

JUSTIFICATION CRITERIA FOR GENDER/SEX CONSIDERATIONS IN RESEARCH

INFORMATION FOR APPLICANTS

This document outlines gender/sex considerations that applicants will need to include in their proposals/applications. It includes links to relevant resources as well as examples of hypothetical justifications for sex and gender-based analyses.

Applicants must consider how to account for sex (a biological attribute) and/or gender (socially constructed roles, behaviours, expressions, and identities) in their research, keeping in mind that the two are not mutually exclusive. Please describe briefly how [gender and/or sex](#) considerations will be integrated into your research. The strongest applications will show integration of these considerations throughout their research process (i.e., within the proposal, where relevant).

It is possible that sex and/or gender may not apply to your research question and if not integrated, please explain why. Please describe and provide rationale for your sample eligibility and inclusion/exclusion criteria (or sample characteristics, if archival) with respect to sex and gender (e.g., will participants of any gender, sex or sexual orientation be eligible, or will eligible participants be, for example, women, female at birth, or those with uteruses, and why?) Please also specify any considerations with respect to sexual orientation (e.g., are individuals of all sexual orientations eligible? If not, what are the inclusion criteria for sexual orientation and their rationale?)

Please note that participants who are divergent with respect to sex, gender, or sexual orientation should be included in all data collection unless there is a compelling reason not to. It is not sufficient to simply state that the sample size of sex, gender, or sexual orientation divergent participants would be too small for group comparisons. Some options to consider include, but are not limited to: (1) plan data analyses to allow for testing whether results differ by inclusion or exclusion of gender/sex divergent participants, even with small samples; (2) if there is evidence of expected sex, gender, or sexual orientation differences, collect a large enough sample and make direct comparisons; (3) consider whether participants' data may be aggregated, clustered, or collapsed (based on theory) in order to create groups that are large enough to analyze.

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RESOURCES

Below are links to helpful resources on considering sex and gender at all stages of research. All applicants are strongly encouraged to review these documents, considering how sex, gender, and sexual orientation may be relevant to their research questions, and consulting relevant literature (e.g., on any evidence of sex/gender effects for key outcomes).

- **Comprehensive toolkits on various aspects of Gender and Sex in Methods and Measurement Research Equity:** <https://cgshe.ca/practice/research-toolkits/>
- **NSERC guide on integrating equity, diversity and inclusion considerations in research, with examples:** https://www.nserc-crsng.gc.ca/NSERC-CRSNG/Policies-Politiques/EDI_guidance-Conseils_EDI_eng.asp
- **Canadian Institutes for Health Research for helpful definitions, further information and detailed examples:** <https://cihr-irsc.gc.ca/e/50836.html>
- **Asking About and Measuring Participants' Genders and Sexes:** <https://cgshe.ca/app/uploads/2022/10/GSMM-Research-Equity-Tool-4.pdf>
- **Beischel, W. J., Schudson, Z. C., Hoskin, R. A., & van Anders, S. M. (2022). The gender/sex 3×3: Measuring and categorizing gender/sex beyond binaries. Psychology of Sexual Orientation and Gender Diversity. Advance online publication. <https://doi.org/10.1037/sgd0000558>**
- **Beyond the Binary - Taking a patient-oriented and trauma-informed approach to building partnerships and dialogue to incorporate gender equity into women's health research:** <https://whri.org/our-initiatives/beyond-the-binary/>

EXAMPLES

We have provided some example justification statements on the following pages. Some portions of these examples may be relevant to your research, but applicants are expected to have actively engaged with the resources and demonstrated their own understanding of how sex, gender, and sexual orientation applies to their specific research questions. This list of hypothetical justifications for sex and gender-based analyses, are provided for illustrative purposes. The following examples are not based on comprehensive literature reviews, as such, we list fictitious citations as "Researcher, 20XX".

WHERE SEX, GENDER, AND/ OR SEXUAL ORIENTATION WERE CONSIDERED AND DEEMED RELEVANT

EXAMPLE 1

This study aims to examine biological factors associated with poor outcomes in patients who received treatment for prostate cancer.

We will investigate biological risk factors for poor treatment outcomes among individuals who have undergone any treatment for prostate cancer within the previous six months. All individuals with a prostate, or who had a prostate within the last six months, will be invited to participate. Thus, individuals of any gender, sex, or sexual orientation will be eligible, provided they had or have a prostate and received treatment for prostate cancer. In turn, individuals without prostates in the last six months will be excluded because they do not have experiences and/or physiology pertinent to our research question. We will follow best practices for assessing sex, gender, and sexual orientation to characterize our sample by, for example, asking separate questions for each and including open-ended response options for participants to offer their own language and explaining how answers to these questions will be used in the research (Researcher, 20XX). We will also follow guidelines for effective recruitment strategies for inclusive research provided by the Centre for Gender and Sexual Health Equity (e.g., precise language,

adequate compensation). We will assess whether patients' gender, sex, and/or sexual orientation influences the strength of associations between biological risk factors for poor treatment outcomes using moderation analyses, given the known impact of gender, sex, and sexual orientation on health-related behaviours and outcomes more broadly (Researcher, 20XX)

EXAMPLE 2

This study aims to examine predictors of treatment-seeking behaviours among individuals with cardiovascular health conditions.

We will investigate predictors of treatment-seeking behaviours among individuals with a chronic cardiovascular health condition. Our study will be inclusive to individuals of any sex, gender, or sexual orientation. Given that patients who are trans and/or gender divergent have unique experiences and known challenges interacting with the healthcare system including discrimination (Researcher, 20XX) and given the well-established gender differences in cardiovascular symptoms, both of which could affect treatment-seeking behaviours (Researcher, 20XX), we will test whether our results differ by sex and gender diversity and sexual orientation.

We will follow best practices for assessing sex, gender, and sexual orientation to characterize our sample by asking separate questions for each construct and including open-ended response options for participants to offer their own language (Researcher, 20XX). Because gender expression has been linked with treatment access and can differ from gender identity (Researchers, 20XX), we will follow recommendations provided by the Centre for Gender and Sexual Health Equity to also assess participants' gender expression. To achieve our desired sample size to make these comparisons, we will specifically promote this study among gender, sex, and sexual orientation divergent communities following guidelines by the Centre for Gender and Sexual Health Equity for effective recruitment (e.g., clear and inclusive recruitment ads, building relationships with community organizations).

We will reflect on and consider sex, gender, and sexual orientation in the interpretation and discussion of our results, including acknowledging any limitations to the diversity of our sample and discussing any observed differences by sex, gender, or sexual orientation in terms of unique implications for different communities.

EXAMPLE 3

This study aims to characterize experiences with using an insulin pump among adults with Type I Diabetes.

In this qualitative study, we will investigate experiences of using an insulin pump among adults with Type I Diabetes. The study will be inclusive to any individuals with Type I Diabetes who currently uses an insulin pump, including those of any sex, gender, or sexual orientation. To our knowledge, there is no evidence of sex, gender, or sexual orientation differences in use of an insulin pump among those with Type I Diabetes. In fact, preliminary data showed similar rates of use and overall satisfaction with the insulin pump among women and men (Researcher, 20XX).

**WHERE SEX, GENDER, AND/OR
SEXUAL ORIENTATION WERE
CONSIDERED AND DEEMED NOT
RELEVANT OR COULD NOT BE
THOROUGHLY CONSIDERED DUE
TO PRACTICAL LIMITATIONS**

There are no prior studies that we are aware of that compared the insulin pump experiences of gender/sex divergent populations to majority populations; however, we do not have a theoretical reason to assume that their experiences will be different. Therefore, we will conduct our primary analyses with our full sample of gender, sex, and sexual orientation diverse individuals included. We will follow best practices for assessing sex, gender, and sexual orientation to characterize our sample by asking separate questions for each and including open-ended response options for participants to offer their own language (Researcher, 20XX). We will aim for at least 10% of our sample to be gender, sex, and sexual orientation diverse individuals by following guidelines for effective recruitment strategies (e.g., precise language and inclusive imagery in recruitment ads) provided by the Centre for Gender and Sexual Health Equity. We will reflect on and consider sex, gender, and sexual orientation in the interpretation and discussion of our results, including acknowledging any limitations to the diversity of our sample.

EXAMPLE 4

This study aims to examine quality of life among individuals with thyroid irregularities.

We will investigate quality of life among individuals with thyroid irregularities, including hypo- or hyperthyroidism. This study will make use of an archival dataset in which participants were asked to indicate their gender and the response options were binary (male or female). Therefore, sex and gender were conflated in their assessment. It is impossible to know whether participants responded to this item based on their sex and/or their gender, to identify whether participants were cisgender or gender/sex divergent, or to consider non-binary sex or gender and additional identities.

The dataset also does not contain data on sexual orientation. Given some evidence of biologically-influenced differences in thyroid disease among males and females (Researcher, 20XX), we will test moderation by binary sex/gender in our sample. We will discuss our results in the context of any existing literature examining gender, sex, or sexual orientation differences for our key construct of quality of life in terms of unique implications for different communities. However, we will acknowledge in all publications of this work the limitations of the assessment of gender/sex and resultant implications for the interpretation of the findings. We will also acknowledge our inability to fully characterize our sample in terms of in terms of sex, gender, and sexual orientation.