

DAIDS Cross-Network Transgender & Gender-Diverse Working Group
Updated Recommendations for Collecting Data on
Gender Identity, Sex Assigned at Birth, Intersex Status, and Sexual Orientation
August 2023

The Division of AIDS (DAIDS) Cross-Network Transgender and Gender-Diverse (TGD) Working Group¹ continues to recommend that the National Institute of Allergy and Infectious Disease (NIAID) HIV/AIDS Clinical Trials Networks consistently use best practices when collecting information related to gender, sex assigned at birth, and sexual orientation from participants. This working group first issued data collection recommendations in 2015, updated them in March 2020, and is now issuing a second update to reflect current best practices, including several key recommendations contained in the consensus report by the [National Academies of Sciences, Engineering, and Medicine \(NASEM\), *Measuring Sex, Gender Identity, and Sexual Orientation* \(2022\)](#).² While our guidance doesn't follow the NASEM recommendations verbatim, it draws inspiration from the report and its guiding principles.

We commend the HIV/AIDS Clinical Trials Networks for adopting our recommendations over the years regardless of the type of trial being conducted (treatment, cure, vaccine, or prevention) and regardless of whether the study is specifically recruiting transgender individuals. By using this approach, the networks have strengthened the integrity of the clinical trial data they are collecting, demonstrated cultural sensitivity, and helped create a more welcoming environment for transgender and gender-diverse people.

The TGD working group recommends that the template provided in this document be used to the greatest extent possible and only be withheld in unusually sensitive situations, such as the high likelihood of a data breach in a context where sexual and gender minorities regularly experience social and structural violence. The TGD working group acknowledges that transgender and gender-diverse people face legal discrimination and social stigma in many communities around the world. Under these circumstances, each participating clinical research site should carefully consider the possibility of this template increasing the risk of physical, psychological, and/or social harm. At the same time, we urge research sites to also consider the scientific, epidemiological, social, legal, and other ramifications of *not* collecting data that accurately reflect the study population and transgender people.

All sites should have systems and processes in place to protect participant privacy and data confidentiality. Policies should be fully described in the informed consent process and in line with all applicable laws, policies, and regulations.³ The need for additional staff training and the capacity of the site to ensure participants' privacy and data confidentiality should be assessed, training provided, and risk mitigation strategies developed as needed.

¹ Formerly known as the DAIDS Cross-Network Transgender Working Group or CNTWG

² The National Academies Press. National Academies of Sciences, Engineering, and Medicine 2022. *Measuring Sex, Gender Identity, and Sexual Orientation*. Washington, DC: The National Academies Press. <https://doi.org/10.17226/26424>.

³ National Institutes of Health, Data Management and Sharing Policy, January 2023: [Principles and Best Practices for Protecting Participant Privacy](https://sharing.nih.gov/data-management-and-sharing-policy/protecting-participant-privacy-when-sharing-scientific-data/principles-and-best-practices-for-protecting-participant-privacy), <https://sharing.nih.gov/data-management-and-sharing-policy/protecting-participant-privacy-when-sharing-scientific-data/principles-and-best-practices-for-protecting-participant-privacy>

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Rationale

Collecting data on research participants' gender identity and sex assigned at birth as two discrete categories is considered a best practice and is recommended by all leading transgender organizations as well as the Institute of Medicine. It is also recommended in the recent consensus report issued by the NASEM:

"Measuring Sex, Gender Identity, and Sexual Orientation recommends that the National Institutes of Health (NIH) adopt new practices for collecting data on sex, gender, and sexual orientation – including collecting gender data by default, and not conflating gender with sex as a biological variable. The report recommends standardized language to be used in survey questions that ask about a respondent's sex, gender identity, and sexual orientation. Better measurements will improve data quality, as well as the NIH's ability to identify LGBTQ+ populations and understand the challenges they face."⁴

Step one of this method asks about participants' current gender identity and includes a variety of options to choose from. Step two asks about the sex they were assigned at birth. Collecting gender identity and sex assigned at birth as two separate demographic markers allows for the accurate identification and categorization of study participants. The likelihood of incorrectly categorizing transgender study participants is high if this method is not used. For example, a participant who selects "Woman" as her gender identity may have been assigned male at birth, and a participant who selects "Female" sex assigned at birth may identify as a man, gender nonbinary, or any other gender identity. Collecting accurate demographic data is crucial to appropriately evaluating study eligibility, understanding how study interventions may or may not work differently across populations, facilitating sub-group analyses by gender identity, and ensuring that safety is monitored properly.

In addition to updating the existing two-step method recommendations with current best practices, the TGD Working Group is now introducing a third step in this data collection process: ascertaining intersex status. Because most people with intersex traits are assigned female or male sex at birth and may not be identified as having intersex traits until later in life—if at all—the NASEM consensus report recommends having a separate question about intersex status. The recommendation specifically states:

"When the National Institutes of Health seeks to identify people with intersex traits (also known as differences of sex development) in clinical, survey, research, and administrative settings, they should do so by using a stand-alone measure that asks respondents to report their intersex status. They should not do so by adding intersex as a third response category to a binary measure of sex."⁵

The authors of the NASEM report acknowledged that this approach might be more cumbersome, but it was the only one tested in people with intersex traits.

Template Use and Limitations:

The TGD Working Group has developed a template form for collecting data on gender identity, sex assigned at birth, and intersex status. However, we acknowledge that this template is limited in that it is written in English and includes some terms that are most familiar and relevant in the United States. We recommend that study teams conduct stakeholder engagement to adapt data collection forms as needed to ensure that culturally appropriate terminology is used. The "stakeholders" we are referring to must include transgender and gender-

⁴ The National Academies Press. National Academies of Sciences, Engineering, and Medicine 2022. *Measuring Sex, Gender Identity, and Sexual Orientation*. Washington, DC: The National Academies Press. <https://doi.org/10.17226/26424>.

⁵ Ibid

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diverse individuals; discrimination against these communities is ubiquitous, and cisgender stakeholders who are not part of these communities may recommend changes from a place of ignorance or bias.

It should also be noted that the two-step method is designed as a means of identifying and correctly characterizing transgender and gender-diverse people. The NASEM authors⁶ as well as the Federal Evidence Agenda on LGBTQI+ Equity⁷ strongly maintain that gender identity is the more critical demographic factor, not sex assigned at birth. They contend that neither question should be mandatory unless the information is critical to eligibility and study conduct. In practice, however, sex assigned at birth and/or gender are required on NIH progress reports, and both variables are often very important in relation to the clinical research questions that DAIDS-funded studies explore. (See [‘Decision Tree’⁸](#) to better understand reporting expectations for different types of studies.) When the collection of data on sex assigned at birth is essential to study conduct (e.g., for safety determinations, to determine what set of laboratory reference ranges to use, for reporting requirements, etc.), it must always be accompanied by the collection of data on gender identity, enabling site staff to be culturally responsive to the individual participant.

The TGD working group acknowledges that the primary value of asking about one’s sex assigned at birth in the context of the two-step method is that, through further analysis relative to reported gender identity, it allows for the passive identification of transgender individuals through assessment of concordant or discordant responses to the two variables. While many research studies and surveys may use sex assigned at birth as a proxy for other information such as reproductive potential, anatomy, assumptions about hormones, etc., sex assigned at birth is not a reliable predictor of these characteristics, which can change over time and vary for many different reasons, including but not limited to surgery and gender-affirming hormone therapy. If specific information is required for study eligibility or conduct (e.g., current anatomy, hormone use, surgical history, etc.) then specific questions pertaining to these requirements should be asked directly of all participants rather than relying solely on reported sex assigned at birth. The NASEM panel strongly recommends against the use of binary sex or sex assigned at birth questions alone to determine these characteristics, and the TGD working group endorses this recommendation.

⁶The National Academies Press. National Academies of Sciences, Engineering, and Medicine 2022. *Measuring Sex, Gender Identity, and Sexual Orientation*. Washington, DC: The National Academies Press. <https://doi.org/10.17226/26424>. Summary page and Chapter 1. “The report also recommends that the standard for NIH be to collect data on gender and report it by default and that collection of data on sex as a biological variable be limited to circumstances where information about sex traits is relevant such as in clinical preventive screenings or for research investigating specific genetic, anatomical, or physiological processes and their connections to patterns of health and disease. In human populations, collection of data on sex as a biological variable should be accompanied by collection of data on gender.”

⁷ National Science and Technology Council, Subcommittee on Equitable Data. *Federal Evidence Agenda on LGBTQI+ Equity, A Report by the Subcommittee on Sexual Orientation, Gender Identity, and Variations in Sex Characteristics (SOGI) Data* of the January 2023. <https://www.whitehouse.gov/wp-content/uploads/2023/01/Federal-Evidence-Agenda-on-LGBTQI-Equity.pdf>

⁸National Institutes of Health, [Decision Tree for Post-Award Inclusion Reporting Based on Sex or Gender, Race and Ethnicity](https://grants.nih.gov/sites/default/files/Decision%20tree-%20Sex-gender%20race-ethnicity_508final%204-12-18.pdf), https://grants.nih.gov/sites/default/files/Decision%20tree-%20Sex-gender%20race-ethnicity_508final%204-12-18.pdf

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Data Analysis

There is no downside to including gender-inclusive options on data collection forms. Even when numbers are small—and even when the number is zero—it is important to accurately represent the study population in data analysis and reporting. It is also important to acknowledge that TGD communities are diverse, and clinical trials data must reflect this diversity. Therefore, distinct groups of TGD people including gender nonbinary people, transgender men, and transgender women, should not be combined in clinical trials data as a single category of “transgender.” Each of these groups has its own unique social, structural, and epidemiological contexts, and therefore data for each of these populations should be disaggregated. The importance of TGD data disaggregation is emphasized in a recent landscape analysis⁹ of over 30 years of milestone HIV clinical trials, in which it was discovered that less than 1% of participants in these trials were identified as transgender, and among the transgender participants, almost all were transgender women with very little representation of gender nonbinary people and transgender men. Data disaggregation helps identify gaps in the research and informs the generalizability of study findings. Using the term “transgender” as an umbrella term has its place when describing the population overall, but data collected through clinical trials should always be disaggregated, provided all conditions for maintaining participant confidentiality have been met. It should also be acknowledged that the term “Gender Nonbinary” is its own umbrella term encapsulating categories such as Genderqueer, Gender Nonconforming, Two-Spirit (another umbrella term), and many more. Combining individual participants under the category of Gender Nonbinary is therefore useful, but disaggregated Gender Nonbinary data should also be made available when possible. It is also necessary to present gender identity data along with the accompanying data on sex assigned at birth such that these two demographic categories can be cross-referenced. TGD participants are likely to be missed without cross-referencing these two demographic characteristics—for example, in a table such as this hypothetical example:

Table 1: Baseline Participant Characteristics – SAMPLE

	Assigned Female Sex at Birth (N = 1,483)	Assigned Male Sex at Birth (N = 947)
Gender Identity		
Cisgender man	0	252
Cisgender woman	408	0
Gender nonbinary	173	64
Man	29	504
Transgender man	58	0
Transgender woman	0	85
Woman	815	42

The chart above allows for the comparison of sex assigned at birth with how people identify their gender to get a more complete understanding of those enrolled in the study. Some transgender individuals don’t identify as such and may just identify as “men” or “women.” The same is true for cisgender individuals who may just identify as “men” or “women.” The example allows you to see that there are 29 individuals who were assigned female sex at birth and identify their gender as “man.” These data can be aggregated with those who identify as

⁹ Scorecard for Transgender and Gender Diverse Inclusion, <https://www.hanc.info/resources/sops-guidelines-resources/community.html#scorecard>

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transgender men for data analysis purposes. The 504 individuals assigned male sex at birth who identify their gender as “man” can be aggregated with cisgender men for data analysis purposes.

Capturing data on gender identity and sex assigned at birth, in addition to data on race, ethnicity, intersex status, and sexual orientation also facilitates data reporting and potential analyses that include the intersection of these demographic characteristics. Data yielding intersectional analyses offer more nuanced and potentially more useful information than data that are limited to single-variable analysis. For example, data that reflect participants as whole people (e.g., non-Hispanic Black cisgender heterosexual women) may allow for more real-world interpretations and applications than data analyzing only one participant characteristic at a time (e.g., cisgender women). Participant data should therefore be reported and analyzed with these intersections in mind, when possible. The use of a uniform data collection process will also assist future attempts at cross-trial analyses.

The TGD Working Group’s Proposed Template

The TGD Working Group recommends the template below be used as a questionnaire administered to participants by research staff. Answer options for participants to select from are listed in alphabetical order so as not to suggest any hierarchy, and selections should be self-reported by the participant—not assumed or otherwise selected on behalf of participants. Site staff are encouraged to document in chart notes if the participant should be referred to by a specific pronoun or gender during study participation. The TGD Working Group further suggests that a list of definitions be given to any staff involved in the collection of demographic data as they may be unfamiliar with these terms, or to use to explain the terms to a study participant (see Appendix 1.)

Furthermore, the TGD Working Group recommends that clinicians read the following statement to participants at the very beginning of the demographic data collection process (which may include additional questions other than the ones that are the subject of this document, shown below).

While some of these questions may feel invasive, we ask each question of all study participants to help researchers have the most accurate and complete information that is important to the study.

The first question, “What is your current gender identity,” allows participants to identify their gender with more than one term. However, the working group acknowledges that it may be helpful for certain data analysis practices to have a single gender identity marker for individual participants. Study teams may opt to add a second question after the one provided in the template above: “Which single term best represents your current gender identity? (select only one).” While the two questions are similar, this approach simplifies the data.

1. What is your current gender identity? (mark all that apply)
 - Cisgender man
 - Cisgender woman
 - Gender nonbinary
 - Man
 - Transgender man/Trans man
 - Transgender woman/Trans woman

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- Two-Spirit (only for American Indian/Alaska Native/Indigenous participants)¹⁰
 - Woman
 - Additional category, please specify _____
 - Decline to answer
2. What was your sex assigned at birth? (e.g., What sex was documented on your original birth certificate?)
- Female
 - Male
 - Decline to answer
3. Have you ever been diagnosed by a medical doctor or other health professional with an intersex condition? This might also be known as variations of sex characteristics or differences of sex development (DSD). “Intersex” can also refer to people who are born with (or who naturally developed) genitals, reproductive organs, or chromosomal patterns that do not fit standard definitions of male or female.
- Yes
 - No
 - Decline to answer

Sexual Orientation

Not all the DAIDS' networks ask about sexual orientation on demographic case report forms (CRFs), but some regularly include the question, and others ask on a protocol-specific basis. For studies that require information about sexual practices, a behavioral assessment or questionnaire may be used regardless of whether sexual orientation is captured. This is necessary because one's sexual orientation does not necessarily correspond to specific sexual behaviors and practices.

The protocol team may want to consider whether a question about sexual orientation is needed. They may want to discuss if and how the data collected will be used in analyses, and/or if information about sexual behavior is more relevant and will already be obtained through behavioral assessment tools. Again, confidentiality of the data collected must be ensured and the protocol team should carefully consider whether collecting this information could cause harm to the participant and/or provider or put them in legal jeopardy.

A person's sexual orientation and gender identity and their potential for sexual exposure to HIV are independent from one another. It should not be presumed that every member within a population that has high HIV

¹⁰ The TGD Working Group supports the recommendations of organizations around the globe including the NASEM, the [Canadian Institutes of Health Research](#), and the [Two-Spirit Dry Lab](#) (whose recommendations are informed by community consensus) which recommend that Two-Spirit be an answer option only for those individuals who have identified their race as Indigenous, including American Indian and Alaska Native (AIAN) study participants. The [NASEM report](#) offers an extensive and compelling rationale for protecting the scientific integrity of demographic data as well as the cultural significance of the term Two-Spirit, which was created by and for Indigenous peoples only. The TGD Working Group therefore recommends that clinicians only offer the selection of this term to participants who self-identify as Indigenous/American Indian/Alaska Native.

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incidence has a similar high likelihood of HIV acquisition, or that one’s gender identity determines their sexual behavior. Sexual behavior(s) should always be captured separately from sexual orientation and gender identity.

If a question about sexual orientation is included, the TGD Working Group recommends using the categories listed below. They are listed in alphabetical order so as not to suggest any hierarchy. The TGD Working Group also suggests that a list of definitions be given to staff who are involved in the collection of demographic data as they may be unfamiliar with some of these terms or may need to use these definitions when explaining the terms to a study participant. (See Appendix 1.)

4. What is your sexual orientation (mark all that apply)?

- Asexual
- Bisexual
- Gay/Lesbian/Same-Gender Loving
- Pansexual
- Queer
- Straight/Heterosexual
- Two-Spirit (only for American Indian/Alaska Native/Indigenous participants)¹¹
- Additional Category, Please Specify _____
- Decline to Answer

¹¹ Ibid

Appendix 1

Definitions

Terms Relating to Gender

Cisgender is the term used to describe someone whose gender identity matches the sex they were assigned at birth. For example, a person assigned female at birth who identifies as a woman is a cisgender woman.

Gender is the social construct of being a man, woman, boy, girl, neither, or both, and it varies by culture.

Gender Identity is a person's internal sense of their gender, or how they identify themselves. One may identify as a man, woman, boy, girl, non-binary, or a variety of other terms. Some people identify differently from day to day and may describe themselves as "gender fluid."

Gender Nonbinary is an umbrella term that refers to people who do not identify within a single category of man or woman. They may identify completely outside the binary, or they may identify with two or more genders. Additional examples of nonbinary gender identity terms include *genderqueer*, *gender non-conforming*, and *Two-Spirit* (another umbrella term used by indigenous peoples around the world).

Transgender or trans describes a person whose gender identity differs from the sex they were assigned at birth.

Transgender Man/Trans Man/Trans Masculine refers to someone who identifies as a man or otherwise identifies with a certain degree of masculinity and was assigned female sex at birth.

Transgender Woman/Trans Woman/Tran Feminine refers to someone who identifies as a woman or otherwise identifies with a certain degree of femininity and was assigned male sex at birth.

Two-Spirit is an umbrella term used by some indigenous people around the world to describe certain people in their communities, including individuals otherwise known as transgender, bisexual, gay, lesbian, and/or queer. The term was created by and for indigenous peoples, and it was not created to be used as an identity marker for non-indigenous people. Because the term "Two-Spirit" can have different meanings that can include both gender identity and sexual orientation, it may be important to ask follow-up questions to understand what it means to a person who uses the term to describe themselves.

Terms Relating to Sex

Intersex is a term used for a variety of conditions that do not seem to fit the typical definitions of female or male; also known as Variations in Sex Characteristics and Differences of Sex Development (DSD). Additionally, it can be used to refer to people who are born with genitals, reproductive organs, or chromosomal patterns that do not fit standard definitions of male or female or develop these differences naturally in puberty.^{12 13}

¹² What's Intersex? Planned Parenthood Website. <https://www.plannedparenthood.org/learn/gender-identity/sex-gender-identity/whats-intersex>

¹³ InterAct; Advocates for Intersex Youth Website; <https://interactadvocates.org/faq/>

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Sex assigned at birth is determined when a health care provider inspects a newborn baby’s genitalia; the infant’s sex is assigned as male or female on their birth certificate.

Terms Relating to Sexual Orientation

Asexual: an umbrella term describing people on a spectrum of sexuality including people who experience no sexual feelings or desires to people who only experience sexual attraction under certain conditions (such as emotional attraction as a prerequisite for sexual attraction).

Bisexual refers to someone who is sexually attracted to two different genders (typically men and women).

Gay, lesbian, or same-gender-loving refers to someone who is sexually attracted to people of the same gender.

Pansexual refers to someone who is sexually attracted to people of all gender identities.

Queer refers to someone who may think of their sexual orientation and/or gender identity as being outside societal norms. The term is considered to be more fluid and inclusive than traditional categories for sexual orientation and gender identity, and some even use the term to describe their political beliefs.

Straight/heterosexual refers to someone who is sexually attracted to people of the opposite gender (man/woman in the traditional binary construct).

Two-Spirit is an umbrella term used by some indigenous people around the world to describe certain people in their communities, including individuals otherwise known as transgender, bisexual, gay, lesbian, and/or queer. The term was created by and for indigenous peoples, and it was not created to be used as an identity marker for non-indigenous people. Because the term “Two-Spirit” can have different meanings that can include both gender identity and sexual orientation, it may be important to ask follow-up questions to understand what it means to a person who uses the term to describe themselves.

Appendix 2

Resources

- DAIDS Learning Portal, The Transgender Training Curriculum for HIV Research
<https://daidslearningportal.niaid.nih.gov/local/pages/?id=16>
- DAIDS Learning Portal, Guidance Documents
<https://daidslearningportal.niaid.nih.gov/local/pages/?id=1>
- Fenway Institute, National LGBTQIA+ Health Education Center
<https://fenwayhealth.org/the-fenway-institute/education/the-national-lgbtia-health-education-center/>
- GLMA: Health Professionals Advancing LGBTQ Equality
<https://www.glma.org/>
- HANC & AVAC Scorecard for Transgender & Gender-Diverse Inclusion
<https://www.hanc.info/resources/sops-guidelines-resources/community.html#scorecard>
- National Center for Transgender Equality
<https://transequality.org/>
- NIH Sexual & Gender Minority Research Office (SGMRO) Research Resources
<https://dpcpsi.nih.gov/sgmro/sgm-research-resources>
- UCSF Center of Excellence for Transgender Health
<https://prevention.ucsf.edu/transhealth>