# SACHRP Recommendations for the Ethical Review and Inclusion of LGBTQI+ Participants in Human Subjects Research DRAFT 07/23/2024_hr. 1645

## Introduction

The Secretary's Advisory Committee for Human Research Protection (SACHRP) has been tasked with providing recommendations for investigators, sponsors,[1] 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.

As noted in SACHRP's Charge, the request of the Office for Human Research Protections (OHRP) is motivated by three primary objectives: (1) 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; (2) Promoting the advancement of LGBTQI+ research and working towards reducing health disparities within LGBTQI+ communities; and (3) Enhancing the knowledge and cultural understanding of research involving LGBTQI+ participants.

In the Charge, OHRP emphasizes that it is imperative for investigators, sponsors, IRBs/HRPPs, research institutions, and other stakeholders to address the ethical and practical considerations associated with LGBTQI+ research participants. It is important to recognize that LGBTQI+ individuals are members of distinct communities, each with unique experiences and specific research needs. In addition, OHRP states that this acknowledgment is essential to protect the rights, dignity, and well-being of research participants and to foster research that benefits both LGBTQI+ individuals and society as a whole by promoting understanding, informing policy changes, and improving outcomes for LGBTQI+ populations.

In response to OHRP's Charge to SACHRP, the recommendations that follow will address specific questions related to research involving LGBTQI+ adult and minor participants, focusing on two key areas. These considerations are essential both for projects addressing broadly relevant research questions and for projects focused on research priorities specifically relevant to LGBTQI+ communities.

1. Ethical, Legal, Regulatory, and Contextual Considerations
    - *Ethical Considerations*
      How can investigators, sponsors, IRBs/HRPPs, and research institutions seek to ensure the adequate inclusion of LGBTQI+ participants and protection of their rights and welfare in research to meet ethical and professional standards?

    - *Laws, Regulations, and Guidelines*
      Given the challenge of applying the myriad laws, regulations, and guidelines that may impact research involving LGBTQI+ participants, how can investigators, sponsors, IRBs/HRPPs, and research institutions seek to ensure the adequate protection of LGBTQI+ participants, ethical conduct of research, and feasibility of conducting research involving LGBTQI+ communities?

    - *Contextual Variables*
      In addition to the application of laws, regulations, and guidelines, how can investigators, sponsors, IRBs/HRPPs, and research institutions 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 in research involving LGBTQI+ participants?

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[1] For purposes of this document, "sponsor" refers to the following: "An individual, organization, institution, or entity that takes responsibility for the initiation, management, and/or financing of a [research project]."

2. Considerations for Establishing an Inclusive and Culturally Sensitive Research Environment
    - *Community Engagement*
      How can investigators, sponsors, IRBs/HRPPs, and research institutions seek to ensure that the priorities, perspectives, values, and needs of LGBTQI+ communities are understood, integrated, and appropriately calibrated into design, review, oversight, implementation, and dissemination of results?

    - *Composition of the Study Team, IRB, and Organizational Leadership*
      How can investigators, sponsors, IRBs/HRPPs, and research institutions actively promote diverse and inclusive representation during the research process (including representation on the study team, IRB, and organizational leadership) to reflect the LGBTQI+ communities' perspectives and experiences?

    - *Cultural Competence*
      What measures should investigators, sponsors, IRBs/HRPPs, and research institutions adopt to foster cultural awareness, competence, and humility regarding LGBTQI+ communities throughout the research process?

    - *Intersectionality*
      How can investigators, sponsors, IRBs/HRPPs, and research institutions effectively address the experiences and challenges LGBTQI+ participants may face due to gender, sexual orientation, and other characteristics and multifaceted identities, such as their race, ethnicity, national origin, color, age, and disability?

3. Considerations for the Design, Review, and Conduct of LGBTQI+ Research.
    - *Research Design and Analysis*
      How can investigators, sponsors, IRBs/HRPPs, and research institutions best incorporate and evaluate LGBTQI+ considerations into research questions, methods, conduct, inclusion/exclusion criteria, the collection and analysis of sexual orientation and gender identity data, and seek to ensure that the research protocol and study-related documents reflect these factors?

    - *Access and Inclusion*
      What strategies should be employed in the development and evaluation of recruitment plans for LGBTQI+ participants to promote representation in research?

    - *Informed Consent*
      How can investigators, sponsors, IRBs/HRPPs, and research institutions seek to ensure that the informed consent process in studies involving LGBTQI+ participants are specifically designed to take into consideration the needs and interests of these communities?

    - *Privacy and Confidentiality*
      Given the potential for discrimination, stigma, and other harm, what additional privacy and confidentiality measures should be considered to protect LGBTQI+ research participants and their partners and other non-research participants?

    - *Oversight, Support, and Security*
      How should investigators, sponsors, IRBs/HRPPs, and research institutions establish and maintain appropriate oversight, infrastructure, security, and other support for research involving LGBTQI+ participants?

    - *Reporting and Dissemination of Findings*
      When reporting and disseminating findings, how should investigators, sponsors, IRBs/HRPPs, and research institutions seek to ensure that findings from research involving LGBTQI+ participants are

reported and disseminated in a way that promotes transparency and community benefit and prevents misrepresentation as well as individual and community (group) harm?

This document is organized to present a series of general recommendations first, followed by specific recommendations within each of the three topic areas enumerated above, concluding with considerations for research with minors. Some recommendations are broadly relevant across all human subjects research and subject populations, while others may be applicable only to individual studies or may not be suitable at all. Nonetheless, SACHRP encourages efforts to promote the ethical conduct of research involving and related to LGBTQI+ communities and the thoughtful consideration and practical implementation of these recommendations, recognizing that not all recommendations may be feasible or appropriate in all circumstances. This acknowledges that while these recommendations aim to guide ethical research practices, some may not be achievable or suitable in all cases due to practical limitations or specific research conditions.

## Background

Ensuring the equitable inclusion of LGBTQI+ participants in research is essential for safeguarding their rights and welfare. As with other underrepresented groups and study populations, Investigators, sponsors, IRBs/HRPPs, and research institutions must adhere to the ethical standards outlined in the Belmont Report[2] and incorporated in applicable agency guidelines and federal regulations (e.g., HHS regulations at 45 CFR part 46 and the FDA Regulations at 21 CFR parts 50 and 56, etc.). This includes actively considering how research decisions, such as recruitment methods and data collection practices, affect the inclusion, privacy, and safety of LGBTQI+ participants in research.

Promoting a scientifically inclusive evidence base demands the alignment of research priorities and research resources with the needs and concerns of LGBTQI+ individuals and communities. Efforts to achieve fairness in the goals, conduct, and impact of research concerning LGBTQI+ populations require recognition of how the current research enterprise needs to improve its efforts to properly identify these populations and tailor study aims and methods appropriately. Inclusion as an afterthought consistently fails. Instead, planning and collaboration across stakeholder groups, from IRBs/HRPPs, sponsors, research institutions, investigators, regulatory bodies, and those with lived experience is needed to best serve the scientific and health needs of LGBTQI+ communities.

Applying these principles and assessing whether research addresses topics relevant to and inclusive of LGBTQI+ communities is important because, according to a 2022 report from the National Academies of Sciences, Engineering, and Medicine (NASEM), there are “major knowledge gaps [regarding] the health needs of [LGBTQI+] people”[3]; LGBTQI+ individuals are underrepresented in research; and research often fails to collect data about sexual and gender identity.

The NASEM report also identified multiple threats stemming from underrepresentation in research, including the risk that research results may not be generalizable to underrepresented participants, preventing them from receiving the benefits of research , resulting in negative health effects and economic costs. Such outcomes are inconsistent with the three Belmont principles–*respect for persons*, *beneficence*, and *justice*–which are the foundation for applicable agency guidelines and federal regulations. Underrepresentation among LGBTQI+ participants is not as thoroughly documented as it is for racial or ethnic populations.

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[2] U.S. Department of Health and Human Services. (1979). The Belmont Report: Ethical principles and guidelines for the protection of human subjects of research. Retrieved from https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html/.

[3] National Academies of Sciences, Engineering, and Medicine. (2022). Improving Representation in Clinical Trials and Research: Building Research Equity for Women and Underrepresented Groups. Washington, DC: The National Academies Press. https://doi.org/10.17226/26479.

The underrepresentation of LGBTQI+ communities limits their access to potential direct and indirect research benefits. It also further marginalizes such individuals by failing to sufficiently recognize and include them. As a result, they may face a number of barriers to healthcare and other non-healthcare related services. It is therefore incumbent on investigators, sponsors, IRBs/HRPPs, and research institutions to take steps toward more ethical and inclusive research and eliminate these disparities.

Ensuring fairness in access requires awareness of the social and cultural circumstances particular to LGBTQI+ groups (and subgroups within these communities), and the thoughtful and informed identification of risks specific to these groups. Investigators, sponsors, IRBs/HRPPs, and research institutions should recognize and respect the complexity of LGBTQI+ participants' identities, ensuring that studies consider intersecting factors such as race, ethnicity, age, disability, socioeconomic status, and other factors. Evidence demonstrates that engaging with various communities and having diverse representation within research institutions fosters more respectful and inclusive research that addresses LGBTQI+ needs and concerns and builds trust.[4]

Failure to tailor research to support the inclusion of individuals with diverse gender identities and sexual orientations also maintains and creates gaps in the evidence base. Including these individuals may provide preliminary information or signals regarding efficacy and harm, even when participant numbers do not allow for statistically sound subgroup analysis.

In summary, inclusive research practices are not only required for sound ethical practice, but also are essential for advancing equity and improving outcomes for all communities. The following provides a summary of general and specific recommendations to address these issues.[5]

## Recommendations

### A. General Recommendations

Investigators, sponsors, IRBs/HRPPs, and research institutions should ensure that the design and conduct of research adhere to applicable legal, regulatory, and ethical standards governing human subjects research, as well as standards for scientific rigor and validity. Addressing the gaps in the scientific evidence base requires particular attention to the inclusion of LGBTQI+ individuals within research. Ethical guidelines related to the inclusion of LGBTQI+ populations in research offer practical recommendations and best practices for upholding ethical standards. These may include guidelines for conducting culturally competent research, fostering trust and collaboration with LGBTQI+ communities, and more. While being cognizant of the specific political, cultural, and institutional attitudes regarding LGBTQI+ communities, investigators, sponsors, IRBs/HRPPs, and research institutions are obligated to promote adherence to ethical principles, regulatory directives, and scientific standards.

Below are recommendations to facilitate research involving LGBTQI+ participants.

#### 1. Selection of Research Questions and Data Collection

To strive for research that is relevant, meaningful, and respectful of the diverse experiences and identities within the LGBTQI+ communities, investigators, sponsors, IRBs/HRPPs, and research institutions should:

- Incorporate LGBTQI+ considerations into research questions, methods, and study protocols to ensure that research questions are relevant, meaningful, and respectful of the various LGBTQI+ identities and experiences. (Stakeholders can achieve this by actively involving LGBTQI+ community members in the

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[4] Id.

[5] The term "should" is used throughout this document to indicate best practices and recommendations. Unless explicitly required by law or regulation, the recommendations provided herein are intended as guidance to promote ethical and inclusive research practices involving LGBTQI+ participants.

research design process, utilizing inclusive language, and considering the unique needs and perspectives of LGBTQI+ individuals throughout the research process.)

- Update applicable forms, paperwork, and data collection instruments to include questions that acknowledge various sexual orientations and gender identities.
- Collect and analyze sexual orientation and gender identity data using inclusive and culturally appropriate terminology.
- Allocate resources for the collection and subgroup analysis of sexual orientation and gender identity data, ensuring appropriate methodology, privacy protections, and transparent reporting.
- Consider establishing separate research streams[6] focusing on the different scientific questions and different health and social needs of the L, the G, the B, the T, the Q, the I, and the (+), as well as possible intersecting impacts of gender, sexual orientation, race, ethnicity, age, disability, and other factors on health outcomes and experiences, as the needs of each community may not be the same.

### 2. Community Engagement

In order to foster research that is respectful, inclusive, and responsive to the needs of LGBTQI+ communities, investigators, sponsors, IRBs/HRPPs, and research institutions should:

- Engage with LGBTQI+ individuals, groups, and communities in defining priorities and development of research protocols, surveys, interview questions, informed consent forms, recruitment materials, and other study-related documents. A collaborative process at every stage of the research process can provide an opportunity for underrepresented voices to emerge, identify priorities, and develop research procedures that are more responsive to the communities' needs, potentially leading to better retention and results.
- Build sustainable partnerships with LGBTQI+ communities to ensure ongoing engagement and collaboration beyond the duration of an individual research project.
- Enlist LGBTQI+ community members and advisors to review research materials to ensure appropriateness.
- Establish mechanisms for ongoing dialogue with LGBTQI+ communities to address questions and concerns arising from the dissemination of findings.

### 3. Confidentiality

Because members of LGBTQI+ communities may experience stigma and discrimination and, in some jurisdictions, may be subject to legal risks, attention to confidentiality protections is necessary, but such concerns should not prevent necessary research from going forward. Strategies to consider include the following:

- Anonymize, de-identify, code, do not collect certain information, limit access to certain data, and/or recommend verification of Certificates of Confidentiality (CoC) protection or the existence of CoCs for studies to ensure that no further application steps are necessary.
- Tailor confidentiality protections to the specific needs and concerns of LGBTQI+ participants and for their partners and other non-research participants who might be at risk of identification because of the research.
- Ensure training of all research staff and conduct appropriate monitoring and assessment of data security.
- Consider variations in law, as risks to LGBTQI+ participants may vary according to location and setting. These variations should be considered in all research especially in multisite research.

### 4. Representation and Training

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[6] The phrase "research streams" means dedicated areas within a research program that focus on the specific health and social needs of distinct groups within the various LGBTQI+ communities.

To promote inclusive and culturally competent research practices, investigators, sponsors, IRBs/HRPPs, and research institutions should:

- Collect demographic information regarding sexual orientation and gender identity to assess membership on IRBs, grant review committees, etc., to allow for the assessment of representation with the option to not disclose if someone does not wish to provide this type of information about themselves. (Implementation should consider legal, practical, and ethical concerns. In addition, specific guidelines on when and how to collect this information should be developed to address potential concerns.)
- Provide opportunities for self-education and training on LGBTQI+ cultural competency, community engagement best practices, and research best practices, and regularly assess the effectiveness of these programs.
- Conduct structured training programs to develop cultural competence that fosters understanding and respect for the beliefs, values, and needs of LGBTQI+ populations, and incorporate this understanding into research design and oversight.

### 5. Inclusive Recruitment

To promote diverse and representative participation in research, investigators, sponsors, IRBs/HRPPs, and research institutions should:

- Ensure recruitment strategies are culturally sensitive, identity-affirming, and responsive to community needs.
- Collaborate with LGBTQI+ community members and organizations to develop recruitment plans that encourage participation within LGBTQI+ communities by using inclusive language, reaching LGBTQI+ populations, and promoting trust. For example, in some communities, it may be necessary to avoid posting recruitment flyers in public locations or including the location of the research in online postings.
- Provide guidance and support to researchers in addressing any potential barriers or challenges to recruiting LGBTQI+ participants.
- Consider the need to periodically reconfirm a participant's orientation or identity throughout the life of a study.

### 6. Disseminate Research Results

Appropriate dissemination of research results to the LGBTQI+ community can facilitate trust and encourage participation. The following are recommendations:

- Collaborate with LGBTQI+ communities to develop dissemination plans.
- Consider dissemination plans beyond traditional academic methods of lectures, presentations, and papers in order to reach the LGBTQI+ communities through study participant portals, emails, newsletters, social media posts, etc.
- Use inclusive language and imagery in publications and other materials that disseminate findings.
- Provide support and resources for community dissemination activities, such as facilitating workshops or training sessions where researchers and LGBTQI+ community members can collaborate on interpreting research findings. This could be accomplished by ensuring that materials are accessible and tailored to the specific needs and preferences of the community and engaging community members in the dissemination process by inviting their input on messaging and outreach strategies, and by offering opportunities for them to share their perspectives and experiences related to the research.

## B. Specific Recommendations

### 1. Ethical, Legal, Regulatory, and Contextual Considerations

- **Ethical Considerations**

  Investigators, sponsors, IRBs/HRPPs, and research institutions should seek to ensure the adequate inclusion of LGBTQI+ participants and protection of their rights and welfare in research to meet ethical and professional standards. These stakeholders have an ethical obligation to take affirmative steps to ensure inclusive research in order to limit known inequities. Ensuring the adequate inclusion of LGBTQI+ participants and protecting their rights and welfare in research are essential for promoting equality, addressing disparities, and upholding ethical and professional standards. Affirmative steps toward inclusive research enhance the generalizability of research findings and ensure that the benefits of research are equitably distributed. This section provides specific suggestions for doing so.

  - Investigators
    - Regularly assess the impact of research activities on LGBTQI+ participants and communities. For example, consider how to collect research data about sexual and gender identities respectfully in all research and evaluate research plans to assess how they might positively and negatively impact participation of LGBTQI+ populations. In addition, be prepared to modify research protocols and research practices as needed to conduct inclusive research. Additionally, gather data and solicit feedback from participants about their experiences to identify opportunities for improvement.

  - Sponsors
    - Support efforts to eliminate the underrepresentation of LGBTQI+ populations in research and seek to ensure they benefit equitably from research results. Collaborate with contract research organizations, institutions, and advocacy groups with demonstrated expertise in identifying and recruiting LGBTQI+ individuals.

  - IRBs/HRPPs
    - Adopt guidance and review criteria that encourages more inclusive research with respect to LGBTQI+ populations, such as using inclusive language in consent forms.
  - Research Institutions
    - Establish mechanisms for tracking, reporting, and addressing the implementation of policies designed to ensure the appropriate inclusion of LGBTQI+ participants in research, thus ensuring that research activities are conducted in accordance with ethical principles and regulatory requirements.
    - Foster a culture of transparency and accountability regarding LGBTQI+ research practices, including mechanisms for reporting and addressing concerns related to ethical conduct or participant safety.

- **Laws, Regulations, and Guidelines**

  Given the challenge of applying the myriad laws, regulations, and guidelines that may impact research involving LGBTQI+ participants, investigators, sponsors, IRBs/HRPPs, and research institutions should seek to ensure the adequate protection of LGBTQI+ participants, maintain ethical conduct of research, and ensure the feasibility of conducting research involving LGBTQI+ communities.

  Given the significance of laws, regulations, and guidelines in either increasing risks to participants (e.g., laws that prohibit gender-affirming care or laws outside of the United States that criminalize LGBTQI+ identities) or protecting them (e.g., some state confidentiality laws or international human rights protections), understanding these factors is crucial.[7] In an unpredictable legal and political environment, risks may change during the life of a study, necessitating stakeholders to modify research

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[7] Other laws, such as Equal Protection, Civil Rights, anti-discrimination statutes, health privacy laws, and international human rights laws, may also impact research involving LGBTQI+ participants by, for example, requiring additional protections or preventing discrimination throughout the research process.

to ensure risks are minimized and reasonable relative to the anticipated benefits, and to assess participants' willingness to continue under altered circumstances. Therefore, it is essential for those conducting, reviewing, sponsoring, and overseeing research to comprehend these laws and their implications.

Recommendations for addressing these potential challenges include the following:

- All Stakeholders
  - Share knowledge and resources regarding laws, regulations, and guidelines that may impact LGBTQI+ research among stakeholders.

- Investigators
  - Recognize when LGBTQI+ research may be impacted by laws, regulations, applicable directives and guidelines.
  - Access institutional resources regarding laws, regulations, and guidelines that may impact LGBTQI+ research.

- Sponsors
  - Support researchers in navigating laws, regulations, and guidelines related to LGBTQI+ research, regardless of where the research is being conducted.

- IRBs/HRPPs
  - Provide education, guidance, and support to researchers in addressing laws, regulations, and guidelines that may impact LGBTQI+ research. Consider and apply 45 CFR 46 (subpart D) as applicable.
  - Ensure that all IRB members disclose any potential conflicts of interest (or the inability to remain impartial), including religious or personal objections to LGBTQI+ research. Members with such conflicts should recuse themselves from the review of the study to maintain impartiality and uphold the integrity of the review process.
  - If individual IRB members have conflicts of interest or are unable to remain impartial, designate alternate reviewers without such conflicts within the same IRB to review the study. This ensures that the research is evaluated fairly and without bias while keeping the review within the established IRB framework.
  - If conflicts of interest cannot be managed (e.g., through recusal and the use of alternate reviewers, etc.) or IRB members are unable to remain impartial, consider transferring the study to another IRB committee or an external IRB. This ensures that the research receives an unbiased and thorough review, adhering to ethical standards and protecting the rights and welfare of participants.

- Research Institutions
  - Establish a mechanism (including partnering with other institutions) to provide accurate, up-to-date information about laws that may increase or mitigate risk to LGBTQI+ individuals participating in research to inform researchers and the IRB. This includes staying abreast of evolving legal and political landscapes and communicating these changes effectively to researchers to ensure compliance and enhance participant protection.
  - Develop plans to minimize and respond to legal demands for information about LGBTQI+ research generally or for data from specific LGBTQI+ research projects and how to protect researchers and participants. 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 research.
  - Establish policies and procedures for addressing legal requests and demands for information related to LGBTQI+ research.

- **Contextual Variables**

  In addition to applying applicable laws, regulations, and guidelines, investigators, sponsors, IRBs/HRPPs, and research institutions should 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 in research involving LGBTQI+ participants.

  Navigating contextual variables in research involving LGBTQI+ participants requires considering directives, standards, organizational policies, local context, diverse viewpoints, and the influence of political and social determinants of health. Collaboration among investigators, sponsors, IRBs/HRPPs, and research institutions is key to effectively address contextual variability. This is important because these contextual factors may impact the risks that potential participants may experience, as well as affect the protections that can be promised to them. These factors may also influence the feasibility of conducting the research and protecting research participants from risk.

  Recommendations for addressing contextual variability that apply to all involved in the research enterprise are as follows:

  - Conduct contextual analysis to understand the specific factors influencing LGBTQI+ participants' experiences and responses to research in different settings.
  - Implement policies and procedures to address potential conflicts or challenges arising from contextual variables in research involving LGBTQI+ participants.
  - Understand that the contextual variables for LGBTQI+ adults and minors may differ and therefore different information and processes for considering these variables may be necessary.

### 2. Considerations for Establishing an Inclusive and Culturally Sensitive Research Environment

- **Community Engagement**

  Investigators, sponsors, IRBs/HRPPs, and research institutions should ensure that the priorities, perspectives, values, and needs of LGBTQI+ communities are understood, integrated, and appropriately considered in the design, review, oversight, implementation, and dissemination of results. Community engagement involves building meaningful interactions and understanding cultural norms among all stakeholders in the research enterprise, including investigators, sponsors, IRBs/HRPPs, and research institutions. Effective engagement ensures that the priorities, perspectives, values, and needs of LGBTQI+ communities are adequately considered throughout the research process.

  Engagement with diverse demographic groups and cultural backgrounds is both an ethical and social responsibility in human subjects research. It is important to establish relationships with prospective participants that are inclusive of various dimensions such as race, gender, religious beliefs, nationality, age, disabilities, and sexual orientation. These considerations often require additional efforts beyond those typically encountered in other research contexts.

  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. To achieve this, investigators, sponsors, IRBs/HRPPs, and research institutions should implement strategies to involve LGBTQI+ communities throughout the research process. Examples of recommended strategies are below.

  - Investigators
    - Involve LGBTQI+ community members in all stages of the research, from design to dissemination of results.

- Sponsors
  - Collaborate with LGBTQI+ advocacy groups and community-based organizations to identify research priorities and facilitate community engagement efforts.
  - Provide support and resources for investigators to engage effectively with LGBTQI+ communities, including funding for community outreach activities, training on cultural competency, and logistical support for community meetings and events.

- IRBs/HRPPs
  - Ask researchers about their community engagement with members of the LGBTQI+ community to inform assessment of the risks and benefits of the research, as well as the recruitment plans and the adequacy of the consent process. Where needed, recommend or require (additional) community engagement.
  - Develop mechanisms for collaborating with LGBTQI+ community organizations and advocates in reviewing research protocols so that community perspectives are integrated into the ethical review process.

- Research Institutions
  - Create mechanisms, such as community advisory boards, to ensure ongoing engagement with LGBTQI+ communities for input and feedback on research priorities, protocols, and dissemination strategies.
  - Provide administrative support and resources for researchers to engage effectively with LGBTQI+ communities, including program evaluation, assistance with community outreach, partnership development, and stakeholder engagement, as well as meeting spaces and technology resources.

- **Composition of the Study Team, IRB/HRPP, and Organizational Leadership**

  Investigators, sponsors, IRBs/HRPPs, and research institutions should actively promote diverse and inclusive representation during the research process, including on the study team, IRB, and organizational leadership, to reflect the LGBTQI+ communities' perspectives and experiences.

  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. To ensure a comprehensive understanding in research involving the LGBTQI+ community, it is essential to incorporate individuals with experience and expertise related to these communities within the study team, the IRB/HRPP, sponsors, and the institution.

  Inclusive representation is important not only for the authenticity and credibility of the research but also to foster an environment where the needs of LGBTQI+ communities are understood and addressed. Representation ensures that decision-making processes benefit from diverse viewpoints, leading to research outcomes that are culturally sensitive and successfully achieve their intended objectives and goals by yielding meaningful, accurate, and reliable results that contribute to the advancement of knowledge.

  To develop an inclusive research environment, LGBTQI+ stakeholders should be involved in significant roles, including scientific priority-setting, research design, HRPP/IRB composition, and leadership positions. This inclusion enhances the relevance and sensitivity of the research, ensuring that it addresses the nuances of LGBTQI+ health, community concerns, and wellbeing. To achieve this goal, investigators, sponsors, IRBs/HRPPs, and research institutions can consider implementing a number of strategies to address these issues, including the recommendations below

  - All Stakeholders

- Consider including LGBTQI+ community members/advisors along with the researcher, clinician, study staff, and research participants to provide a safe and affirming space for the research to occur.
- Regularly assess and monitor diversity and inclusion metrics within study teams, IRBs/HRPPs, and organizational leadership to track progress and identify gaps.

- Sponsors
  - Partner with LGBTQI+ advocacy groups and community organizations to identify potential candidates for study team, IRB/HRPP, and leadership roles.
  - Provide funding and training to support development of research related to and researchers focusing on the needs and concerns of LGBTQI+ individuals.

- IRBs/HRPPs
  - Establish guidelines for assessing the diversity and inclusivity of IRB members and IRB/HRPP staff, research protocols and study teams during the IRB review process.
  - Regularly evaluate and assess the diversity and inclusivity of IRB membership and decision-making processes and address any gaps.

- Research Institutions
  - Develop policies and procedures for recruiting and retaining LGBTQI+ individuals in research roles at all levels within an organization.
  - Establish and support mentorship programs and support networks for LGBTQI+ researchers to provide professional development opportunities, training, and other resources.

- **Cultural Competence**

  Investigators, sponsors, IRBs/HRPPs, and research institutions should consider adopting measures to foster cultural awareness, competence, and humility regarding LGBTQI+ communities throughout the research process. Cultural competence refers to the ability of individuals and organizations to effectively interact, work, or engage with people from diverse cultural backgrounds and communities. This involves understanding, respecting, and appropriately responding to the cultural differences and similarities within, among, and between groups. In the research context, investigators, sponsors, IRBs/HRPPs, and institutions play an important role in promoting understanding, sensitivity, and inclusivity throughout the research process. To cultivate an inclusive and culturally sensitive research environment, it is necessary to include measures throughout the research process.

  Below are recommendations aimed at fostering cultural competence.

  - IRBs/HRPPs
    - Develop guidelines to evaluate cultural competency of research protocols involving LGBTQI+ participants (e.g., consider factors such as inclusivity of language, sensitivity of recruitment strategies, and appropriateness of data collection methods).

  - Research Institutions
    - Include LGBTQI+ community members/advisors who can advocate for inclusivity and support the creation of an inclusive environment.

- **Intersectionality**

  Investigators, sponsors, IRBs/HRPPs, and research institutions should effectively address the experiences and challenges LGBTQI+ participants may have due to gender, sexual orientation, and other characteristics and multifaceted identities, such as race, ethnicity, national origin, color, age, and disability.

Intersectionality explores how various social identities intersect. Recognizing and addressing the intersectionality of LGBTQI+ identities with other characteristics such as race, ethnicity, age, disability, and others is crucial for conducting ethical and inclusive research. Intersectionality helps to better understand and address the complexities and interconnection of discrimination and inequality in society. It emphasizes the importance of the unique challenges individuals face with intersecting identities. Understanding the discriminations, recognizing the forms of discrimination and how they interact with each other, and acknowledging that traditional forms of social justice may not fully address the complexities of identity and marginalization.

Investigators, sponsors, IRBs/HRPPs, and research institutions should therefore consider adopting strategies to understand and mitigate the unique challenges faced by LGBTQI+ individuals with intersecting identities. Possible recommendations include developing policies and practices that acknowledge and address these layered experiences, ensuring that research is ethical, inclusive, and equitable.

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

- **Research Design and Analysis**

  Investigators, sponsors, IRBs/HRPPs, and research institutions should incorporate and evaluate LGBTQI+ considerations into research questions, methods, conduct, inclusion/exclusion criteria, and the collection and analysis of sexual orientation and gender identity data to ensure that the research protocol and study-related documents reflect these factors.

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

  - 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.

  Recommendations aimed at incorporating LGBTQI+ considerations into research design and analysis are below.

  - All Stakeholders[8]
    - Select research methods that are inclusive and sensitive to LGBTQI+ participants.

  - Research Institutions
    - 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.

- **Access and Inclusion (*Recruitment*)**

  Strategies should be employed in the development and evaluation of recruitment plans for LGBTQI+ participants to promote representation in research.

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[8] Federal agencies should also be considered in these efforts to ensure compliance with federal regulations and to support initiatives that promote the inclusion of LGBTQI+ considerations in research design and analysis.

Developing and evaluating recruitment plans for LGBTQI+ participants requires careful consideration of strategies to promote inclusion towards representation in research. Collaborative efforts among investigators, sponsors, IRBs/HRPPs, research institutions and LGBTQI+ communities are essential to identify and implement effective recruitment and retention strategies that address the needs and concerns of these communities. This is important because researchers without the lived experience of the participants they are studying , must consider how to best remove obstacles or address the inequities encountered by these research participants through meaningful communication and collaboration. The approach also emphasizes the need to ensure the ethical protection of LGBTQI+ participants throughout the research process, consistent with the Belmont Report's principle of justice, by ensuring the equitable distribution of research benefits and burdens.

The following is a list of recommendations to address issues related to access and inclusion:

- Investigators
  - Implement patient screening processes that are inclusive, gender affirming and relevant to the study at hand (for example, explaining why questions about sexuality and gender are masked while emphasizing confidentiality of data).
  - Revise forms, paperwork, and data collection instruments to include questions that account for differences in sexual orientation and gender identity.
  - Tailor recruitment materials and outreach efforts that are appropriate for LGBTQI+ communities such as using inclusive and gender affirming language and imagery.
  - Offer potential subjects an opportunity to speak or meet with other LGBTQI+ research participants in research that may be willing to share their research experiences.
- IRBs/HRPPs
  - Ensure that recruitment plans for LGBTQI+ participants are carefully reviewed and evaluated to promote representation, address specific needs, and include inclusive and culturally appropriate language and imagery.
  - Maintain rigorous ethical oversight to protect LGBTQI+ participants, ensuring that recruitment materials do not inadvertently marginalize or stigmatize LGBTQI+ individuals.
- Sponsors
  - Consider a LGBTQI+ research participant peer program that allows potential LGBTQI+ research participants to contact other LGBTQI+ research participants who can better empathize with their unique circumstances.
  - Support researchers in specific outreach efforts to attract LGBTQI+ populations, such as innovative social media campaigns or recruiting during local events geared towards LGBTQI+ attendees.

- **Informed Consent**

Investigators, sponsors, IRBs/HRPPs, and research institutions should seek to ensure that the informed consent process in studies involving LGBTQI+ participants is specifically designed to take into consideration the needs and interests of these communities.

Designing an informed consent process that is sensitive to the self-identification needs and interests of LGBTQI+ communities is essential for ensuring respectful ethical research conduct and participant autonomy. Using inclusive, nonbinary vocabulary and creating safe, confidential research environments are steps towards initiating a more inclusive information exchange for LGBTQI+ participants.

Below are specific recommendations.

- IRBs/HRPPs
  - Develop template language that is culturally sensitive and inclusive of diverse LGBTQI+ identities.

    - Incorporate LGBTQI+ perspectives into the review of the consent process and recruitment strategies for LGBTQI+ participants to ensure an inclusive, safe, and confidential experience.

  - Investigators
    - Ensure that language throughout the consent process is culturally appropriate and inclusive.
    - Provide a safe and confidential environment for LGBTQI+ participants for the consenting process and to discuss their research participation without fear of discrimination or stigma.

  - Research Institutions
    - Provide training for research staff on culturally competent communication and interaction with LGBTQI+ participants.

- **Privacy and Confidentiality**

  Given the potential for discrimination, stigma, and other harm, additional privacy and confidentiality measures should be considered to protect LGBTQI+ research participants, their partners, and other non-research participants when appropriate. This is important because of a history of discrimination, disenfranchisement, and lack of awareness about LGBTQI+ communities and their specific needs.

  Recommendations to address these issues are below.

  - All Stakeholders
    - Develop comprehensive privacy and confidentiality measures that address the unique vulnerabilities and concerns of LGBTQI+ participants. This could include measures such as having research IDs, not recording names (in either consents or databases), working in safe spaces, detailed and clear training to data collectors on confidentiality, anonymity, and data protection, technical protections against hacking of data storage spaces, conducting a risk assessment on their data storage mechanisms, and testing if there are ways to break data protection procedures and access participant data.

  - IRBs/HRPPs
    - Provide investigators with example approaches for asking about sexual orientation or gender identity (for example, a less detailed approach, or adding a third response option to traditional binary measures that meet data needs, while minimizing burden, sensitivity, and privacy risk).
    - Seek consultation from individuals with expertise in recognizing threats of misuse or abuse of technologies or technology services commonly used by LGBTQI+ communities as part of the IRB's review.

- **Oversight, Support, and Security**

  Investigators, sponsors, IRBs/HRPPs, and research institutions should establish and maintain appropriate oversight, infrastructure, security, and other support for research involving LGBTQI+ participants.

  Oversight, support, and security are important for ensuring the ethical conduct, safety, and well-being of LGBTQI+ participants in research. Investigators, sponsors, IRBs/HRPPs, and research institutions must collaborate to establish and maintain mechanisms for oversight, infrastructure, security, and support throughout the research process. This is crucial because LGBTQI+ participants often face unique social vulnerabilities and health disparities, making the ethical management and security of their data imperative. Proper oversight and support ensure that research practices respect and address these sensitivities and fosters an environment where LGBTQI+ participants feel safe and valued. Establishing these mechanisms not only enhances participant trust and cooperation but also bolsters the credibility and applicability of the research findings to diverse populations.

Below are examples of recommended strategies.

- All Stakeholders
  - Develop specialized oversight and support mechanisms that address the specific needs of LGBTQI+ participants.

- Investigators
  - To support continuous quality improvement efforts, facilitate clear communication channels, such as focus groups with LGBTQI+ research participants to address any concerns or challenges experienced through health care seeking and health research experiences to elicit ideas for research to improve LGBTQ+ health disparities.

- **Reporting and Dissemination of Findings**

When reporting and disseminating findings, investigators, sponsors, IRBs/HRPPs, and research institutions should ensure that findings from research involving LGBTQI+ participants are reported and disseminated in a way that promotes transparency and community benefit and prevents misrepresentation as well as individual and community (group) harm.

Reporting and disseminating findings from research involving LGBTQI+ participants requires careful consideration to promote consistent and innovative communication transparency, community benefit, and prevent harm. This involves ensuring that findings are shared timely, are accurately represented, ethically shared, and accessible to relevant communities. This is important because current research efforts often engage communities and patients on the front end and during the research with significant dissemination gaps developing after the research has been completed. LGBTQ+ community members may thus conclude that research teams will fail to "close the loop" regarding their research project - by failing to inform them of what has been learned at the end of a lengthy process of organizing and analyzing the information they collect.

Examples of recommended strategies are below.

- Research Institutions
  - Provide training and resources to investigators on best practices for disseminating findings to LGBTQI+ communities. Develop mechanisms for tracking and evaluating the impact of dissemination activities, including feedback mechanisms and metrics for success.

### 4. Special considerations for minors

Although many of the recommendations in this document apply broadly to both adults and minors, there are special considerations for minors that may differ from those for adults. Minors face unique challenges and vulnerabilities, particularly regarding privacy and confidentiality, as their parents or guardians may not be aware of their LGBTQI+ identity. It is essential to ensure that minors' rights, well-being, and privacy are protected throughout the research process. Community engagement efforts should reflect the specific needs and perspectives of LGBTQI+ minors, involving youth advisory boards or other mechanisms to ensure their voices are heard and respected. Engaging with organizations that specialize in supporting LGBTQI+ youth can provide valuable insights and enhance the relevance and sensitivity of the research.

To address these challenges, tailored strategies should be considered. The following recommendations outline key considerations and best practices for conducting research involving LGBTQI+ minors:

- Ethical Considerations
  - Carefully assess the risks and benefits of research involving LGBTQI+ minors. For example, consider the potential psychological impact of participation and implement measures to minimize harm.
  - Establish continuous monitoring mechanisms to ensure the safety and wellbeing of minor participants throughout the study. This could include regular check-ins with participants and a system for reporting and addressing any issues that arise.
  - Regularly collect feedback from minor participants about their experiences in the research. Use this feedback to make necessary adjustments to protocols and practices to better protect and support participants.

- Privacy and Confidentiality
  - Ensure that data collection methods are designed to protect the privacy and confidentiality of minor participants. This may involve using codes or pseudonyms instead of names and securing data in a way that prevents unauthorized access.

- Confidential Communication Channels
  - Establish confidential communication channels tailored for minors to express their concerns or questions about the research without fear of disclosure. This can include secure messaging systems or private, one-on-one discussions with researchers, ensuring that these methods are appropriate for younger participants based on their development stage.

- Recruitment
  - Develop recruitment materials specifically designed for minors that are discreet and respectful of minors' privacy. Avoid public postings that could inadvertently disclose a minor’s participation in LGBTQI+ research, recognizing the heightened need for confidentiality because of their age.
  - Consider online recruitment through platforms that are commonly used by LGBTQI+ youth, ensuring these platforms provide adequate privacy protections.
  - Partner with organizations that specialize in supporting LGBTQI+ youth for recruitment. These organizations can help identify potential participants and provide a trusted bridge between researchers and the community.

- Informed Consent/Assent
  - Understand the laws regarding consent to healthcare and/or research for minors (e.g., mature minors, emancipated minors, and minors who are legally permitted to independently consent to certain types of healthcare). These legal distinctions vary by jurisdiction and are crucial for ensuring that LGBTQI+ minors can provide legally valid and informed consent to participate in research.
  - Researchers should consider applying for waivers of parental permission in accordance with U.S. federal regulations, such as 45 CFR 46.408(c), when it is not reasonable to obtain parental permission. This can be crucial in protecting the privacy of minors who have not disclosed their LGBTQI+ identity to their parents. (A waiver of parental permission is not permissible for FDA regulated research.)
  - Use language in consent and assent forms and discussions that is appropriate for the age and comprehension level of the minor participants. Ensure that minors fully understand what participation entails, including any potential risks and benefits.

- Support Services
  - Provide access to counseling or support services for minors participating in the research. This can help address any emotional or psychological concerns that arise during the study while also providing age-appropriate support and resources.

- Community Engagement

- Establish youth advisory boards that include LGBTQI+ minors. These boards can provide valuable insights into the specific needs and concerns of younger participants and help shape research protocols to be more youth friendly.
- Collaborate with LGBTQI+ youth organizations to develop and review research protocols, consent forms, and other study related documents in order to ensure that they are culturally sensitive and relevant to the community's needs.

By incorporating these considerations, investigators, sponsors, IRBs/HRPPs, and research institutions can create a more supportive and ethical environment for LGBTQI+ minors participating in research. This approach not only safeguards their privacy and confidentiality but also fosters inclusivity in research.

## Conclusion

These "SACHRP Recommendations for the Ethical Review and Inclusion of LGBTQI+ Participants in Human Subjects Research" highlight the need for inclusive practices that safeguard the rights and welfare of LGBTQI+ individuals in research. The 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.

Central to these recommendations is the equitable inclusion of LGBTQI+ participants, which is fundamental to advancing equality and improving outcomes across all areas of 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.

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