



Ethical Review and Inclusion of LGBTQI+ Participants in Human Subjects Research

Fact Sheet on Advisory Committee Recommendations

2024



Office for
Human Research
Protections

TABLE OF CONTENTS

Purpose _____ 3

OHRP’s Charge to SACHRP _____ 3

The Role of SACHRP _____ 3

Overview of SACHRP’s Recommendations _____ 4

Involved Individuals and Entities _____ 5

Considerations for Research Design, Review, and Conduct _____ 6

Conclusion _____ 7

Additional HHS Resources _____ 7

Purpose

This fact sheet provides a summary from the Office for Human Research Protections (OHRP) of recommendations made by an advisory committee reporting to the Assistant Secretary for Health about the ethical oversight and inclusion of Lesbian, Gay, Bisexual, Transgender, Queer, Intersex, and other orientations and identities (LGBTQI+) participants in human research. The highlighted recommendations align with the Assistant Secretary for Health's mission to address inequities, promote equity, and advance LGBTQI+ access to care and health equity across the U.S.ⁱ Advisory committee recommendations described in this fact sheet do not necessarily represent the official views or policies of OHRP, the Office of the Assistant Secretary for Health (OASH), or the Department of Health and Human Services (HHS).

OHRP's Charge to SACHRP

In 2023, OHRP charged the Secretary's Advisory Committee on Human Research Protections (SACHRP) with providing recommendations for investigators, sponsors, IRBs, human research protection programs (HRPPs), and research institutions regarding the ethical and regulatory considerations for research involving LGBTQI+ participants, including both adults and minors. OHRP's charge described three primary objectives for SACHRP in developing its recommendations:

- (1) Ensuring the ethical protection of LGBTQI+ participants in research
- (2) Promoting the advancement of LGBTQI+ research and working toward reducing health disparities within LGBTQI+ communities
- (3) Enhancing the knowledge and cultural understanding of research involving LGBTQI+ participants

The Role of SACHRP

SACHRP provides expert advice and recommendations to the Secretary of Health and Human Services, through the Assistant Secretary for Health, on issues and topics pertaining to or associated with the protection of human research subjects. The Committee works to advise the Secretary on how to improve the quality of the system of human research protection programs, including the responsibilities of investigators, institutional review boards (IRBs), administrators, and institutional officials, and the role of OHRP and other offices within HHS.ⁱⁱ

SACHRP's recommendations are the result of considerable Committee effort, deliberation, and consensus building. Once the Committee votes to provide recommendations on an issue, its recommendations are transmitted to the Director of OHRP, the Assistant Secretary for Health, and the Secretary, for their consideration, and posted on OHRP's website.

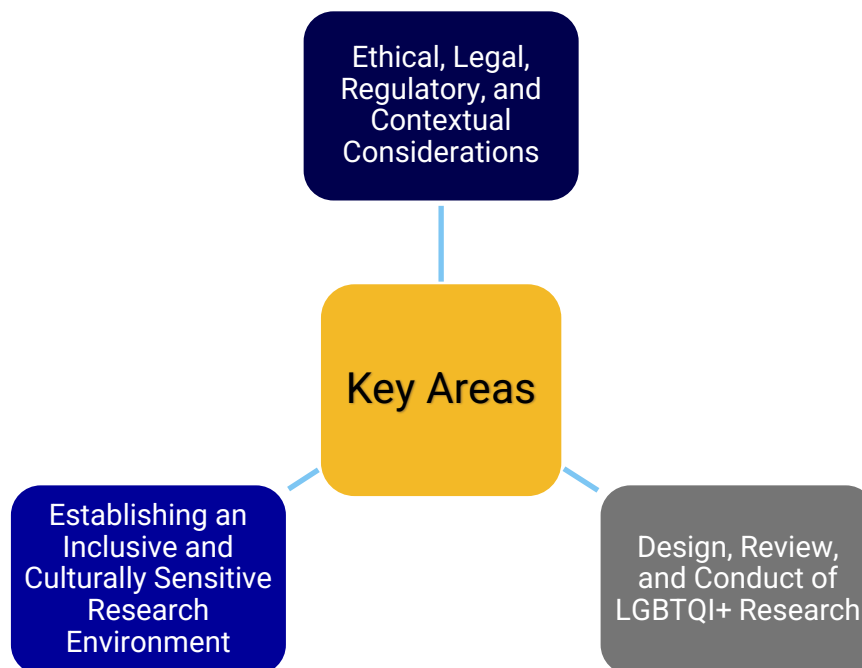
Overview of SACHRP's Recommendations

In July 2024, SACHRP voted to provide recommendations to the Assistant Secretary for Health and the Secretary regarding research that involves LGBTQI+ participants.^{iii, iv} These include suggestions for how institutions, IRBs, sponsors, HRPPs, and investigators can aim for research that is respectful, relevant, and responsive to LGBTQI+ communities, uphold appropriate confidentiality protections, and support dissemination of research results to LGBTQI+ individuals.

“The development of an inclusive research enterprise requires the meaningful involvement of LGBTQI+ stakeholders in scientific priority-setting, research design, assessment of perceived risks and benefits, study implementation, regulatory oversight, and the analysis and dissemination of results.”

SACHRP identified specific recommendations that focus on three key areas deemed essential both for research specifically relevant to LGBTQI+ communities and for research more broadly:

- (1) Ethical, Legal, Regulatory, and Contextual Considerations
- (2) Considerations for Establishing an Inclusive and Culturally Sensitive Research Environment
- (3) Considerations for the Design, Review, and Conduct of LGBTQI+ Research



KEY STATEMENTS

- “[P]lanning and collaboration across involved groups, from IRBs/HRPPs, sponsors, research institutions, investigators, regulatory bodies, and those with lived experience is needed to best serve the needs and concerns of LGBTQI+ communities.”
- “It is important to recognize that LGBTQI+ individuals are members of distinct communities, each with unique experiences and specific research needs.”
- “Failure to tailor research to support the inclusion of individuals with diverse gender identities and sexual orientations maintains and creates gaps in the evidence base.”
- “Minors face unique challenges and vulnerabilities, particularly regarding privacy and confidentiality...It is essential to ensure that minors' rights, well-being, and privacy are protected throughout the research process.”
- “Appropriate dissemination of research results to the LGBTQI+ community can facilitate trust and encourage participation.”
- “[I]nclusive research practices are not only required for sound ethical practice, but also are essential for advancing equity and improving outcomes for all communities.”

Involved Individuals and Entities

SACHRP’s recommendations include considerations and potential actions for investigators, sponsors, IRBs/HRPPs, and research institutions.

Investigators

Sponsors

IRBs/HRPPs

Research Institutions

SACHRP noted these parties “...must adhere to the ethical standards outlined in the Belmont Report^v and incorporated in applicable agency guidelines and federal regulations...” and recommended they also uphold “standards for scientific rigor and validity.” SACHRP also pointed out the importance of diversity and inclusion among those that conduct and oversee research, and not just among study participants. For example, SACHRP recommended IRBs/HRPPs “[e]stablish guidelines for assessing the diversity and inclusivity of IRB members and IRB/HRPP staff, research protocols and study teams during the IRB review process” and research institutions “[e]stablish and support mentorship programs and support networks for LGBTQI+ researchers to provide professional development opportunities, training, and other resources.”

“Promoting diverse and inclusive representation in study teams, IRBs/HRPPs, and organizational leadership is crucial to ensuring that the perspectives and experiences of LGBTQI+ communities are accurately reflected and respected throughout the research process.”

SACHRP’s recommendations highlight the diversity within and among LGBTQI+ communities and explain why it is important that investigators, sponsors, IRBs/HRPPs, and research institutions take into account intersecting factors, such as race, ethnicity, age, disability, and socioeconomic status.

Considerations for Research Design, Review, and Conduct

SACHRP's recommendations focus on the design, review, and conduct of LGBTQI+ research. While SACHRP noted that these recommendations "may not be achievable or suitable in all cases," the recommendations include the following points to consider:

- ☑ Consider factors such as gender identity, sexual orientation, and gender expression when defining inclusion/exclusion criteria.
- ☑ Establish meaningful reference or consultation groups to ensure that data interpretation is respectful and sympathetic in the ways intended, and accurate in meaning.
- ☑ Evaluate the need for anonymity and/or identifiability of data relative to the study design and question, despite classical views that assume a need for guaranteed anonymity for LGBTQI+ participants in research.
- ☑ Select research methods that are inclusive and sensitive to LGBTQI+ participants.
- ☑ Offer infrastructure and resources, such as methodological support services and/or connections with collaborative research centers, to facilitate the implementation of LGBTQI+ inclusive research methodologies.
- ☑ Implement patient screening processes that are inclusive, gender affirming and relevant to the study at hand.
- ☑ Revise forms, paperwork, and data collection instruments to include questions that account for differences in sexual orientation and gender identity.
- ☑ Ensure that language throughout the consent process is culturally appropriate and inclusive.
- ☑ Develop comprehensive privacy and confidentiality measures that address the unique vulnerabilities and concerns of LGBTQI+ participants.
- ☑ To support continuous quality improvement efforts, facilitate clear communication channels, such as focus groups with LGBTQI+ research participants.
- ☑ Provide training and resources to investigators on best practices for disseminating findings to LGBTQI+ communities.
- ☑ Consider adopting tailored strategies for research involving LGBTQI+ minors in order to address, for instance, vulnerabilities that may be different from those faced by adults.

“Incorporating LGBTQI+ considerations into research design is critical for ensuring the relevance, validity, and ethical integrity of studies including LGBTQI+ participants.”

Conclusion

The SACHRP recommendations address three main topic areas: ethical, legal, regulatory, and contextual considerations; establishing an inclusive and culturally sensitive research environment; and considerations for the design, review and conduct of LGBTQI+ research. These recommendations focus on considerations for investigators, sponsors, IRBs/HRPPs, and research institutions for ethical review and inclusion of LGBTQI+ adult and minor participants in human subjects research.

“SACHRP emphasizes the importance of adhering to ethical standards, fostering community engagement, ensuring confidentiality, and promoting cultural competence. By thoughtfully considering and practically implementing these recommendations, investigators, sponsors, IRBs/HRPPs, and research institutions can create a research environment that respects and addresses the needs and experiences of LGBTQI+ participants.”

For the full SACHRP recommendations for the ethical review and inclusion of LGBTQI+ participants in human subjects research, visit OHRP’s website [here](#).

Additional HHS Resources

- [HHS Sexual Orientation and Gender Identity \(SOGI\) Data Action Plan](#)
- [OASH Health Equity Fact Sheet](#)
- [SAMHSA Top Health Issues for LGBT Populations Information & Resource Kit](#)
- [OCR Guidance on Gender Affirming Care, Civil Rights, and Patient Privacy](#)
- [LGBTQI+ Older Adults – Know Your Rights Resource Guide](#)

ⁱ <https://www.hhs.gov/about/news/2024/04/01/oash-health-equity-fact-sheet.html>

ⁱⁱ <https://www.hhs.gov/ohrp/sachrp-committee/charter/index.html>

ⁱⁱⁱ <https://www.hhs.gov/ohrp/sachrp-committee/recommendations/2024-july-25-letter/index.html>

^{iv} <https://www.hhs.gov/ohrp/sachrp-committee/recommendations/ethical-review-inclusion-lgbtqi-participants-human-subjects-research/index.html>

^v <https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/read-the-belmont-report/index.html>