**Recommended Approach to Data Collection**

**The Two-Step Method**

**March 2020**

*(Based on the recommendation made to DAIDS and Network Leadership April 2015)*

The Division of AIDS Cross-Network Transgender Working Group (CNTWG) recommends that the NIAID HIV/AIDS clinical trials networks adopt the use of consistent and comprehensive terminology on clinical trial data collection forms when requesting information regarding gender identity. Such information should be collected independently of sex assigned at birth, utilizing the two-step method.[[1]](#footnote-1)

This would ensure that accurate data on current gender identity is captured distinctly from sex assigned at birth, treating these as two discrete parameters, which are also distinct from one’s sexual orientation. This change would be consistent with current recommendations from the Institute of Medicine and current practices by the Centers for Disease Control and Prevention, which use a “two-question system” that separates gender identity from sex assigned at birth in its adult HIV case report form and Enhanced HIV/AIDS Reporting System.[[2]](#footnote-2) A more inclusive form, regardless of the type of trial being conducted (HIV treatment or prevention), will contribute to the robustness of the clinical trial data, demonstrate cultural sensitivity by network staff, and contribute to creating a welcoming environment for transgender people.

The CNTWG acknowledges that transgender people face legal discrimination and social stigma in many communities around the world. Under those circumstances, even if the template is adopted for use for a given protocol, each participating clinical research site should carefully consider whether its use would increase the risk of physical, psychological, and/or social harm to any transgender participants. If the template may incite, facilitate, or otherwise result in increased discrimination or stigma, or have legal ramifications, we do not recommend its use at that site. In all other instances where the template is appropriate for use, the need for additional staff training and the capacity of the site to ensure participants’ confidentiality with respect to gender identity should be assessed.

**Rationale:**

The two-step method for collecting data on participants’ gender identity and sex assigned at birth is considered a best practice and is recommended by all leading transgender organizations as well as the Institute of Medicine. 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.

This method 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 (e.g., a participant who checks “Woman” as her gender identity may have been assigned male at birth, and a participant who checks “Female” sex assigned at birth may identify as a man, gender non-conforming, or any other gender identity). Collecting accurate demographic data is crucial to understanding how study interventions may (or may not) work differently across populations.

The category of “transgender male” or “transgender female” has most commonly been included on demographic data collection forms for studies that are specific to or actively targeting those populations. But transgender people may be eligible for and interested in participating in studies that are not specific to transgender populations, and forms for those studies should also be inclusive. Rather than requiring a transgender person to identify as “other,” inclusion of “transgender” as a category on data collection forms for all studies would show sensitivity to these populations. The addition of a space for participants to write in the term they use to name their identity is another way to demonstrate sensitivity. The CNTWG feels that the terminology/content of the data collection form should be standardized across protocols to assure consistency in the use of recommended gender identity categories. There is no downside to including this information, given that categories can always be combined if necessary, for purposes of data analysis and reporting. Use of an inclusive data collection form as the established template ensures that this data is captured accurately and that transgender people feel included and acknowledged for who they are. A uniform data collection process would also assist future attempts at cross-trial analyses.

Capturing data on gender and sex assigned at birth, in addition to data on sexual orientation, race and ethnicity, would also facilitate data reporting and potentially 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 where possible.

**Proposed Categories for Gender Identity:**

The CNTWG recommends the categories below be included on data collection forms. They are listed in alphabetical order so as not to suggest any hierarchy. The CNTWG suggests that a list of definitions should be given to staff who are administering the collection of demographic data as they may be unfamiliar with these terms. (See Appendix 1.) If the question is being asked in a survey/questionnaire format, the definitions can be included next to the question. The footnoted items reflect the discussions of the CNTWG and may be relevant to include in instructions for completing the form, or in development of country-specific and culturally-specific versions of the form.

[Questions to be read aloud to the participant]

1. The next question asks about gender. Gender is the internal sense of how we identify as either a man, woman, neither, both, non-binary or non-conforming, terms that are often used to describe any identity that doesn’t fit neatly into the categories of man or woman. “I am asking whether you identify as a cisgender man, a cisgender woman, genderqueer, gender non-conforming, gender non-binary, a man, a transgender man, a transgender woman, Two-Spirit, a woman, an additional category, or if you prefer not to answer. If you identify as more than one of these categories, please let me know. ”

* How do you currently identify your gender? (mark all that apply)2,3

*Note to staff:* *The response is participant driven. Please mark all the categories indicated by the participant.*

* Cisgender Man
* Cisgender Woman
* Genderqueer
* Gender Non-conforming, Gender Non-binary
* Man
* Transgender Man/Trans Man
* Transgender Woman/Trans Woman
* Two-Spirit
* Woman
* Additional Category, Please Specify \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
* Decline to Answer

2This item must be self-reported by the participant. Site staff are encouraged to document in chart notes if the participant prefers to be referred to by a specific pronoun or gender during study participation.

3It was noted that some of the terms listed may differ by geographic location, particularly in non-US settings. Genderqueer, in particular, may not be used outside of the US and in those instances, “gender non-conforming” or gender non-binary may be more appropriate. It is important to obtain input from community stakeholders, community members, and representatives from local community groups serving these populations to determine which terms are more culturally appropriate or most commonly used in any given region or country.

1. This question is about the sex that was assigned to you at birth. “When I ask about your sex assigned at birth, I am asking about what sex you were determined to be at birth, which is generally done when a health care provider examines a baby’s genitals (sex organs).”

* What was your sex assigned at birth?
* Female
* Male
* Intersex4
* Decline to Answer5

4In some settings, it may be culturally and geographically appropriate to include a third option: intersex. The existence of “intersex” challenges the idea that sex is binary. In South Africa, for example, it is approximated that 1 in every 50 people have atypical (different from the norm) sex organs. For data analysis purposes, the concordance or discordance of gender identity and birth sex responses would determine how to combine the fields, with discordant responses being treated as “transgender”.

5 Because the question about sex assigned at birth can be problematic for some transgender and gender non-conforming people, it is best to include a “decline to answer” option and also a rationale for asking this question, such as, “some biological processes are impacted by the sex you were assigned at birth, so it is important to record this information.” The rationale can easily be included with instructions given to staff who are administering the collection of demographic data, or it can be included next to the question if being asked in a survey/questionnaire format.

Not all the networks ask about sexual orientation on demographic case report forms (CRF) 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 information garnered will be used in analyses, and/or if information about sexual behavior is more relevant and will already be obtained through behavioral assessment tools.

If a question about sexual orientation is included, the CNTWG recommends the categories below be used. They are listed in alphabetical order so as not to suggest any hierarchy. The CNTWG also suggests that a list of definitions be given to staff who are administering the collection of demographic data as they may be unfamiliar with some of these terms. (See Appendix 1.) If the question is being asked in a survey/questionnaire format, the definitions can be included next to the question.

1. What is your sexual orientation (mark all that apply)?6

*Note to staff:* *The response is participant driven. Please mark all the categories indicated by the participant.*

* Bisexual
* Gay/Lesbian/Homosexual/Same-Gender Loving
* Pansexual
* Queer
* Straight/Heterosexual
* Two-Spirit
* Additional Category, Please Specify \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
* Not sure
* Prefer not to answer

6If the participant does not understand the question, read the categories to the participant.

The chart below provides a visual of the how the two-step method is used.

In this example, options are listed alphabetically to avoid the perception of hierarchy. People are given the opportunity to specify their gender identity using a term not listed on the form (the category of “Other” is avoided as it is not anyone’s identity), and they may also decline to answer. Intersex has also been included as an option for sex assigned at birth because official documents recognizing intersex status are becoming more available to intersex people (even in cases where the sex initially assigned at birth was not intersex). Because the question about sex assigned at birth can be problematic for some transgender and gender non-conforming people, it is best to include a “decline to answer” option and also a rationale for asking this question, such as, “some biological processes are impacted by the sex you were assigned at birth, so it is important to record this information.” The rationale can easily be included with instructions given to staff who are administering the collection of demographic data, or it can be included next to the question if being asked in a survey/questionnaire format.

1. **What is your current gender identity?**

* Cisgender Man
* Cisgender Woman
* Genderqueer
* Gender Non-binary
* Gender Non-conforming
* Man
* Transgender Man/Trans Man
* Transgender Woman/Trans Woman
* Two-Spirit
* Woman
* Additional Category, Please Specify\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
* Decline to Answer

1. **What was your sex assigned at birth?**

* Female
* Male
* Intersex
* Decline to answer

**Other Issues:**

A person’s gender identity and sexual behavioral risk for HIV are independent from one another. It should not be presumed that just because a particular population of individuals is statistically more vulnerable toHIV, that every individual within that population is “at risk”, or that one’s gender identity determines sexual risk behavior. It is important to capture information about specific sexual behavior in addition to gender identity for each individual person.

**Appendix 1**

**Definitions**

**Gender Categories**

**Cisgender** is the term used to describe someone whose gender identity matches the sex they were assigned at birth. This term comes from chemistry, where “cis” means “sameside.”

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

**Gender Identity** is a person’s internal sense of their gender, or how they identify themselves. People may identify as a man, woman, boy, girl, as neither, or both.

**Genderqueer** is used to describe people who don’t identify as a man or a woman; they do not subscribe to conventional gender distinctions. It may also be considered a catch-all term for gender identities other than man and woman.

**Gender Non-binary** refers to people whose gender identity does not fit neatly into the gender categories of man or woman. They may identify completely outside the binary or may identify with two or more genders.

**Gender Non-conforming** refers to a person whose gender expression is not consistent with the societal or cultural norms expected of that gender. People who are gender non-conforming do not follow other peoples’ ideas or stereotypes about how they should look, or act based on the female or male sex they were assigned at birth.

**Transgender or trans** describes a person whose gender identity differs from the sex they were assigned at birth and is defined by the person’s present identity.

**Transgender Man/Trans Man** refers to someone who identifies as a man but was assigned female sex at birth.

**Transgender Woman/Trans Woman** refers to someone who identifies as a woman but was assigned male sex at birth.

**Two-Spirit** is a modern umbrella term used by some indigenous North Americans to describe certain people in their communities - gay, lesbian, bisexual, as well as gender non-conforming individuals. Because the term “Two Spirit” can have different meanings, it is important to ask someone who uses the term to describe themselves, what it means to them.

**Sex Assigned at Birth**

**Intersex** is a term used for a variety of conditions in which a person is born with reproductive and/or sexual anatomy that doesn’t seem to fit the typical definitions of female or male.

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

**Sexual Orientation**

**Bisexual** refers to someone who is emotionally and sexually attracted to people of the same and opposite genders.

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

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

**Queer** refers to someone who may think of their sexual orientation and/or gender identity as 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 emotionally and sexually attracted to people of the opposite gender.

**Two-Spirit** is a modern umbrella term used by some indigenous North Americans to describe certain people in their communities - gay, lesbian, bisexual, and/or gender non-conforming. Because the term “Two Spirit” can have different meanings, it is important to ask someone who uses the term to describe themselves, what it means to them.

1. Reisner SL, Conron KJ, Tardiff LA, et al. Monitoring the health of transgender and other gender minority populations: validity of natal sex and gender identity survey items in a U.S. national cohort of young adults. *BMC Public Health.* 2014; 14:1224 [↑](#footnote-ref-1)
2. [The Health of Lesbian, Gay, Bisexual and Transgender People, IOM, March 31, 2011](http://www.iom.edu/~/media/Files/Report%20Files/2011/The-Health-of-Lesbian-Gay-Bisexual-and-Transgender-People/LGBT%20report%20release%20presentation.pdf)

   [Centers for Disease Control and Prevention, Fast Facts, HIV Infection and Transgender People, August 2011](http://www.cdc.gov/hiv/transgender/pdf/transgender.pdf)

   [Collecting Sexual Orientation and Gender Identity Data in Electronic Health Records: Workshop Summary](http://www.ncbi.nlm.nih.gov/books/NBK154073/#ch5.s1), 2013 [↑](#footnote-ref-2)