

Participant inclusivity in research | Gender, sex and sexual orientation¹

In keeping with principles of equity, diversity and inclusion, the Behavioural Research Ethics Boards (BREB) consider the principles of inclusion during the review of research ethics applications and will issue provisos when it is believed that people are inadvertently or unfairly being excluded from participating in research because of the way their gender, sex, or sexual orientation are described. (See TCPS 2 (2018) Article 4.1)². This guidance is designed to expand on the principles 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 BREB does not typically prescribe language usage, 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 their research population, 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

Cis-gender refers to people who feel their gender identity aligns with the sex they were assigned at birth.

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, refer to the Statistics Canada page for appropriate language usage:

<https://www23.statcan.gc.ca/imdb/p3VD.pl?Function=getVD&TVD=1326727>.

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.³

Sexual orientation refers to a person's emotional, physical, and sexual attraction to other people.

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

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² 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](#))

³ <https://cihr-irsc.gc.ca/e/47830.html>

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 their gender identity or sex, 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...”).
- e. Consider including a “Prefer not to answer” option for all questions.
- f. For use of “Two-Spirit” in demographic data collection, refer to: <https://cihr-irsc.gc.ca/e/52214.html>.

Format for gender, sex and sexual orientation-related questions

The BREB recommends using the current standards provided by Statistics Canada (October, 2021).

For gender: <https://www23.statcan.gc.ca/imdb/p3VD.pl?Function=getVD&TVD=1326727>

For sex: <https://www23.statcan.gc.ca/imdb/p3VD.pl?Function=getVD&TVD=1326697>

Other Resources

Canadian Professional Association for Transgender Health

CPATH Ethical Guidelines for Research Involving Transgender People & Communities:

<http://cpath.ca/wp-content/uploads/2019/08/CPATH-Ethical-Guidelines-EN.pdf>

CPATH Resources page: <http://cpath.ca/en/resources/links/>

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>