Participant inclusivity in research | Gender, sex and sexual orientation

The TCPS 2 (2018) states that “Issues of fair and equitable treatment arise in deciding whether and how to include individuals, groups or communities in research, and the basis for the exclusion of some” and “researchers shall not exclude individuals from the opportunity to participate in research on the basis of attributes such as culture, language, religion, race, disability, sexual orientation, ethnicity, linguistic proficiency, gender or age, unless there is a valid reason for the exclusion.” (Article 4.1) The TCPS 2 does not provide guidance on how to ensure inclusivity.

This guidance is designed to expand on the principles stated in the TCPS2 as they relate to gender, sex and sexual orientation. A separate discussion of inclusivity in the context of ethnicity, race and culture is also available.

While the Behavioural Research Ethics Board (BREB) considers the principles of inclusion during the review of research ethics applications, it does not typically prescribe language usage. BREB members review descriptions in the ethics application of gender identity, sex, sexual orientation and ethnicity, among other factors, in the context of the research being proposed. Research that addresses particular participant groups should use language that is most appropriate/acceptable for that group.

Researchers are encouraged to consider ways in which language might unintentionally be exclusionary, and to stay current with community standards in order to ensure that the language they use to describe inclusion criteria and recruitment activities, as well as the terminology used in supporting documents and research instruments, does not unintentionally exclude or stigmatize particular groups. The following general guidelines and resources are provided for your consideration.

Know your terms

Gender identity refers to the internal/psychological sense of self, regardless of what sex a person was assigned at birth. When asking about gender as a category, words like woman, man, and trans/non-binary should be used.²

Sex refers to a set of biological attributes in humans and animals. It is primarily associated with physical and physiological features including chromosomes, gene expression, hormone levels and function, and reproductive/sexual anatomy. Sex is usually categorized as female or male but there is variation in the biological attributes that comprise sex and how those attributes are expressed.³

Sexual orientation refers to a person’s emotional, physical, and sexual attraction to other people. When asking about sexual orientation as a category, words like gay/lesbian, bisexual/pansexual, and heterosexual should be used. Please note that the term “homosexual” is not recommended as it is often used in a pejorative tone.⁴

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¹ The BREB would like to thank Dr. Hannah Kia for her generous assistance with this guidance.
² Adapted from "Inclusive Survey and Data Collection Practices Concerning Gender, Sex, and Sexual Orientation,” American University, The Center for Diversity & Inclusion. https://www.american.edu/ocl/cdi/upload/recommendations-on-language_r.pdf
³ https://cihr-irsc.gc.ca/e/47830.html
⁴ Ibid.
Inclusion / exclusion criteria

The BREB asks that researchers clarify in the inclusion criteria (Box 5.2) if specific identities will be included/excluded based on gender, sex or sexual orientation, and that the rationale for the inclusion/exclusion be provided.

For studies that require participants with particular sex organs (e.g. research on the impact of ovarian cancer treatment), researchers should indicate that they are looking for participants who have the required sexual organ(s) (have been diagnosed/are living with the sex-specific health issue), rather than specifying female or male participants.

Language describing inclusion criteria based on assigned sex (e.g., exclusively seeking participants who are “born female” or even “assigned female at birth”), may inadvertently exclude intersex or transgender people. To illustrate:

a. An intersex person may have been assigned female at birth (by virtue of being born with a vulva), despite having XY chromosomes and identifying since early youth as a boy/man. When asked, “what sex were you assigned at birth,” such a participant would need to answer “female,” even though this is not an accurate representation of their identity.

b. If researchers articulate that they are looking for women participants, a lot of trans men and male-identified intersex folks might not be inclined to take part, if doing so would represent them as “female participants.”

This has historically meant that, for example, trans men, along with many intersex and non-binary individuals assigned female at birth, have been left out of research on breast, cervical, and ovarian cancer. It has also meant that many trans women, along with non-binary and intersex individuals assigned male at birth, have been systemically underrepresented in research on prostate cancer.

Recommendations for recruitment materials and consent forms

Before creating your recruitment materials/ads and consent forms, review your terms for potentially exclusionary language, e.g.:

Research on ovarian cancer

a. Use “persons who have been diagnosed with ovarian cancer,” instead of “women who have been diagnosed with ovarian cancer.”

b. Use “You have been invited to participate in this research because you have been diagnosed with ovarian cancer” instead of “…because you are a woman who has been diagnosed with ovarian cancer.”

Research that looks at gender identity regardless of sex

a. Use “Eligible participants will be those who identify as women and are over the age of 25” instead of “Eligible participants will be women over the age of 25.”

b. Use “You have been invited to participate because you identify as a woman.”

Recommendations for designing demographic questions

Terms are evolving. Review your survey instruments to ensure the terminology is current and avoids inadvertent exclusion of research participants.

a. If your research does not require that participants identify as men or women, female or male, consider removing the question.
b. Participants may find it offensive or dehumanizing to have no option except to be included in an “Other” category. To reduce this effect, researchers may wish to include a “Not listed” option with space for the respondent to provide their chosen identifier. Another approach is to include an option: “You don’t have an option that applies to me. I identify as __________.”

c. Consider how the hierarchy of options is represented in your research, and may be operating to exclude or stigmatize some people, for example when “other” is used as a catchall for anyone who does not fit within binary definitions (☐ man ☐ woman ☐ other).

d. Include an explanation of why the question is being asked: either in the consent form (“we will be asking some demographic questions in order to…”) or in the survey itself (“gender data will be used to…”).

**Recommended question format | gender**

Q. With which gender do you most identify?
☐ Man
☐ Woman
☐ Transgender woman | Trans woman
☐ Transgender man | Trans man
☐ Non-binary
☐ Two-Spirit
☐ Not listed ______________________
☐ Prefer not to answer

**Recommended question format | sex**

Q. How would you describe your sex?\(^5\)
☐ Female
☐ Male
☐ Intersex
☐ Not listed ______________________
☐ Prefer not to answer

**Recommended question format | sexual orientation**

Q. What is your sexual orientation?
☐ Heterosexual
☐ Gay/lesbian
☐ Bisexual/pansexual
☐ Queer
☐ Two-Spirit
☐ Not listed ______________________
☐ Prefer not to answer

\(^5\) Unless the research pertains to specific sexual organs/anatomy, researchers should consider prioritizing questions about gender/gender identity over questions about sex.
**Resources**

Rainbow Health Ontario. Provides an overview of the issues to consider when designing research instruments.  

Canadian Professional Association for Transgender Health  
CPATH Ethical Guidelines for Research Involving Transgender People & Communities:  

Includes provincial, federal, international

Inclusive Survey and Data Collection Practices Concerning Gender, Sex, and Sexual Orientation, American University, The Center for Diversity & Inclusion  
[http://nebula.wsimg.com/4c27929f438a2dee7c064e1c5b2a7b51?AccessKeyId=B6885E9DB42D0C2EAC6F&disposition=0&alloworigin=1](http://nebula.wsimg.com/4c27929f438a2dee7c064e1c5b2a7b51?AccessKeyId=B6885E9DB42D0C2EAC6F&disposition=0&alloworigin=1)

Information and Data Collection Involving Gender and Sexuality  
[https://center.dso.iastate.edu/sites/default/files/Documents/Classroom/Asking%20about%20Gender%20and%20Sexuality.pdf](https://center.dso.iastate.edu/sites/default/files/Documents/Classroom/Asking%20about%20Gender%20and%20Sexuality.pdf)