGBTQI+ participants in research, in alignment with the regulations outlined in 45 CFR part 46, which govern the protection of human subjects in HHS-supported or conducted research
- Promoting the advancement of LGBTQI+ research and working to reduce health disparities within LGBTQI+ communities
- Enhancing the knowledge and cultural understanding of research involving LGBTQI+ participants

SACHRP was charged with providing recommendations on three key areas, with specific questions that SACHRP was asked to address:

- Ethical, legal, regulatory, and contextual considerations

- Establishing an inclusive and culturally sensitive research environment
- Considerations for the design, review, and conduct of LGBTQI+ research

Background. Ms. Coleman highlighted key points from this section.

- *The importance of equitable inclusion.* It is essential for safeguarding rights and welfare, as well as adherence to ethical standards.
- *The need for scientifically inclusive research.* Research should be aligned with the needs of LGBTQI+ communities and individuals. Inclusion should not be an afterthought. Rather, it requires planning and collaboration across stakeholder groups to understand their life experiences. Failure to do so creates gaps in our understanding of this population.
- *Consequences of underrepresentation.* The National Academies of Science and Engineering (NASEM) report of 2022 observes that findings may not be generalizable if there are knowledge gaps related to the health need of people who are LGBTQI+. Underrepresentation marginalizes these individuals, creating barriers to health care and other essential services.
- *Importance of fair and informed access.* Researchers need awareness of social and cultural circumstances of LGBTQI+ individuals. Through inclusion, they can build trust.
- *Tailored approaches to research.* Thoughtful strategies can help avoid gaps in the evidence base.
- *The ethical and practical imperative for inclusive research.* Attention to these issues is necessary to advance equity and improve outcomes across all communities.

General recommendations. SACHRP chose to distinguish between “general recommendations” and “specific recommendations” because, during the drafting process, the committee realized that many of the recommendations could apply to multiple stakeholders. To avoid repetition, two sections were developed to address this.

Specific recommendations. SACHRP recommendations specific to LGBTQI+ communities begin by stating ethical, legal and regulatory, and contextual considerations in study conduct. Ethical considerations include the need to ensure inclusion and protection of LGBTQI+ participants to promote equity and address disparities, as well as to take affirmative steps to conduct inclusive research, enhancing generalizability and equitable benefit distribution. Researchers also need to understand the impact of laws, regulations, and guidelines on LGBTQI+ research, including risks and protections. To address contextual variables, researchers should take into account and be able to navigate the influence of directives, standards, organizational policies, local context, and diverse viewpoints, as well as the influence of political and social determinants of health.

The SACHRP recommendations also emphasize the importance of establishing an inclusive and culturally sensitive research environment. This ensures that LGBTQI+ participants feel respected, represented, and actively engaged by the research team. Additionally, practical considerations are provided related to the design, review, and conduct of LGBTQI+ research, including guidance on recruitment strategies and dissemination of findings.

Special considerations for minors. Although many SACHRP recommendations apply broadly to both adults and minors, there are special considerations for minors that may differ from those for adults. SACHRP notes that the recommendations in the section are not exhaustive. A few of the relevant areas include the following:

- *Community engagement*. Collaborate with LGBTQI+ youth organizations and youth advisory boards to ensure cultural relevance.
- *Ethical considerations*. Assess risks, monitor safety continuously, and adapt protocols based on feedback.
- *Privacy*. Ensure confidentiality through pseudonyms and secure data. Provide private, secure communication channels tailored to minors’ development.
- *Recruitment.* Use discreet materials and partner with LGBTQI+ organizations.
- *Informed consent*. Understand consent laws, consider parental waivers, and use age-appropriate language.

Key takeaways. SACHRP recommendations emphasize the need for inclusive research practices that protect the rights and welfare of LGBTQI+ participants. Inclusion is not just an aspiration, but a process that is essential for improving research outcomes. Adhering to ethical standards, engaging with communities, protecting confidentiality, and promoting cultural competence are critical for inclusive research.

SACHRP encourages all stakeholders to review the recommendations and consider how to address them in their work. By implementing these recommendations, researchers, sponsors, IRBs, and institutions can create a respectful and supportive environment that meets the needs of LGBTQI+ participants in research.

THE COMPLEX AND EVOLVING CONCEPTS OF SEX AND GENDER

- *Catherine Clune-Taylor, Ph.D., B.M.Sc. Assistant Professor, Program in Gender and Sexuality Studies, Princeton University*

Dr. Clune-Taylor provided an overview of traits related to sex and gender, highlighted relevant protections and benefits for intersex research participants, and closed with an illustrative case study.

Sex and gender. Dr. Clune-Taylor explained that sex and gender comprise a multitude of traits. At least six different components define the biological sex of human beings, and each of these is more complicated than most people believe.

- *Gonads.* While most assume the possibilities are limited to ovaries and testes, an individual might have both or neither. Having one ovary and one teste is known as "hermaphroditism."
- *Chromosomes.* Assumed possibilities are XX or XY, but numerous additional possibilities and permutations might be encountered—for example, XO, Sry+ XX, XYY, or XYYY. In addition, an individual might have "mosaic" chromosomes (e.g., XO/XX, XO/XY, XX/XY, XX/XYY, or XY/XYY). It is even possible for an individual to have different chromosomal makeups in different parts of the body—a condition known as "chimeric."
- *Hormones.* We tend to assume people either have primarily androgens (e.g., testosterone) or primarily estrogens, but in fact there is a large range of possible variations. Variations can also occur across the lifespan. People could have more androgens than typical, for example, and an individual for whom this is the case might still identify as female.
- *Internal reproductive structures.* Familiar possibilities include the uterus, cervix, fallopian tubes, urethra, vas deferens, epididymis, and seminal vesicles, and we might assume these all occur in specific locations and positions. In fact, there is large variation here as well. An individual might have some or all of these, and these structure could occur in places where we do not expect to find them.
- *External genitalia.* Assumed possibilities include the vagina, clitoris, labia minora and majora or penis and scrotum, with urethra exiting at the tip of the penis. However, external genitalia may be developed and differentiated in many different ways. While we tend to use an individual's external genitalia for binary sorting, a person may have a penis but not have XY chromosomes. People can develop along different pathways with a wide spectrum of possibilities.
- *Other genital variations.* A variety of other conditions do not call gender into question and are not considered pathological. Examples include diphallia (double penis) and double vagina (with or without a double uterus).

There is also a wide range of variations among secondary sex characteristics such as breast development, sex-typical fat distribution, and hair growth patterns. Males may develop breasts or have characteristically feminine fat distributions. Some believe that brain organization is also a trait linked to sex and gender, though this is somewhat controversial.

Clearly, sex and gender are complex—and so is accounting for them in scientific research. Researchers do not generally identify the biological sex trait of epistemic interest or justify the choice of a particular trait over another. Sorting women and men based on their chromosomes may or may not be the best identifier for sex based on the study goal. Adding further complexity is that many individuals have intersex characteristics without knowing it.

Intersex participants: protections and benefits. Dr. Clune-Taylor noted that people with known intersex characteristics are generally excluded from research on the grounds that they are categorically complex and rare. Exclusion raises important ethical, political, and epistemological issues for research. However, since sex is rarely checked, intersex people are in studies already, though without the researcher knowing it. Their undetected presence could undermine the rigor of the study. This is especially likely since some recent studies suggest that intersex characteristics may be much less rare than we thought (Hannah-Shmouni et al., 2017).

Intersex people are extensively studied, typically with a view of predicting identity in order to determine surgical interventions to enable surgical sex assignment in infants. This research rarely aims at improving the health outcomes of those with intersex conditions. Further, there is rarely consultation with intersex community members regarding research priorities or design.

Case study: Osteoporosis and sex/gender. Osteoporosis is taken to be a condition that is sex-linked, but in fact the condition tracks better with cultural norms such as drinking less milk than typical and having less exposure to sunlight. For example, Anne Fausto-Sterling found that Ashkenazi Jewish men from ultra-orthodox populations also have high rates of osteoporosis (Fausto-Sterling, 2005). Fausto-Sterling writes, "[P]arsing medical problems into biological (or genetic or hormonal) components in opposition to cultural or lifestyle factors has outlived its usefulness for biomedical theory" (p. 1493). Instead, the author advocates for the use of Dynamic Systems Theory and Life Course Analysis. She observes, "The sex-gender or nature-nurture accounts of difference fail to appreciate the degree to which culture is a partner in producing body systems commonly referred to as biology—something apart from the social" (p. 1516). In conclusion, Dr. Clune-Taylor suggested, "Embodiment is a dynamic system of biocultural formation that reaches beyond gender."

ETHICAL ENGAGEMENT OF MINORITY AND UNDERSERVED POPULATIONS IN RESEARCH

- *Jennafer (Jenn) Kwait, M.H.S., Ph.D., Research Scientist, Whitman-Walker Institute*

Dr. Kwait focused her remarks on what the Whitman-Walker Institute has learned from its years of experience in engaging communities in research. "It's in our DNA," she stressed. The Institute's mission is to expand "the body of knowledge that strengthens the health care we provide, and the health and well-being of our community, particularly sexual and gender diverse people and persons living with or at risk of HIV. Through research, advocacy, and education, we empower all persons to live healthy, love openly, and achieve equality and inclusion." Whitman-Walker Health, the Institute's affiliated entity, is a Federally Qualified Health Center with a 40-year history providing HIV and LGBTQI+ health care services and community-based care.

The Institute's initiatives aim to reshape systems to promote health equity for underserved communities, and engage in authentic dialogue with community members to ensure its agenda focuses on priorities and health outcomes identified by those is serves in the health center and broader DC community.

Whitman-Walker has several ways of translating these aims into real-world work. Dr. Kwait highlighted three of them:

- Organization-based Community Advisory Group (CAG)
- Study-specific Community Advisory Boards (CAB)
- Projects focused on community engagement and building community capacity to be full partners in research

Whitman-Walker Institute Community Advisory Group. This is a relatively new group started about 2 years ago. Its scope includes advancing community engagement in all steps of the research process; creating meaningful research, policy, and education initiatives that lead to positive outcomes for all communities; and fostering relationships with individuals from communities around DC. Its current priorities are:

- To establish key health issues and under-represented topics for research and education within Whitman-Walker's work. Where are the Institute's blind spots? How can the Institute move forward to address community priorities?
- To build strategies for identifying these issues in collaboration with group members and Institute staff.

The Community Advisory Group (CAG) meets once a month. Participants are compensated, which Dr. Kwait described as a core feature. It is important to give fair compensation, given the value of everyone's time.

Dr. Kwait reported candidly that Institute and CAG participants are together moving through a process to figure out the most effective ways to collaborate, with initial meetings focused on ironing out goals and identifying and addressing differences in approach and anticipated roles. For example, in the early phases of the Institute and CAG partnership, there was discussion among the CAG members about their role and expectations to create a report or other product for the Institute, given their dedication and commitment to this effort. After shared dialogue with the CAG and Institute staff, they landed on emphasizing the role of the CAG to instead provide ongoing input about research efforts and priorities to guide the Institute direction and find opportunities for further community partnership.

The CAG shares health care and service needs, which are key foundations for the discussion of research gaps and needs. The Institute team also spent time providing a "Research 101" to enable opportunities to identify possible connections between service needs and research possibilities.

The CAG has responded to the Institute's requests for review of existing projects and new grant possibilities and provided advice on how to collaborate with the community on each of these. Next steps will include exploring ways to translate community priorities and gaps in care into funded work.

Study-specific community advisory boards. Dr. Kwait then shared an example of a study-specific community advisory board (CAB), based on her experience working with MACS/WIHS Combined Cohort study, for which Whitman-Walker is a sub-site to Johns Hopkins in Baltimore (whose local site is called SHARE) for this multi-site study. The MWCCS has a National Community Advisory Board (NCAB), and each MWCCS study site has a local CAB. The MWCCS website notes that a community advisory board is defined as "a collective group of study participants and organization representatives that provide community information and assistance to the research project." Study participants are encouraged to participate in the CAB in order to "help build and foster partnerships between researchers and local study communities impacted by HIV/AIDS."

Participants from the Johns Hopkins/Whitman-Walker local site (SHARE) participate in a CAB that helps to define the SHARE research agenda and how it is carried out. The CAB also monitors and provides feedback about the quality of interactions between SHARE staff and participants. It has also provided input on other SHARE activities, such as recruitment of new participants, new study components, and challenges or positive feedback related to visits. Meetings are held virtually once a month in most months of the year. Serving on the CAB has always been a volunteer role and participants are not compensated.

Lessons learned. Dr. Kwait shared the following lessons learned based on the Institute's long experience working closely with subjects:

- Compensate people for their time.
- Clarify the goals and purpose of community engagement in partnership with the community.
- Align goals determined by funding with the community perspective, including balancing community-led work with direction from the study team.
- Take the time to build rapport and trust. This is ongoing work and not a finite task. Sometimes this work involves repairing broken trust.
- Embrace failure and mistakes. Own them and take the time to repair relationships, even though it can be hard to shift the focus from study tasks, science, and timelines.
- Meet people where they are in terms of how they best process information. This includes not only using the right communication methods, but also paying attention to language, amount of information, and content of material.
- Consider what happens to the advisory group when the study ends and build this into the work from the beginning. Is the engagement structure sustainable?

- What does sustainability of community engagement structures look like?
- Collaborate with other researchers who are advancing on-the-ground community engagement.

Dr. Kwait closed with a provocative question: Health care and services, rather than research, are often priorities for community members. How do we continue to work together to make connections between service needs and research as part of our engagement?

THE IMPORTANCE OF SOGI DATA COLLECTION IN RESEARCH

- *Christina N. Dragon, M.S.P.H., CHES, Measurement & Data Lead, SGMRO, NIH*

Ms. Dragon explained why it is important to collect research data on SOGI (Sexual Orientation and Gender Identity). She began by reviewing landmarks in the increasing visibility of LGBTQI+ individuals, legal and government actions to repress or support them, and actions by the affected communities themselves. Examples include the Eisenhower administration's Executive Order (EO) banning homosexuals from federal employment (1953), the Stonewall Inn Rebellion (1969), the Defense of Marriage Act (1996), the repeal of the EO banning federal employment by gay people (1998), and the present onslaught of state-level anti-LGBTQI+ legislation. Ms. Dragon stressed the importance of broadening the research "umbrella" to include this population so that the influences on daily life—as well as health and well-being – can be understood.

The first comprehensive report on health and research issues related to LGBTQI+ individuals was issued by the National Academies of Science, Engineering and Medicine in 2011. Authors observed that these populations "often are combined as a single entity for research and advocacy purposes," but noted that in fact each is a distinct population group with its own specific health needs. The report called for comprehensive demographic data in research.

A consensus report by the Academies in 2020 further explored the well-being of these populations and also stressed the need for systematic inclusion of demographic information in studies. A further study by NIH in 2022, "Measuring Sex, Gender Identity, and Sexual Orientation," specifically explored research strategies. Ms. Dragon reiterated that members of the population have always participated in studies, but they have not been visible. This is finally changing.

The critical consensus reports cited above have focused federal efforts to embrace research challenges and advance equitable data. A series of working groups have provided recommendations and guidance, culminating in *The Federal Evidence Agenda on LGBTQI+ Equity* (2023), which provides a roadmap for opportunities for the federal government to continue to build evidence and leverage data to advance equity for LGBTQI+ people. This wide-ranging EO has many components and requirements. It recognizes that advancing equity and full inclusion will require improvements in data collection and the use of evidence, and it calls for specific actions to improve federal data collection practices. These include:

- Development of a *Federal Evidence Agenda on LGBTQI+ Equity*
- Development and implementation of agency-specific SOGI Data Action Plans
- Recommendations for agencies on the best practices for collection of SOGI data on federal statistical surveys

Guiding principles stressed in the *Federal Evidence Agenda* are: inclusiveness (people deserve to count and be counted); precision (use precise terminology that reflects the constructs of interest); autonomy (respect individual identity and self-reporting); parsimony (collect only necessary data); and privacy (use data in a manner that benefits respondents and respects their privacy and confidentiality).

While these crucial steps are encouraging, persistent measurement challenges remain. Those cited by Ms. Dragon include the following:

- There are no official statistical standards or consensus-based common data elements. Researchers do not agree on which elements are important, and some believe we need to identify different elements from those that exist.

- Labels and definitions are fluid and rapidly changing. It is not clear how people will interpret questions about their sexual identity. Adding to the challenge, many terms are unfamiliar to straight and cisgender populations.
- Until recently, research on the population focused on survey methodology, not on collecting administrative and clinical data.
- Little research is available on measuring variations in sex characteristics and intersex people.
- There is a need to translate questions and response options, as well as research and reports into languages other than English, and to make information accessible to low-literacy populations.

In conclusion, Ms. Dragon pointed to differences in three kinds of SOGI data that might be collected: administrative, clinical, and health. She stressed that robust SOGI data for demographic purposes is important for basic reporting on differing populations in studies. In the context of clinical data, anatomical inventories and hormonal milieu have historically not been considered standard information. As this changes, the persistent use of binary sex or gender as a proxy for anatomy or hormonal profile will be disrupted.

ETHICAL CHALLENGES OF RESEARCH WITH LGBTQIA+ POPULATIONS

- *Katharine B. Dalke, M.D., M.B.E., Vice Chair for Clinical Operations, Department of Psychiatry, Penn Medicine, Benjamin Rush Associate Professor of Clinical Psychiatry, Perelman School of Medicine at the University of Pennsylvania, Affiliated Faculty Member, Eidos LGBTQI+ Health Initiative at the University of Pennsylvania*

Dr. Dalke addressed unique challenges in research with LGBTQI+ communities, including a variety of “moral hazards” and potential blind spots. She spoke from the perspective of an investigator who identifies as bisexual and intersex. Dr. Dalke began by noting that there are many people who, like her, are “both/and”—both investigators and community members. Based on anecdotal evidence, she suspects that this is a common phenomenon, but the data is not available to confirm this impression. Dr. Dalke sees the both/and phenomenon as positive, since researchers can offer both their lived experience and connections with community organizations and service providers, facilitating collaboration that can improve understanding.

The LGBTQI+ community is not a monolith; it is “hugely diverse and intersectional,” encompassing individuals with a wide range of experiences, as well as diverse racial and ethnic backgrounds. What is true for one group may be untrue for another. For example, both trans and intersex individuals experience gender dysphoria, but in reality, those experiences are very different. This means that when people who belong to one community are asked to speak on behalf of them all, confusion may result.

Moral hazard comes into play when there is conflict between deeply held community beliefs and research findings. In intersex research on outcomes from early surgery performed on children with characteristics typical of both sexes, data from parents and adults who experienced the surgery as children differ. The world in which people practice or move can create pressure to explore questions in a certain way. Researchers must be cognizant of the cultural context in which they pursue their research and avoid privileging certain types of evidence.

At the moment, Dr. Dalke observed, cultural wars are at a “fever pitch.” Many investigators have been targeted by social media and their findings have been taken out of context. Some have left public universities for private ones to protect themselves from possible Freedom of Information Act (FOIA) requests that might place them in jeopardy. It is important to work within institutions to provide proactive affirmation and support for investigators. Institutions should also proactively establish policies and procedures for addressing legal requests and demands for information related to LGBTQI+ research. These plans should encompass strategies for safeguarding researchers and participants, such as legal support, confidentiality measures, and advocacy for the rights of LGBTQI+ individuals involved in the research.

Dr. Dalke specifically urged investigators to consider steps to ensure confidentiality for CAB and professional advisers. Also, she urged investigators to make sure that their dissemination plans protect participants’ privacy.

Dr. Dalke encouraged IRBs, mentors, and institutions to support investigators by offering training and mentorship. These opportunities should recognize and validate the cultural context in which investigators are asking questions. They should also encourage investigators to consider a wide range of research methods.

PANEL DISCUSSION AND AUDIENCE QUESTIONS

- *Karen Parker, Ph.D., M.S.W., Director, Sexual & Gender Minority Research Office, National Institutes of Health*

Dr. Parker said that members of the public watching the presentation had asked many questions, some of which have been answered live by the person to whom they were directed.

She shared key takeaways from the presentations. She clearly heard the need for research that is respectful and impactful, benefitting people who are LGBTQI+. She also heard that there are complex challenges that must be addressed. Presenters highlighted that community engagement is critical; it should be respectful, and members should be compensated for their time. Precision in language is important. Speakers cautioned that pre-existing assumptions could shape the research in ways that lead to erroneous conclusions. Data collection should be sensitive to nuance and to the distinctions among people who are LGBTQI+, as well as the fact that many people belong to more than one subgroup. It is important to think carefully about confidentiality, privacy, security, and safety for investigators as well as participants.

Putting SACHRP recommendations into practice. Dr. Parker saw the SACHRP 2024 recommendations on the topic as a place to begin a real sea change within the research community. She invited comments from the panel on what challenges researchers and institutions will face in putting these recommendations into practice.

Ms. Coleman observed that successful implementation of the recommendations will require institutional leadership to make this a priority and ensure adequate resources. Navigating different laws and regulations will be a challenge, especially in multisite research. Today's political climate also poses challenges that must be navigated. None of these, she stressed, is an insurmountable obstacle. Dr. Parker agreed that institutional leadership is critical.

Safety and privacy. Noting that speakers have highlighted challenges related to safety and privacy, Dr. Parker asked whether there are specific actions researchers and institutions could take to mitigate these risks.

Dr. Dalke recommended several risk mitigation strategies:

- Conduct recruitment in a way that allows people to maintain anonymity.
- Plan participation in clinical or other settings in which privacy can be assured.
- With minors, be aware that some may not be want to be "outed" to their parents.

On the investigator side, institutions should assure investigators that their jobs are secure and that the institution can withstand public pressure. Some institutions have provided security for investigators who have become media targets. Institutions should also be prepared for legal requests for information and have a strategy in place for response. Dr. Clune-Taylor observed that, unfortunately, it is not possible to fully protect researchers. If people are planning to report study findings, the investigator must be identified. However, if reporters from alt-right groups appear and expect to record sensitive conversations, a policy should be in place such that these requests can be denied. She developed a written policy she is happy to share.

Dr. Kwait said research staff may need support to learn the skills required to facilitate hard conversations with community groups and individuals. When a "detour" is needed to address emerging concerns, institutional support and understanding are critical.

Dr. Parker shared that NIH's portfolio of studies relevant to sexual and gender minority (SGM) populations has been growing since 2015, and a smaller proportion of SGM-related projects are now related to HIV/AIDS. Previously, the main research concerns were related to transmitting the disease. Now, the portfolio is shifting to explore a broader range of questions. Investigators are beginning to see career paths opening in new areas.

Lessons learned. Dr. Parker invited comments on lessons learned. Are there failures we can learn from in the effort to ensure we are doing the best and most ethical work possible?

Dr. Clune-Taylor observed that the chat for the webinar included a number of questions about sex and gender characteristics and appropriate identifiers. She provided the example of a study she is doing with an endocrinologist and an intersex person as Co-Principal Investigators. The team has completed a pilot version of the study using open-ended questions to collect qualitative data on how people in the LGBTQI+ community identify themselves. This type of study provides a starting point that may inform quantitative survey data.

CLOSING COMMENTS

Dr. Lau thanked all speakers for sharing thoughts and expertise. She also expressed appreciation for the many people watching online, expressing the hope that the seminar has brought insight.

REFERENCES

Fausto-Sterling, A. (2005). The bare bones of sex: Part 1—Sex and gender. *Signs: Journal of Women in Culture and Society*, 30(2), 1491-1527.

Hannah-Shmouni, F., Morissette, R., Sinaii, N. et al. (2017). Revisiting the prevalence of nonclassic congenital adrenal hyperplasia in US Ashkenazi Jews and Caucasians. *Genet Med 19, 1276–1279.* https://doi.org/10.1038/gim.2017.46

National Academies of Sciences, Engineering, and Medicine (2011). Consensus study report: The health of lesbian, gay, bisexual, and transgender people: Building a foundation for better understanding. https://nap.nationalacademies.org/catalog/13128/the-health-of-lesbian-gay-bisexual-and-transgender-people-building

National Academies of Sciences, Engineering, and Medicine (2022). *Improving representation in clinical trials and research: Building research equity for women and underrepresented groups.* The National Academies Press. https://doi.org/10.17226/26479

National Academies of Sciences, Engineering, and Medicine. (2020). *Understanding the well-being of LGBTQI+ populations. National Academies Press.* https://doi.org/10.17226/25877.

National Institutes of Health, National Library of Medicine (2022). *Measuring sex, gender identity, and sexual orientation.* National Academies Press. https://www.ncbi.nlm.nih.gov/books/NBK578625

National Science and Technology Council. (2023). *Federal evidence agenda on LGBTQI+ equity.* Subcommittee on Sexual Orientation, Gender Identity, and Variations in Sex Characteristics (SOGI) Data, Subcommittee on Equitable Data. Office of Science and Technology Policy. https://www.whitehouse.gov/wp-content/uploads/2023/01/Federal-Evidence-Agenda-on-LGBTQI-Equity.pdf.

Secretary's Advisory Committee on Human Research Protections (SACHRP) (July 25, 2024). SACHRP recommendations for the ethical review and inclusion of LGBTQI+ participants in human subjects research. https://www.hhs.gov/ohrp/sachrp-committee/recommendations/ethical-review-inclusion-lgbtqi-participants-human-subjects-research/index.html

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