SACHRP Recommendations for the Ethical Review and Inclusion of LGBTQI+ Participants in Human Subjects Research

For Investigators, Sponsors, Institutional Review Boards (IRBs), Human Research Protection Programs (HRPPs), and Research Institutions

October 2, 2024

Linda Coleman
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Stanford | RESEARCH

Title	**SACHRP Recommendations for the Ethical Review and Inclusion of LGBTQI+ Participants in Human Subjects Research**
Date	July 24, 2024
Purpose	To provide “recommendations for investigators, sponsors, institutional review boards (IRBs), human research protection programs (HRPPs), and research institutions regarding the ethical and regulatory considerations for research involving Lesbian, Gay, Bisexual, Transgender, Queer, Intersex, and other orientations and identities (LGBTQI+), including both adult and minor participants. LGBTQI+ is an acronym commonly used to define these orientations and identities, where the “+” includes those not specifically mentioned and those that may evolve in the future.”
Scope	The recommendation are pertinent for projects addressing broadly relevant research questions **and** for projects focused on research priorities specifically relevant to LGBTQI+ communities.
Reference	SACHRP Recommendations for the Ethical Review and Inclusion of LGBTQI+ Participants in Human Subjects Research | HHS.gov July 25, 2024 - Letter to the HHS Secretary | HHS.gov

Introduction

OHRP's Charge focused on three Objectives:

- "Ensuring the ethical protection of LGBTQI+ participants in research, aligning 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 towards reducing health disparities within LGBTQI+ communities; and
- Enhancing the knowledge and cultural understanding of research involving LGBTQI+ participants."

Ethical, Legal, Regulatory, and Contextual Considerations.

Recommendations address specific questions related to research involving LGBTQI+ adult and minor participants, focusing on three key areas.

Considerations for Establishing an Inclusive and Culturally Sensitive Research Environment.

Considerations for the Design, Review, and Conduct of LGBTQI+ Research.

❖ SACHRP Recommendations
3 Focus Areas

Background Section

1. **Importance of Equitable Inclusion**
   - Safeguarding Rights and Welfare
   - Adherence to Ethical Standards
2. **The Need for Scientifically Inclusive Research**
   - Aligning Research with LGBTQI+ Needs
   - Avoiding Inclusion as an Afterthought
3. **Insights from the NASEM Report**
   - Knowledge Gaps in LGBTQI+ Health Needs
   - Risks of Underrepresentation
   - Outcomes are Inconsistent with Belmont Principles
4. **Consequences of Underrepresentation**
   - Limited Access to Benefits
   - Barriers to Services
5. **Importance of Fair and Informed Access**
   - Awareness of Social and Cultural Circumstances
   - Building Trust Through Inclusion
6. **The Need for Tailored Research Approaches**
   - Avoiding Gaps in the Evidence Base
7. **The Ethical and Practical Imperative for Inclusive Research**
   - Advancing Equity and Improving Outcomes

General Recommendations

Purpose

To guide researchers, sponsors, IRBs/HRPPs, and institutions in designing and conducting ethical, inclusive, and scientifically rigorous research involving LGBTQI+ participants.

Key Focus Areas Include

- Adherence to legal, regulatory, and ethical standards.
- Inclusion of LGBTQI+ individuals in research.
- Best practices for conducting culturally competent research.

General Recommendations

Research Questions and Data Collection

Key Recommendations

- Incorporate LGBTQI+ considerations into research design.
- Use inclusive language and involve LGBTQI+ community members in the research process.
- Update data collection instruments to include diverse sexual orientations and gender identities.
- Allocate resources for subgroup analysis to address diverse needs and intersecting identities.

General Recommendations

Community Engagement

Key Recommendations

- Engage with LGBTQI+ communities in defining research priorities and protocols.
- Build sustainable partnerships for ongoing collaboration
- Involve community members and advisors in reviewing research materials.
- Establish mechanisms for continuous dialogue throughout the research process.

General Recommendations

Confidentiality Protections

Key Recommendations

- Implement robust confidentiality measures, such as anonymization and de-identification.
- Tailor privacy protections to the specific needs of LGBTQI+ participants.
- Train research staff on data security and confidentiality protocols.
- Consider legal variations and risks, especially in multisite studies.

General Recommendations

Promoting Representation and Training

Key Recommendations

- Collect demographic data on sexual orientation and gender identity for better representation.
- Provide training on LGBTQI+ cultural competence and community engagement.
- Conduct structured training programs to foster understanding and respect for LGBTQI+ needs.

General Recommendations

Strategies for Inclusive Recruitment

Key Recommendations

- Develop culturally sensitive and identity-affirming recruitment strategies.
- Collaborate with LGBTQI+ organizations to enhance recruitment efforts.
- Address barriers to participation and regularly update participant information.

General Recommendations

Dissemination of Research Results

Key Recommendations

- Collaborate with LGBTQI+ communities to develop dissemination plans.
- Use inclusive language and imagery in all dissemination materials.
- Provide support for community-led dissemination activities.

Specific Recommendations

Ethical, Legal, Regulatory, and Contextual Considerations

Ethical Considerations

Ensure inclusion and protection of LGBTQI+ participants to promote equality and address disparities.

Take affirmative steps to conduct inclusive research, enhancing generalizability and equitable benefit distribution.

Laws, Regulations, and Guidelines

Understand the impact of laws, regulations, and guidelines on LGBTQI+ research, from risks to protections.

Contextual Variables

Be able to navigate contextual variables such as the influence of directives, standards, organizational policies, local context, diverse viewpoints, and the influence of political and social determinants of health.

Specific Recommendations

Establishing an Inclusive and Culturally Sensitive Research Environment

Community Engagement Integrate LGBTQI+ community perspectives into research design, implementation, and dissemination.	**Cultural Competence** Foster cultural awareness and competence throughout the research process.
Composition of the Study Team, HRPP/IRB, and Organizational Leadership Promote diverse representation on research teams and leadership to reflect LGBTQI+ perspectives.	**Intersectionality** Address the unique challenges faced by LGBTQI+ participants with intersecting identities.

Specific Recommendations

Design, Review, and Conduct of LGBTQI+ Research

Research Design and Analysis
Incorporate LGBTQI+ considerations into all aspects of research, including questions, methods, and data analysis.

Access and Inclusion (Recruitment)
Develop recruitment strategies that promote representation and inclusivity for LGBTQI+ participants.

Informed Consent
Ensure the consent process is sensitive to LGBTQI+ needs, using inclusive language and creating safe environments.

Privacy and Confidentiality
Implement additional measures to protect LGBTQI+ participants from discrimination and stigma.

Oversight, Support, and Security
Establish robust oversight and support systems for research involving LGBTQI+ participants.

Reporting and Dissemination of Findings
Report and disseminate findings transparently, promoting community benefit and preventing harm.

Special Considerations for Minors

“Although many of the recommendations … apply broadly to both adults and minors, there are special considerations for minors that may differ from those for adults.”

- **Community Engagement**: Collaborate with LGBTQI+ youth organizations and youth advisory boards for cultural relevance.
- **Ethical Considerations**: Assess risks, monitor safety continuously, and adapt protocols based on feedback.
- **Privacy**: Ensure confidentiality through pseudonyms and secure data.
- **Confidential Communication**: 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.
- **Support Services**: Provide counseling and emotional support throughout the research process.

Key Takeaways

SACHRP's recommendations emphasize the need for inclusive research practices that protect the rights and welfare of LGBTQI+ participants.

Importance of Inclusion

- Inclusion of LGBTQI+ individuals is essential for improving research outcomes.
- Adhering to ethical standards, engaging with communities, including those with lived experiences, protecting confidentiality, and promoting cultural competence are critical for inclusive research.

Call to Action

- 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

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October 2, 2024

Slides available at www.clune-taylor.com/upcoming-presentations

Overview

- Sex and Gender: A Multitude of Traits
- Intersex Participants: Protections and Benefits
- Case Study: Osteoporosis and Sex/Gender

Sex and Gender: A Multitude of Traits

Sex and Gender:
A Multitude of Traits

Biological sex in *humans* is defined in terms of ***at least* six different components**.

- **Gonads**
    - Assumed Possibilities: Ovaries, Testes
    - Additional Possibilities: 1 ovary and 1 teste (“hermaphroditism”) Ovotestes, Streak Gonads
- **Chromosomes**
    - Assumed Possibilities: XX, XY
    - Additional Possibilities: XO, Sry+ XX, XYY, XYYY etc.
        - **You can also have mosaics:** (e.g. XO/XX, XO/XY, XX/XY, XX/XYY, XY/XYY, etc).

Biological Sex in Humans

- **Hormones**
  - Primarily Androgens (e.g. Testosterone) or Primarily Androgens
  - Additional Possibilities: Large range of variations, with variations across the lifespan
    - Dependent on *hormone sensitivity*

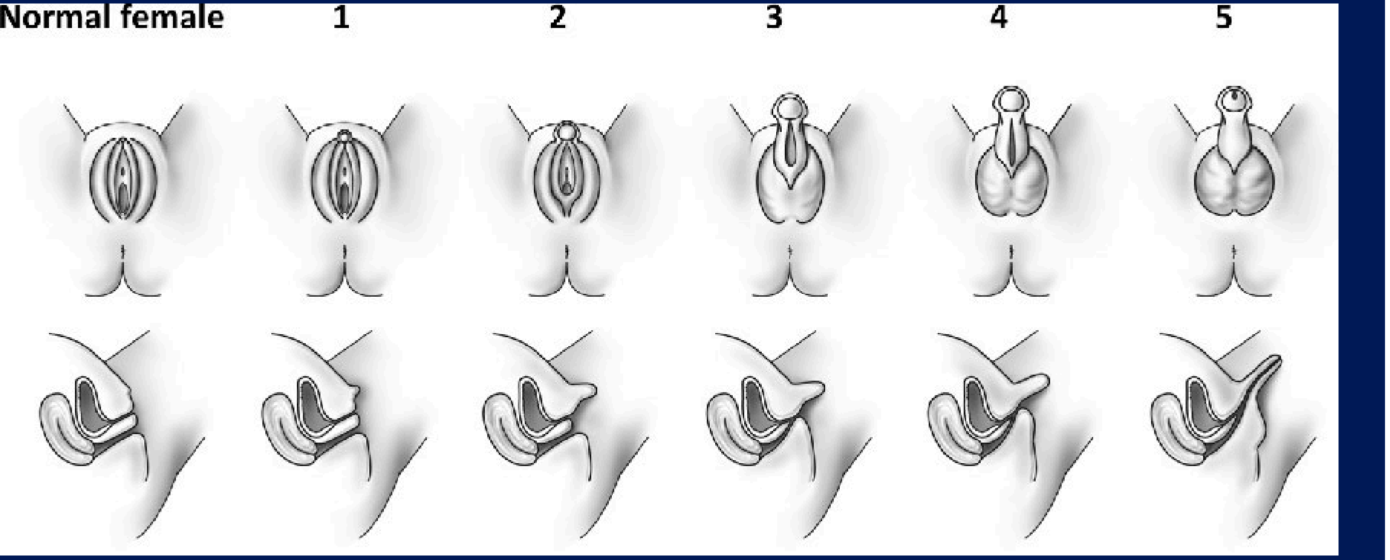
- **Internal Reproductive Structures**
  - Assumed possibilities: Uterus, cervix, fallopian tubes or urethra, vas deferens, epididymis, seminal vesicles (*all location specific*)
  - Additional Possibilities: Large variation

Biological Sex in Humans

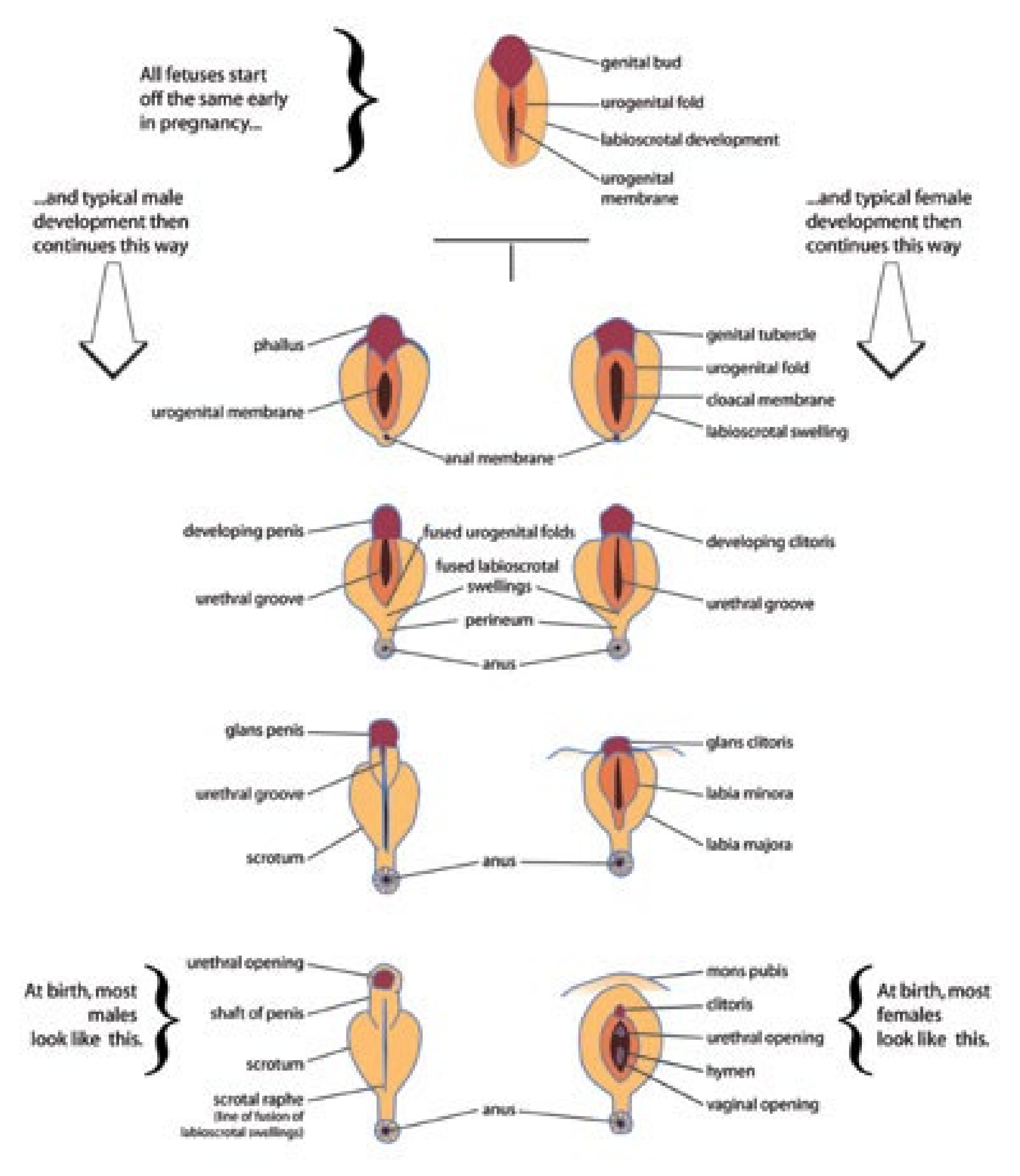
External Genitalia

- Assumed possibilities: Vagina, clitoris, labia minora and majora or penis and scrotum, with urethra exiting at the tip of the penis.
- Additional Possibilities: Wide range of variations.
  - Other Genital Variations ***not*** associated with intersex conditions and ***not*** considered pathological: Diphallia (Double Penis), Double Vagina (with or without a double uterus), etc.

Sexual Differentiation in Humans



The Prader Scale



Biological Sex in Humans

Secondary Sex Characteristics

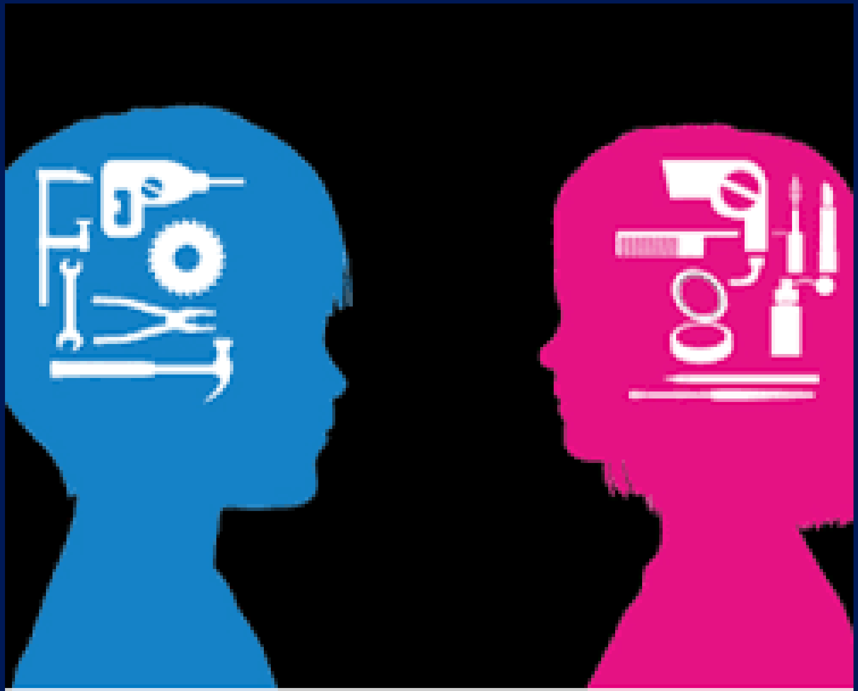
- Assumed possibilities: Breast development, sex-typical fat distribution and hair growth patterns, etc.
- Additional Possibilities: Wide range of variations

A Potential 7th Sex Trait:? Brain Sex/Gender

Gender in Humans

We can differentiate between:

- Gender Identity (e.g. trans man or woman, cis man or woman non-binary, agender, etc.),
- Gender Role/Behavior/Expression,
    - Secondary Sex Differences
- Gendered Relations./Experiences/Oppression
- Sexuality?



Sex (and Gender) are Complex

….and thus, so is accounting for them in scientific research.

- **Sex:** external genitalia, internal reproductive structures, gonads, chromosomes, hormones (and brain structures?), secondary sex characteristics

None of these traits necessarily sort or develop together.

However, we generally assume that they do.

- We often don’t clearly identify the biological sex trait of epistemic interest or justify the choice of a particular trait over another.
- We don’t check our definition against our actual population.
- One trait can often be taken as a proxy for another (e.g. m=external genitalia= XY).

Intersex Participants: Protections and Benefits

Intersex Exclusion and Inclusion in Research

Biomedical research generally excludes intersex subjects for being 1) categorically complex and 2) rare.

- Sex is rarely checked (intersex people are in your studies.
- Less rare than we think (Hannah-Shmouni et al., 2017).

Exclusion raises important ethical, political, and epistemological issues for research.

A protestor holds #EndIntersexSurgery signs at the NYC protest of Dr. Dix Poppas. Photo by Casey Orozco-Poore.

Intersex Exclusion and Inclusion in Research

Intersex people are nonetheless extensively studied.

- Evidence to support surgical sex assignment in infants.
- Increase knowledge about abnormal and normal sex/gender development.

- 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.

interACT
Advocates for Intersex Youth

interACT Policy Statement on Participation in Research

Case Study: Osteoporosis and Sex/Gender

Osteoporosis: Sex, Gender or Both?

- Drawing on 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.

- Osteoporosis is taken to be sex-linked but, in fact, tracks ***racialized norms of gender*** regarding activity.
  - Independent of sex? No → Sex as biological/ Gender as Cultural.

> "[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" (1493).

This is why she advocates for the use of **Dynamic Systems Theory** and **Life Course Analysis.**

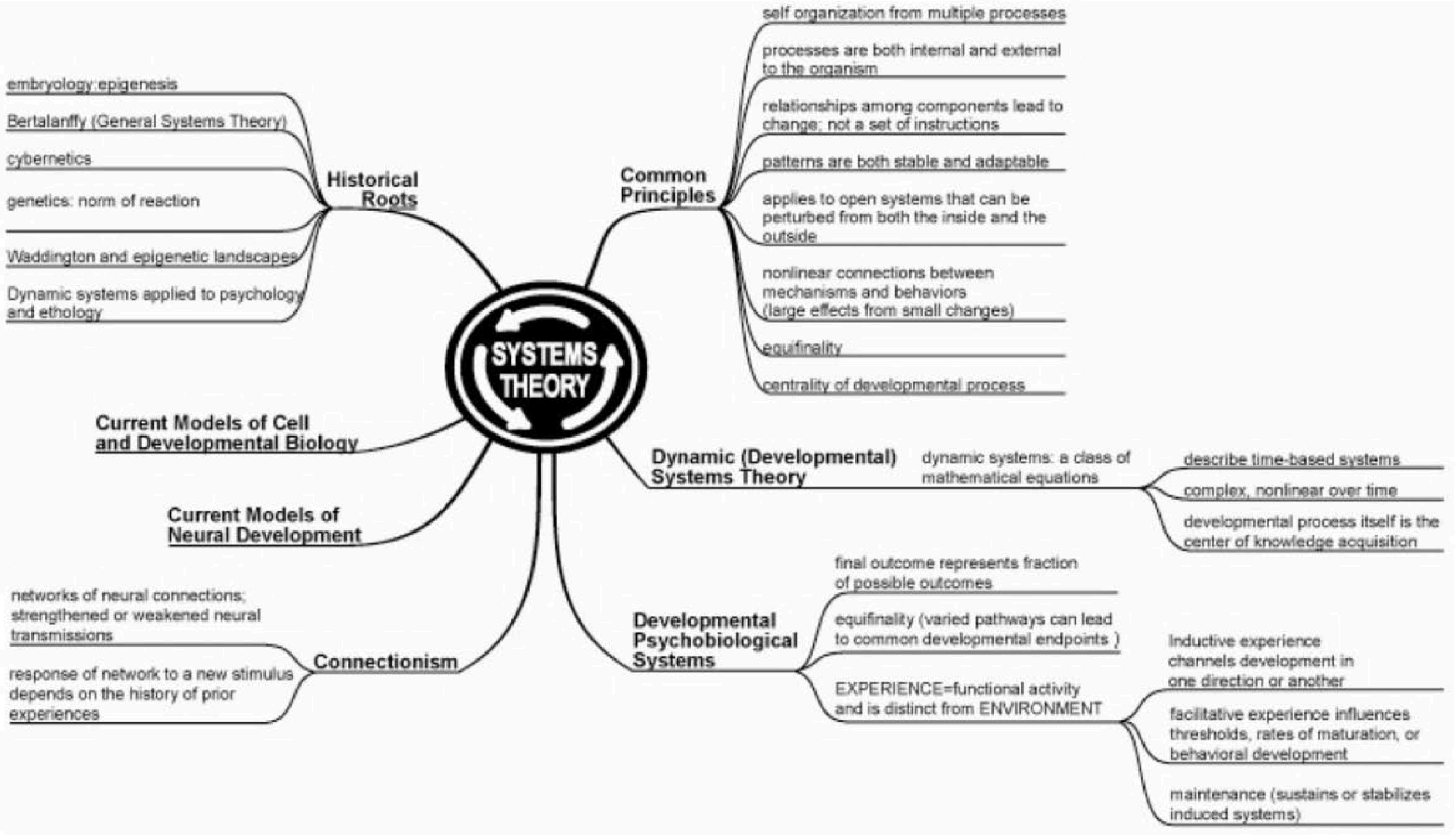


Figure 2 Overview of systems theories

“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” (1516).

Embodiment is a **dynamic system** of **biocultural formation** that reaches beyond gender.

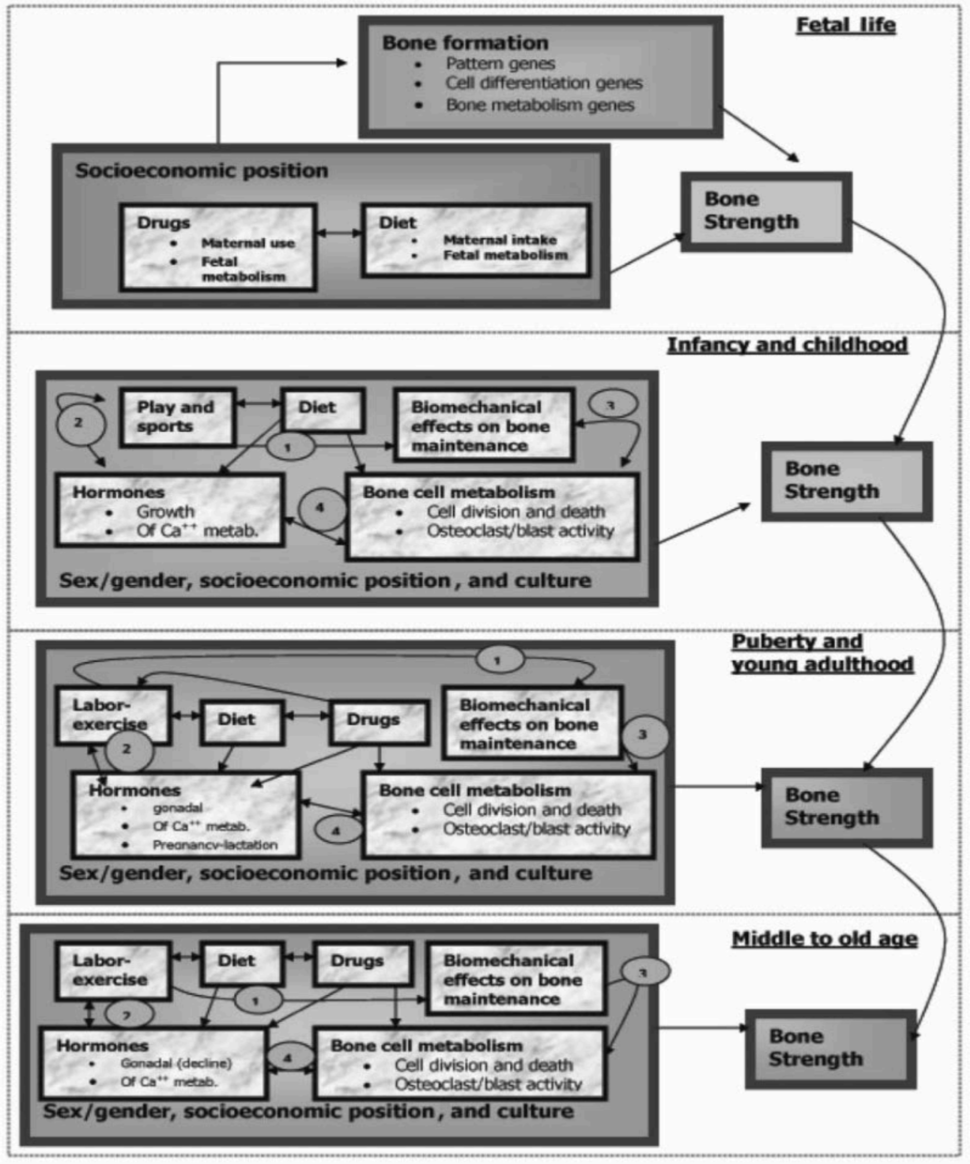


Figure 3 A life history–systems overview of bone development. (1) Physical activity has direct effects on bone cell receptors and indirect effects by building stronger muscles, which exert physical strain on bones, thus stimulating bone synthesis. (2) Physical activity that takes place outdoors involves exposure to sunlight, thus stimulating vitamin D synthesis, part of the hormonal system regulating calcium metabolism. (3) Biomechanical strain affects bone cell metabolism by activating genes concerned with bone cell division and bone (re)modeling. (4) Hormones affect bone cell metabolism by activating genes concerned with bone cell division, cell death, bone (re)modeling, and new hormone synthesis.

Ethical Engagement of Minority and Underserved Populations in Research

Jenn Kwait, PhD, MHS

Whitman-Walker Institute

Whitman-Walker Institute “expands 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 (WWH), the Institute’s affiliated entity, is an FQHC with a 40-year history providing HIV and LGBTQ+ health care services. It offers a range of community-based care, including medical, dental, mental health, substance use treatment, pharmacy services; legal services; and public benefits navigation in three DC locations.

Our initiatives aim to:

- reshape systems to promote health equity for underserved communities
- engage in authentic dialogue with community members to ensure our agenda focuses on priorities and health outcomes identified by those we serve

Community Engagement in Whitman-Walker's Research

Different structures and goals:

- Organization-based Community Advisory Group (CAG)
- Study-specific Community Advisory Boards (CAB)
- Projects focused on community engagement and building capacity

Whitman-Walker Institute Community Advisory Group

Goals:

- Advance our community engagement in all steps of the research process and our policy and education initiatives
- Create meaningful research, policy, and education initiatives that lead to positive outcomes for all communities by focusing on understanding and addressing community needs, engaging community members from the outset, and building trust through authentic experiences
- Foster relationships with individuals from communities around DC, including leaders from other community-based organizations, healthcare providers, and other social networks to facilitate genuine, informed, and reciprocal relationships between the Whitman-Walker Institute and the diverse communities of Washington, DC

Whitman-Walker Institute Community Advisory Group

Group Priorities:

- Establish key health issues and under-represented topics for research and education within Whitman-Walker's work
- Build strategies for identifying these issues in collaboration with group members and Institute staff

Logistics:

- Meetings are once a month (virtually and in-person)
- Participants are compensated

Whitman-Walker Institute Community Advisory Group

Examples of Meeting Topics:

- Whitman-Walker Institute intro and Community Advisory Group role
- Service needs and priorities
- Research 101 – spent time making connections between identified service needs and research connections
- Review of a Research Needs Assessment project (DC CFAR-funded)
- Whitman-Walker's role in the MACS/WIHS Combined Cohort Study (NIH-funded)
- Community engagement for a PCORI-funded project and future directions for research
- Review of new grants, including one around community engagement in chemsex research

MACS/WIHS Combined Cohort Study

13 clinical research sites (plus sub-sites) currently following over 5,000 participants
Whitman-Walker is a sub-site to Johns Hopkins University – historically a MACS site focused on sexual minority men.

“MWCCS is a collaborative research effort that aims to understand and reduce the impact of chronic health conditions—including heart, lung, blood, and sleep (HLBS) disorders—that affect people living with HIV. The study is designed to investigate a spectrum of questions relating to the basic science, clinical science, and epidemiology of HIV infection in the U.S., with a focus on comorbidities among men and women living with HIV.”

NHLBI is the primary steward of MWCCS, working in close collaboration with NIH Office of AIDS Research and several co-funding Institutes.

https://statepi.jhsph.edu/mwccs/about-mwccs/

MWCCS Community Advisory Board Defined

"A Community Advisory Board (CAB) is a collective group of study participants and organization representatives that provide community information and assistance to the research project. Each of the MWCCS study sites has a local CAB and study participants are encouraged to participate in order to help build and foster partnerships between researchers and local study communities impacted by HIV/AIDS."

https://statepi.jhsph.edu/mwccs/ncab/

JHU and Whitman-Walker MWCCS Site CAB

Local site (SHARE) CAB:

- Participants from the JHU and Whitman-Walker sites (Baltimore and Washington)

Goals:

- Help define the SHARE research agenda and how it is carried out
- Monitor and provide feedback about the quality of interactions between SHARE staff and participants
- Provide input about other SHARE activities, such as recruitment of new participants

Logistics:

- Meetings are held once every month, except July and August (virtually since COVID)
- Participants are not compensated (has always been a volunteer role)
- CAB Chair section in the SHARE newsletter to participants

JHU and Whitman-Walker MWCCS Site CAB

Recent agenda:

- Review of minutes
- MWCCS updates
- SHARE 40th Anniversary Updates
- NCAB Updates

Examples of other topics discussed:

- Experience with visits, including challenges (e.g., use of iPad for neurocognitive assessment) and positive feedback
- Suggestions for new recruitment flyers
- Input about new study components, such as smell assessment and internalized HIV stigma recently

Project SHINE (PCORI)

Goals:

- Build community capacity to engage as full partners and co-leads in patient-centered comparative effectiveness research (CER) – this focuses on partnership in all research phases
- Identify under-researched topics related to sexual and reproductive health (SRH) for LGBTQ+-identifying people assigned female sex at birth (AFAB)
- Build an ongoing and sustainable partnership between community members and researchers around improving SRH, along with other health-related topics, through patient-centered CER

PCORI Contract # EACB-26853

Lessons Learned

- Compensate people for their time

- Clarity of goals and purpose of community engagement (CAB, capacity-building) and role of community partners is essential
  - Define goals in partnership with community
  - Align goals determined by funding with community perspective, including balancing:
    - community-led work with direction from study team to meet funded goals
    - time devoted to open dialogue with advancing needed tasks to accomplish study

Lessons Learned, continued

- Take the time to build rapport and trust; sometimes this work is repairing broken trust (on-going work and not a finite task)

- Embrace failure and making mistakes; own mistakes and take shared action and needed time to repair (can be hard for researchers to shift from study tasks, science, and timelines)

- Meet people where they are in terms of how people best process information, for example using close caption; using chat in an agreed-upon way; paying attention to language, amount, and content of material (how long have we all trained to be investigators!); and meeting people after engagement activities to review

Lessons Learned, continued

- Consider what happens to the advisory group when the study ends – build this into work from beginning
  - What does sustainability of community engagement structures look like (e.g., role with other researchers, funding)

- Disseminate process and content to communities and continue discussion about implications for community engagement in next steps (e.g., interventions, follow-up research)

- Collaborate, collaborate, collaborate with other researchers who are advancing on-the-ground community engagement!

Lessons Learned, continued

Other food for thought!

- How do we to study distressing experiences in a community-driven way?
  - Consideration of participant well-being and needs when asking about potentially distressing experiences – this also applies to CAB and other meetings, such as our capacity-building work

- 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?

Lessons Learned, continued

More food for thought!

- What does “participant” mean to you? What does “engagement” mean to you and in the context of the work? What does “engagement” mean to community members who you are your partners? How to structure engagement so that it is an authentic collaboration? Does community collaboration have finite periods?
- What are some ways that you do your work that may not promote or advance equity in the community engagement process?

Always welcome to reach out:

jkwait@whitman-walker.org

Thank you.

WHITMAN-WALKER
Health System

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The Importance of SOGISC Data Collection in Research

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Office of the Director
National Institutes of Health

National Institutes of Health
Sexual & Gender Minority Research Office

2 October 2024

Data = Visibility: A History

~630-570 BC Sappho

1886: Psychopathia Sexualis published

1897-1923: Havelock Ellis publishes volumes on Psychology of Sex

1905: Theory of Sexuality published

1924: Society for Human Rights founded

1928: *Orlando* and *The Well of Loneliness* published

1948: *Kinsey Report* Published

1950: Mattachine Society founded

1952: Christine Jorgensen "Ex-GI becomes blonde bombshell!"

1953: President Eisenhower signs EO 10450 banning homosexuals from federal employment

1953: Evelyn Hooker starts research

1955: Daughters of Bilitis founded

1963: March on Washington

1964: Civil Rights Act signed

1965: Philadelphia Independence Hall picket for "reminder day"

June 1965: Griswold v. Connecticut

1966: Compton's Cafeteria Riot

June 1967: Loving v. Virginia

June 1969: Stonewall Inn Rebellion

1973: APA removes homosexuality from mental disorders

1989: Price Waterhouse v. Hopkins

1994: Don't Ask, Don't Tell enacted

1996: Defense of Marriage Act made law

1998: EO 10450 language banning gay fed employment repealed

2003: Lawrence v. Texas

2010: Don't Ask, Don't Tell Repeal

2012: APA removes "disorder" from gender identity

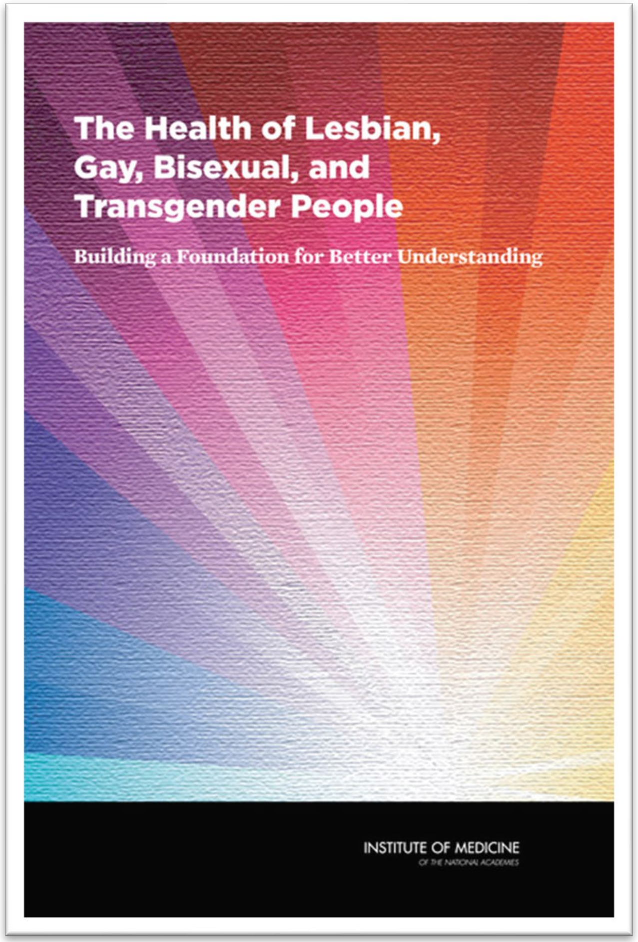
2013: Windsor v. United States

2015: Obergefell v. Hodges

2020: Bostock v. Clayton County

2022-Present: Onslaught of state-level anti-LGBTQ+

NASEM Reports

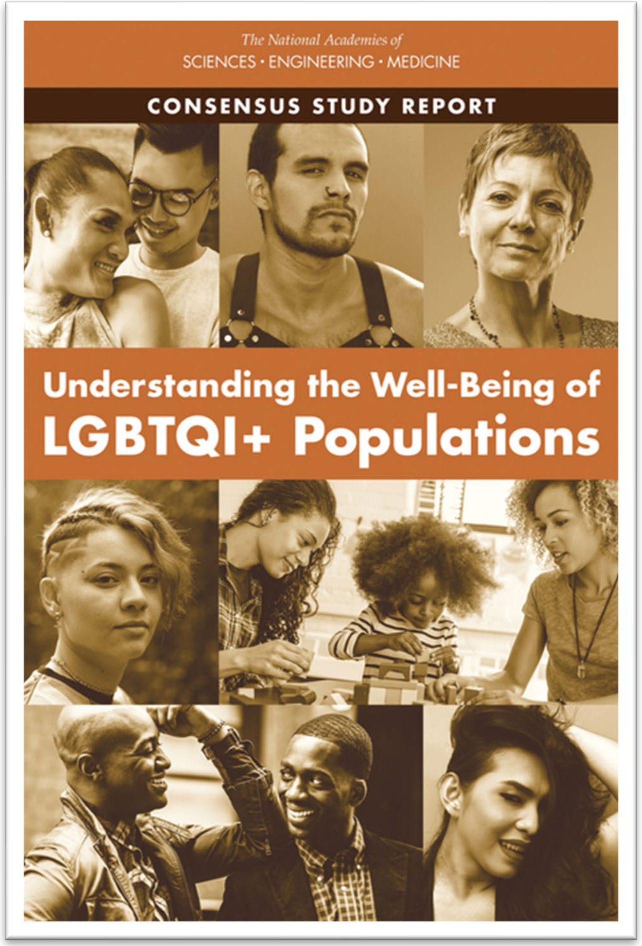


The Health of Lesbian, Gay, Bisexual, and Transgender People

Building a Foundation for Better Understanding

INSTITUTE OF MEDICINE
OF THE NATIONAL ACADEMIES

2011



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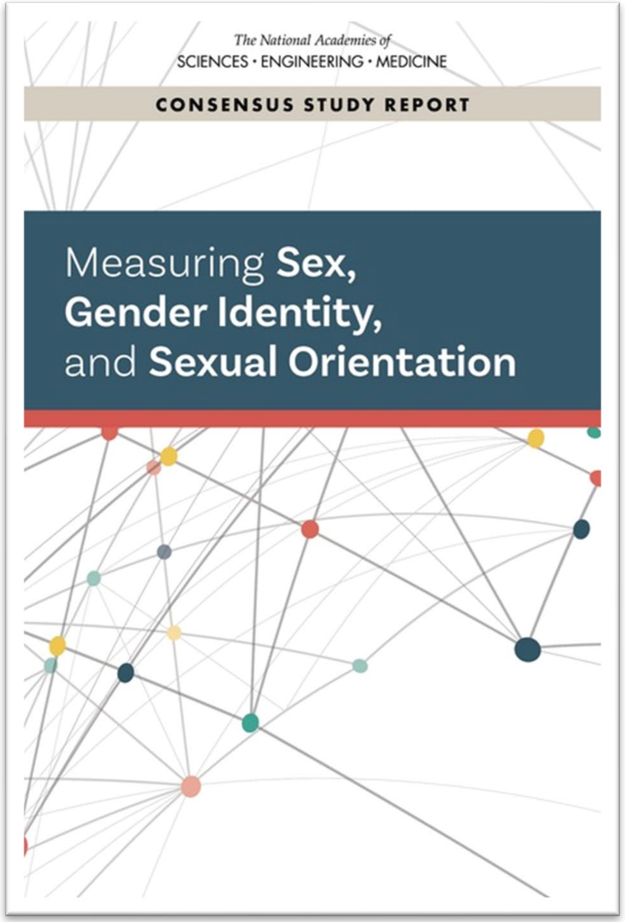
CONSENSUS STUDY REPORT

Understanding the Well-Being of LGBTQI+ Populations

2020



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CONSENSUS STUDY REPORT

Measuring **Sex, Gender Identity,** and **Sexual Orientation**

2022

Federal Landscape

National Academies Consensus Studies drive and focus LGBTQI+ Data Efforts Across Time

2010–2014

Interagency Working Group on Measuring Relationships in Federal Household Surveys (**MRFHS IWG**)

2015–2016

Interagency Working Group on Measuring Sexual Orientation and Gender Identity (**SOGI IWG**)

2018 to present

FCSM Measuring Sexual Orientation and Gender Identity Research Group (**SOGI RG**)

2022 to 2023

Interagency Working Group on EO 14075 Federal Evidence Agenda on LGBTQI+ Equity (January 2023)

2023 to Present

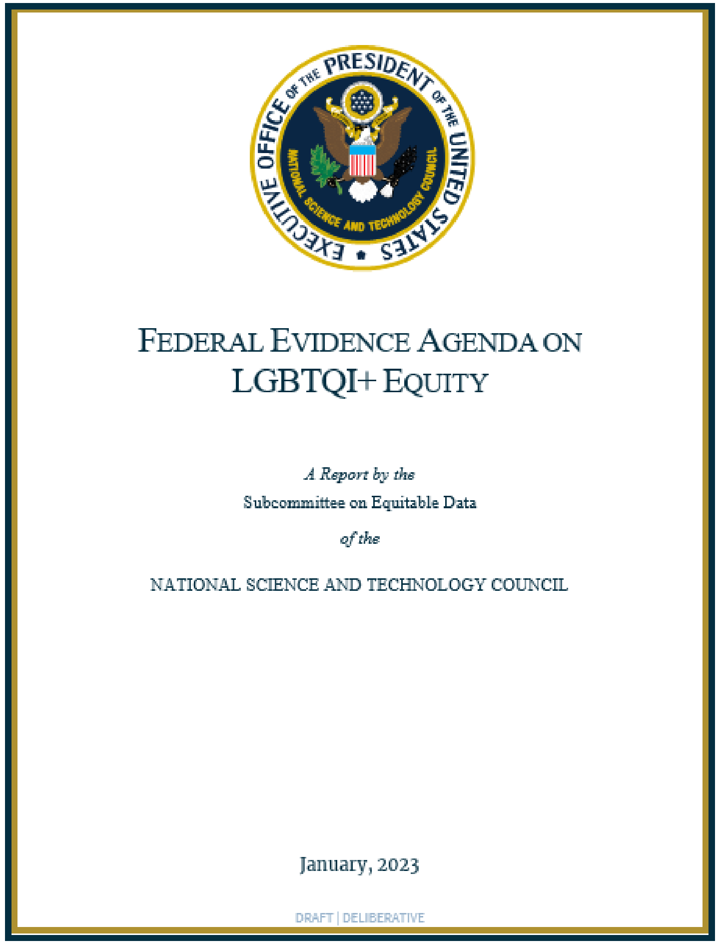
Federal SOGI Data Action Plan ongoing efforts to advance equitable data

Nearly exclusive focus on developing and testing questions for large national surveys

Persisting Measurement Challenges

- No official statistical standards or agreed on common data elements
- Labels/definitions are fluid and rapidly changing
- Many terms are unfamiliar to straight and cisgender populations
- Need for translations into languages other than English
- Research previously focused on survey methodology not administrative and clinical data collection
- Dearth of research on measuring variation in sex characteristics and intersex people

Advancing Equality for Lesbian, Gay, Bisexual, Transgender, Queer, and Intersex Individuals (LGBTQI+)



FEDERAL EVIDENCE AGENDA ON LGBTQI+ EQUITY

A Report by the
Subcommittee on Equitable Data
of the
NATIONAL SCIENCE AND TECHNOLOGY COUNCIL

January, 2023

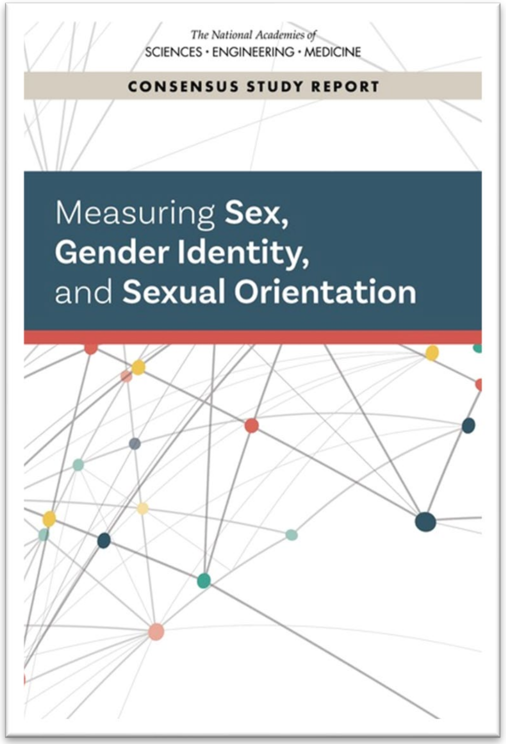
DRAFT | DELIBERATIVE

- Wide-ranging EO with many components and requirements
- Recognition that advancing equity and full inclusion requires improvements in data collection and evidence use
- Emphasis on promoting inclusive and responsible Federal data collection practices:
    - Development of Federal Evidence Agenda on LGBTQI+ Equity
    - Development and implementation of agency SOGI Data Action Plans
    - Recommendations for agencies on the best practices for collection of SOGI data on Federal statistical surveys

https://www.whitehouse.gov/wp-content/uploads/2023/01/Federal-Evidence-Agenda-on-LGBTQI-Equity.pdf

Guiding Principles

- **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
- **Privacy**
  - Use data in a manner that benefits respondents and respects their privacy and confidentiality



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CONSENSUS STUDY REPORT

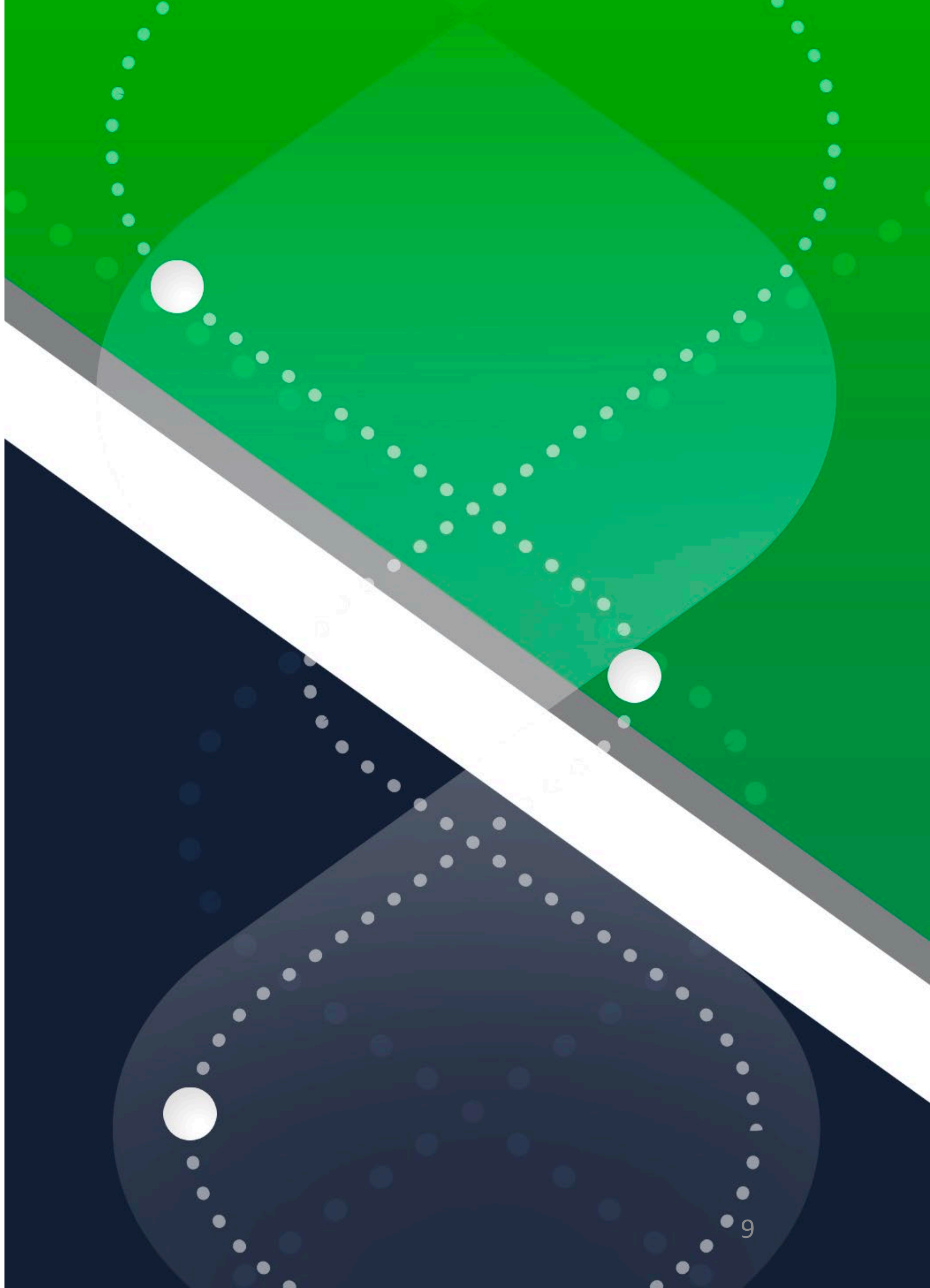
Measuring **Sex, Gender Identity,** and **Sexual Orientation**

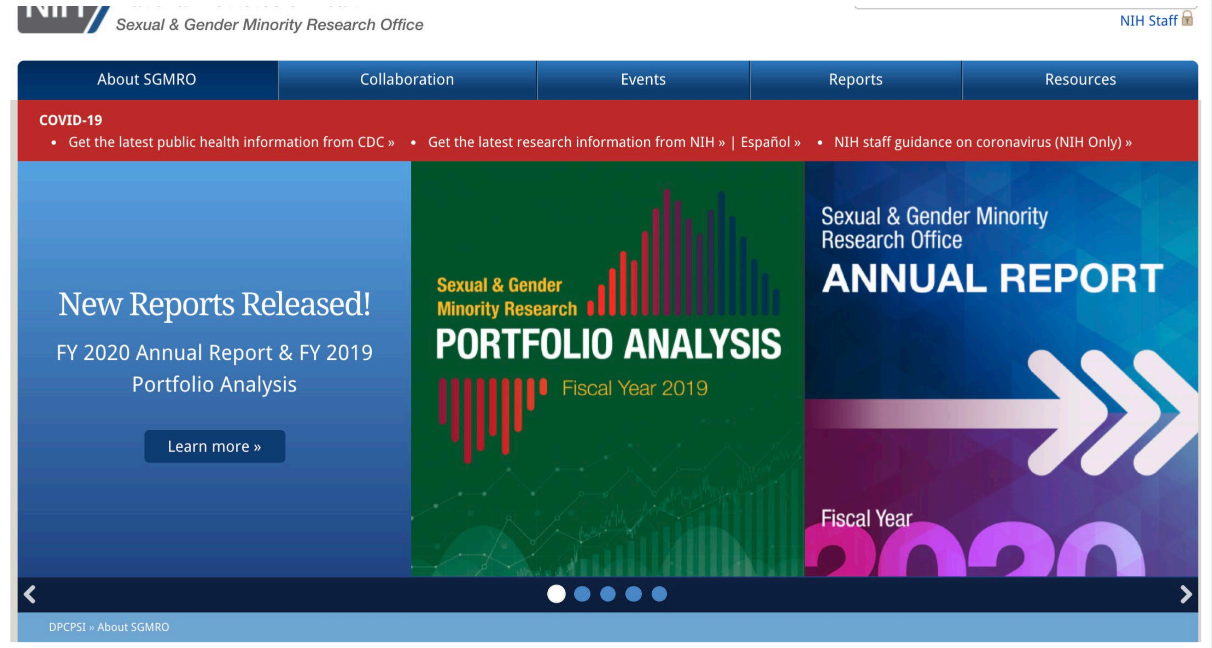
Ethics of Exclusion

- Administrative Data vs. Clinical Data vs. Health Survey Data
  - Robust SOGI data for demographic purposes is important for basic reporting on differing populations in studies
  - Clinical information like anatomical inventories and hormonal milieu have historically not been considered standard information
  - Disrupting persistent use of binary sex or gender as a proxy for anatomy or hormonal profile can be expected
  - Reference range values may be applied inappropriately with incomplete information

THANK YOU!

Christina.Dragon@nih.gov





Sexual & Gender Minority Research Office

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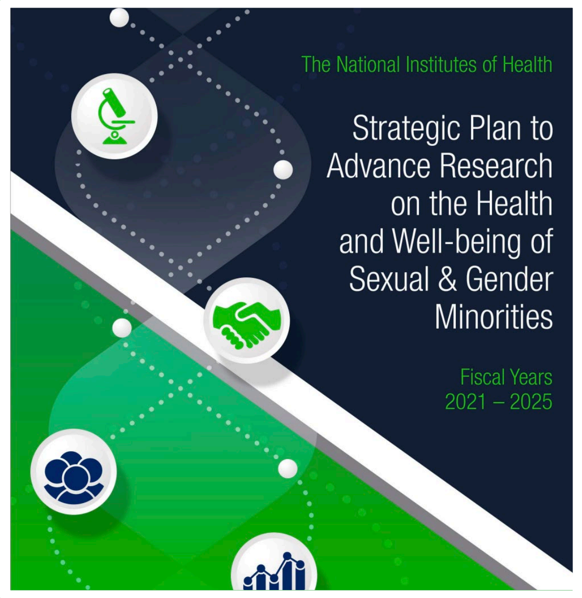

The National Institutes of Health

Strategic Plan to Advance Research on the Health and Well-being of Sexual & Gender Minorities

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