

UNIVERSITY OF BRITISH COLUMBIA DIVISION OF CARDIOLOGY CARDIOVASCULAR EXCELLENCE IN ACTION



Providence Health Care



Research Guidance Document: Integration of Sex and Gender in Biomedical Research

This document provides guidelines for integrating sex- and gender-based analysis (SGBA) into biomedical research to inform health care. Considering sex and gender differences allows researchers to identify health variations, enhance scientific discovery, and develop more personalized treatments for diverse populations. This document provides a concise overview of the key aspects—what, why, who, when, and how—of integrating sex and gender in health research, along with a list of tools and references.

The Importance of Integrating Sex and Gender Considerations in Health Research?

- The terms *sex* and *gender* refer to distinct but interconnected factors influencing health. *Sex* includes biological attributes such as chromosomes, gene expression, and anatomy, which determine whether an individual is assigned as female, male, or intersex at birth. *Gender*, on the other hand, encompasses socially and culturally constructed roles, behaviors, norms, identities, and power dynamics, shaping how individuals are socialized, present themselves, and embody roles of femininity or masculinity (1,2).
- Definitions according to Canadian Institute of Health Research (CIHR), https://cihr-irsc.gc.ca/e/48642.html:
 - 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.
 - Gender refers to the socio-culturally constructed roles, behaviors, expressions and identities
 of girls, women, boys, men, and gender diverse people. It influences how people experience
 themselves and each other, how they act and interact, and the distribution of power and re sources in society. Gender identity is not confined to a binary (girl/woman, boy/man) nor is it
 static; it exists along a continuum and can change over time. There is considerable diversity in
 how individuals and groups understand, experience and express gender through the roles they
 take on, the expectations placed on them, relations with others and the complex ways that
 gender is institutionalized in society.
- Both sex and gender significantly impact health research, influencing molecular processes, clinical traits, treatment responses, health outcomes, and disease progression. They also affect access to healthcare, health-seeking behaviors, healthcare utilization, and patient experiences (3–5).
- Since 2010, the Canadian Institutes of Health Research (CIHR) have mandated that grant applicants address the consideration of sex and/or gender in their proposals. This requirement reflects a broader trend among funding bodies:
 - The European Commission's Horizon 2020 guideline, issued in 2014, underscores the importance of sex and gender inclusion in grant evaluation and monitoring.
 - Similarly, the NIH's 2015 policy mandates the consideration of sex as a biological variable in study design, analysis, and reporting (6).
 - Penalties are now applied during peer review to proposals that omit or fail to convincingly argue against the relevance of sex and gender.
 - A sex- and gender-informed perspective can improve research methodology, reduce bias, promote equity in health outcomes, and foster innovation.
 - Integrating sex and gender considerations enhances responsible, inclusive science that benefits

diverse populations (3,5).

Why Integrating Sex and Gender in Research is Essential for Accurate, Equitable, and Effective Health Outcomes?

- First, there are inherent differences in physiology and in the (social) determinants of health between sexes that significantly impact health outcomes. These differences—such as variations in hormone levels, immune system responses, and cardiovascular health—can directly influence how diseases manifest and how individuals respond to treatments. For example, pharmacokinetics and pharmaco-dynamics can vary between sexes, affecting the efficacy and safety of drugs (7).
- Second, historically, the neglect of women in clinical studies and the exclusion of sex considerations have led to significant failures, errors and false conclusions, such as medications that were ineffective or harmful for females (3,5).
- Third, considering sex and gender improves research methodology by accounting for variables in study design that could impact results.
- Finally, for research to be representative and generalizable, it must include sex- and gender-diverse populations, reflecting the full spectrum of human biology so that findings apply to all. Integrating sex and gender into research promotes unbiased science, safety, and fairness.

Who Should Integrate Sex, Gender, and Equity, Diversity, and Inclusion (EDI) in Health Research?

Researchers must apply sex and gender considerations throughout the entire research process. This includes defining research questions, selecting study populations, designing methodologies, analyzing data, interpreting results, and disseminating findings. Additionally, Equity, Diversity, and Inclusion (EDI) principles are important— not only for ensuring diverse study participants but also for building diverse research teams. A diverse team brings a range of perspectives, experiences, and expertise, which can significantly enhance the quality and relevance of the research.

When to Integrate Sex and Gender Considerations in the Research Process?

- Sex and gender considerations should be integrated from the start of research planning and included at every stage—defining research questions, designing methodologies, analyzing data, and interpreting and disseminating results.
- Investigators are mandated to complete CIHR training modules (<u>https://cihr-irsc.gc.ca/e/49347.html</u>) early in the process to gain the skills needed to effectively integrate sex and gender perspectives, result-ing in more inclusive and impactful research outcomes.

How to Effectively Integrate Sex and Gender Considerations in Health Research?

- We identified gaps in the literature regarding specific steps for integrating sex and gender into research, emphasizing the need for clear examples. Many researchers find it challenging to apply a sex and gender lens in their proposals (3).
- Table 1 provides key questions and considerations for the planning and design of research.
- The checklist may help to systematically incorporate and address sex and gender considerations throughout their study design, methodology, data analysis, and reporting.
- In health studies, sex- and gender-based information should be collected using self-reported data, with separate measures for sex assigned at birth and current gender identity.
- Researchers should offer non-binary gender options and include preferred pronouns.
- The Two-Step Gender Measure is a method used in research to collect more accurate and inclusive data on gender identity. It involves two separate questions to distinguish between a person's sex assigned at birth and their current gender identity, helping avoid conflating sex and gender. The two steps are:
 - Sex Assigned at Birth: "What was your sex assigned at birth?" (options typically include

male, female, intersex, or prefer not to say).

- Current Gender Identity: "What is your current gender identity?" (options include male, female, non-binary, genderqueer, prefer not to say, or an open-ended response).
- Additionally, demographic factors like race and socioeconomic status should be incorporated to address intersectionality. Open-ended questions promote self-expression, while confidentiality protects sensitive information.
- Careful planning is essential when testing for sex or gender differences to avoid statistical artifacts (6). Rather than assuming universal sex and gender differences, researchers should adopt methods that improve the detection of true differences where they exist. Observational research requires careful attention to potential biases and confounders to enhance the credibility and impact of findings in biomedical research.

Sample Size Considerations for Integrating Sex and Gender in Health Research

- Conduct a power analysis that accounts for potential differences in outcomes based on sex and gender. This analysis will help determine the minimum sample size needed to detect meaningful differences with adequate statistical power for each subgroup.
- Stratify the sample by sex and gender to ensure adequate representation of diverse groups within the population being studied. This approach facilitates comparisons between groups and enhances the generalizability of findings.
- Consider the variability in responses or outcomes that may exist among different sexes and genders. A larger sample size may be necessary if significant differences are anticipated in how males, females, and gender-diverse individuals respond to interventions or exhibit health outcomes.
- Plan for subgroup analyses to examine outcomes separately by sex and gender. This involves collecting sufficient data within each subgroup to allow for meaningful comparisons and conclusions.
- Recognize that individuals may belong to multiple intersecting groups (e.g., sex, gender, race, ethnicity). When feasible and appropriate, plan for analyses that explore how these intersecting identities may influence outcomes.
- Consider an iterative approach to sample size determination, where initial estimates may be adjusted based on preliminary data or ongoing analyses, especially if unexpected differences between sexes or genders are observed.
- Include a descriptive table (perhaps as a supplement if there are limits on the number of tables) that includes rates of predictors and outcomes among key subgroups in your sample—this is especially important for groups for whom we have limited data (e.g., asexual people).
- Consider reporting unadjusted statistics so others can use your data.
- Aggregating across groups is not always the answer to running your analyses—investigate alternative statistical methods that may not require aggregation, like bootstrap analyses, Bayesian methods, and nonparametric alternatives to group comparisons (1,8,9).

Reporting Guidelines for Sex, Gender, and Demographic Considerations in Research

The International Committee of Medical Journal Editors (ICMJE) has published guidance on sex and gender reporting, recommending the inclusion of representative populations in all study types, provision of descriptive data for sex and other relevant demographic variables, and stratification of reporting by sex (https://www.icmje.org/icmje-recommendations.pdf).

• The Sex and Gender Equity in Research (SAGER) guidelines are designed to promote systematic reporting of sex and gender in research, offering researchers and authors a standardized tool for incorporation into scientific publications. These guidelines aim to enhance the quality of scientific research reporting, serve as a valuable resource for authors and peer-reviewers, maintain flexibility across various research areas and disciplines, and ultimately improve the communication of research findings (7).

• A research sexual orientation and gender diversity (SOGD) Research Manuscript Writing Checklist can be found in (1)



Figure 1. SAGER Guidelines for Reporting Sex and Gender Equity in Research

Preferred terminology and common pitfalls to avoid (10,11):

- Avoid Using "Females" and "Males" as Nouns
 - Avoid: females, males (as nouns).
 - Preferred: women, girls, men, boys.
- However, "female" and "male" can be used as adjectives. Examples: female patients, male children, female technician, male technician.
- Usage of Gender Terms. Use gender terms in their adjectival form.
 - Avoid: transman, transwoman, trans.
 - Preferred: transgender man, transgender woman, transgender person.
- Parallel Comparisons. Maintain symmetry in comparisons.
 - Avoid: men and transgender men, normal and trans people.
 - Preferred: cisgender men and transgender men, cisgender people and transgender people.
- Acknowledging Non-Binary Genders. Use inclusive language to refer to non-binary genders. Examples: transgender, gender-nonconforming, genderqueer, gender-nonbinary, gender-creative, agender, queer (varies by individual), two-spirit (specific to Indigenous and Native American communities).
- Avoid Inferring Binary Categories Avoid terms that imply binary relationships.
 - Avoid: opposite sex, opposite gender.
 - Preferred: another sex, mixed sex, another gender, mixed gender.
- Sex Assignment Terminology. Use accurate and respectful language regarding sex assignment.
 - Avoid: birth sex, natal sex, born male, born female.
 - Preferred: assigned sex, sex assigned at birth, person assigned male at birth, person assigned female at birth.
- Neutral Terms When Sex and Gender Are Irrelevant. Opt for neutral terms in general contexts.
 - Avoid: man, male nurse.
 - Preferred: human, nurse.

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| CIHR RESOURCES GENERAL | |
|---|--|
| How to integrate sex and gender into research | https://cihr-irsc.gc.ca/e/50836.html |
| Distinguish between and define sex and gen- | |
| der in health research; | Scroll down, resources: |
| Identify sex and gender differences in the mecha- | All applicants, biomedical, clinical, |
| nism, disease or treatment under study; | health systems and services, popula- |
| Identify methods for integrating sex and gender | tion health |
| variables in health research contexts. | |
| Online training Modules | https://cihr-irsc.gc.ca/e/49347.html |
| Sex and Gender in Biomedical Research | |
| Sex and Gender in Primary Data Collection | |
| with Human Participants | |
| Sex and Gender in the Analysis of Secondary Data from Hu- | |
| man Participants | |
| Key considerations for the appropriate integration of sex and | https://cihr-irsc.gc.ca/e/50835.html |
| gender in research | |
| How to study the impact of sex and gender in medical re- | https://www.ncbi.nlm.nih.gov/pmc/ar |
| search: a review of resources | ticles/PMC5073798/ |
| Sex and gender interactive training modules; idem for peer re- | https://www.cihr-irsc-igh-isfh.ca/ |
| viewers | |
| Clinical research: Guidance Documents, key articles and re- | https://cihr-irsc.gc.ca/e/50836.html |
| ports | |
| A gender, sex, and health research case book | https://cihr-irsc.gc.ca/e/documents/ |
| | What a_Difference_Sex_and_Gen- |
| | der_Make- en.pdf |
| Gender Stratified: Guidance on Measuring and Reporting | https://www.cihi.ca/sites/de- |
| Health Inequalities | fault/files/document/measuring- |
| | health-inequalities-toolkit-gender- |
| | stratifier-en.pdf |
| Reviewer Guidance to Evaluate Sex as a Biological Variable | https://grants.nih.gov/grants/peer/gui |
| (SABV) | delines_general/sabv_deci |
| | sion_tree_for_reviewers.pdf |
| Key considerations for the appropriate integration of sex as a | https://cihr-irsc.gc.ca/e/docu- |
| biological variable | ments/sgba_criteria_sex-en.pdf |
| Key considerations for the appropriate integration of gender | https://cihr-irsc.gc.ca/e/docu- |
| as a social determinant of health | ments/sgba criteria gender-en.pdf |

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Table 1. Guiding Questions and Considerations for Integrating Sex and Gender in Research

| Proposal | Questions | Considerations |
|------------------------|---|--|
| Literature review | Does the literature review consider sex and gender? | Address knowledge, gaps, missed opportunities or questions about sex/gender raised in the lit- erature Articulate that disease does or does not have a difference in incidence or prevalence on the basis of sex. Outline, severity and risk differences, treatment, and experiences of health condi- tion. |
| | What sex-and gender assumptions are relevant to the project? | Sex Considerations: Determine if sex is a covariate, confounder, or explanatory variable. Assess the relevance of sex-related characteristics (e.g., physiology, anthropometric factors, biomechanics, injury thresholds, pain tolerance levels). Consider how sex-related factors interact with gender, ethnicity, age, socio-economic status, and lifestyle. Gender Considerations: Relevance in relation to different gender identities, norms, and relations. Relevant factors intersecting with gender, such as age, socio-economic status, and ethnicity. Opportunities missed by not analyzing data on gender and intersecting facto |
| Research objectives | Do the objectives include sex/gender? | If the objective includes both men and women, make that explicit Example: To investigate the impact/efficacy of [specific intervention, treatment, or condition] on cardi- ovascular (primary/secondary) health outcomes, comparing and analyzing data for both men and women. To identify potential sex-specific effects and improve personalizedapproaches. |
| Population | Did you consider sex/gender in the inclu- sion/exclusion criteria? How were these criteria defined and applied to ensure balanced representation? Have you evaluated the potential for selec- tion bias related to sex and gender? What steps were taken to minimize or ad- dress this bias in your study design and re- cruitment process? | Specify sex/gender considerations to ensure balanced representation. Be aware of unfairly exclu- sion on the basis of sex/gender. Define criteria to reflect diverse sex/gender characteristics and apply consistently. Assess potential biases related to sex/gender in the sample selection. Implement strategies to reduce sex/gender bias in design and recruitment. Oversampling of underrepresented groups may be necessary to avoid bias. Provide a transparent rationale for excluding or underrepresenting certain populations. |

| Population | Were sex/gender considerations factored | Ensure the sample size is inclusive; includes all sexes/genders to achieve disaggregated analy- |
|--------------|--|---|
| continued | into the calculation of sample size? | sis. |
| | How did these considerations influence the | Acknowledge that reduced sample sizes per sex group can limit statistical power. |
| | determination of the study's statistical | Design studies with an understanding that some outcomes may differ by sex and apply power |
| | power? | calculations for each sex when necessary. |
| | | Verify that the sample size is adequate for analyzing secondary outcomes independently, |
| | | Consider focused studies on one sex if feasible, and assess the relevance of secondary out- |
| | | comes for gender-related differences. |
| | | In quantitative research, calculate appropriate sample sizes for gender comparisons. |
| | | In experimental studies, consider factorial designs to reduce the sample size required for sex- |
| | | based comparisons. |
| Recruit- | Have you considered how sex and gender | Identify and address potential sex/gender barriers to participation, including representation |
| ment, Re- | impact the recruitment and retention of | on recruitment materials. |
| tention | study participants? Specifically, how do you | Recruitment materials should explicitly encourage participation from a broad spectrum of gen- |
| | ensure broad and equitable participation | der identities and sexual orientations. |
| | across different sexes? | Develop a plan to ensure broad participation, considering gendered differences in help-seek- |
| | | ing behaviors and the need for flexible hours or support for caregiving responsibilities. |
| | | Address retention barriers such as child care, travel costs, and sex-specific dosing regimens. |
| | | In all communication materials, be aware of stereotyping. |
| Data Collec- | Do the data collection tools capture info rel- | Design tools (e.g., surveys, focus group questionnaires, patient intake forms) to capture di- |
| tion | evant to sex and gender? | verse sex/gender information for robust analyses. |
| | | Ensure participant intake forms and tools capture both sex (e.g., male, female) and gender |
| | | identities (e.g., man, woman, transgender, two-spirit). |
| | | Include variables in data collection tools to analyze the influence of sex/gender, including life |
| | | stages such as pregnancy or menopause. Include adequate samples of females, males, and, |
| | | where relevant, intersex individuals. Record intersecting factors such as age, lifestyle, and so- |
| | | cio-economic status. Ensure equal access for women, men, and gender-diverse individuals. |
| | | Analyze and report variables disaggregated by sex/gender. Avoid using gender as a proxy for |
| | | birth sex in surveys. Validate gender measurement instruments in the target sample popula- |
| | | tion. In product and systems design, account for anthropometric, biomechanical, and physio- |
| | | logical factors that vary by sex. Consider how the sex and gender of the researcher may impact |
| | | research outcomes. Determine if oversampling is needed to ensure sufficient participation of |
| | | gender-diverse individuals (Vaughan, 2017). |
| Bias | Mitigate selection bias | Consider selection bias by ensuring recruitment strategies are inclusive of all sex and gender |
| | Specifically consider and mitigate forms of | identities and do not inadvertently favor certain groups. |
| | bias e.g., selection, measurement, | Account for underrepresented gender identities during recruitment to avoid skewing the |

| | recording, reporting | sample. |
|------------|---|---|
| | | Address any specific barriers to participation for certain gender groups and consider strategies |
| | | to mitigate these challenges. |
| | Measurement | Ensure the tools for data collection, such as surveys or intake forms, capture both sex and gen- |
| | | der identity. Verify that the instruments measuring gender identity reflect participant diversity |
| | | and are validated for the study population. |
| | | Measure sex- and gender-specific variables, like hormonal cycles and menopause, accurately |
| | | and consistently. |
| | Recording | Record sex and gender data accurately, avoiding assumptions or simplifications that could lead |
| | | to misclassification. |
| | | Avoid recording gender as a binary variable; ensure it accounts for nonbinary and other gen- |
| | | der-diverse identities. |
| | | Include intersecting factors like age, race, and socio-economic status along with sex/gender to |
| | | capture a comprehensive view of participant demographics. |
| | Reporting | Report sex- and gender-disaggregated data transparently, ensuring results from all gender |
| | | groups are included in the analysis. Generalize findings appropriately to all gender groups, |
| | | avoiding biases in how results are framed. Discuss differences in outcomes between sex/gen- |
| | | der groups adequately, rather than overlooking them in the reporting process. |
| Analysis | Does the proposal include a plan to analyze | Include a plan to analyze the impact of sex/gender on study findings. Ensure statistical methods |
| | the impact of sex/gender on study findings? | account for sex/gender differences in outcomes. Disaggregate data by sex/gender to identify any |
| | | significant variations in results. Examine interactions between sex/gender and other variables to |
| | | capture nuanced effects. Consider potential biases in interpretation that may arise from oversim- |
| | | plifying sex/gender data. |
| Knowledge | Has sex/gender been considered in the | Include sex/gender considerations in disseminating research findings. |
| ranslation | knowledge translation plan? | Clear plan for selecting and tailoring interventions based on sex/gender, addressing |
| | | potential barriers and facilitators. |

References

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Checklist for Addressing Sex and Gender in Research

Relevance of Sex/Gender to Research Have you analyzed how sex and gender relate to your research topic? Have you reviewed existing literature on sex and gender differences in your field? **Study Design and Proposal** Does your proposal explain how sex and gender issues will be addressed? If not included, have you П provided a rationale? Does your study design ensure that potential sex/gender differences will be investigated (e.g., П through data collection and analysis)? Methodology and Data Collection Are traditional cardiovascular risk factors or other variables explored for differences between sexes and genders? Have you considered intersecting factors (e.g., age, ethnicity, disability) alongside sex and gender in your methodology? Are your research tools (e.g., questionnaires, surveys) designed to capture relevant sex/gender dif-ferences? Are the research groups sex/gender-balanced? **Ethical Considerations** Have you considered ethical implications related to sex and gender in your research? Is safety and privacy assured for all participants, particularly in cases of gender identity disclosure? П **Data Analysis** Have you disaggregated and analyzed your data by sex/gender? Are statistical analyses and visual presentations (e.g., tables, graphs) highlighting relevant sex/gen-П der differences? How will intersectional factors, such as socioeconomic status or ethnicity, be accounted for in your analysis? **Reporting and Dissemination** Are you using gender-sensitive language in your reporting? Have you included stakeholders with expertise in gender in your dissemination strategy? П Are you planning specific publications or events focused on gender-related findings? **Research Team Composition** Is there a gender balance within the research team, especially in decision-making roles? \square Have you ensured the inclusion of gender-diverse populations in your study? **Instrument Selection and Application** Have you selected instruments that accurately measure gender dimensions (e.g., norms, relations) and that are validated for diverse populations? Are the questions in your research tools sensitive to the cultural and gender norms of the partici-pants? **Study Protocol and Population** Are gender-diverse populations included and appropriately represented? Have you considered the need for oversampling gender-diverse or minority populations? П Is access to participation equitable for all genders? **Publication and Reporting Standards** Have the SAGER (Sex and Gender Equity in Research) guidelines been applied in your reporting? Does the publishing medium require specific considerations for reporting sex and gender? Have you paid attention to inclusive language and gender-sensitive language П

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Gender sensitive communication

https://eige.europa.eu/publications-resources/toolkits-guides/gender-sensitive-communication/practical-tools-checklists-and-summary-tables