

Key considerations for the appropriate integration of sex as a biological variable

Situations when sex may not be applicable:

Research has previously demonstrated that sex is not a determinant, such as the study of:

- The structural or molecular biology of proteins, carbohydrates or lipids
- Pathogens grown in-vitro in an acellular environment
- The pre-clinical design and application of some biomedical technologies

The applicant must provide compelling justification for excluding sex as a biological variable.

Situations when sex is applicable:

The following key considerations apply for reviewers to rate the integration of sex as a biological variable in order to meet standards for rigour and reproducibility in science, and to allow for the discovery of sex differences and their underlying mechanisms where appropriate.

Strength:

- ✓ Inclusion or recruitment of male and female cells, tissues, animals or humans when studying models of disease that affect males and females
- ✓ Documentation and analysis of the sex of the cells, tissues, animals or humans used in the protocol
- ✓ Proposed experimental design that disaggregates results by sex
- ✓ Builds on what is already known about sex differences and sex-related mechanisms in the field of study

Weakness:

- ✗ Does not provide a compelling justification for a single-sex study
- ✗ Ignores observed sex differences already reported in the literature, or fails to build on published data in the design of the proposed studies
- ✗ Does not report the sex of the cells, tissues, animals or humans being studied
- ✗ Does not describe sex disaggregation in the analysis plan when both sexes are being studied
- ✗ Conflates and/or confuses the terms sex and gender

Key considerations for the appropriate integration of gender as a social determinant of health in clinical, health system and population health studies

Both sex and gender should be considered in human and database studies whenever possible.

Situations in which gender may not be applicable to a study:

The integration of gender as a sociocultural determinant of health **may not be applicable** in research describing:

- Certain clinical studies of disease pathophysiology and treatment
- Certain single-sex studies using existing datasets
- Secondary data analyses where it is impossible to create a new gender variable

The applicant must provide compelling justification for why it is not possible or relevant to report on gender.

Situations in which gender is applicable:

The following key considerations apply for rating the quality of integration of gender as a sociocultural determinant of health in the proposal as a strength or a weakness:

Strength:

- ✓ Literature review: reports what is known about gender, gender theories, and/or intersectionality in the field of study, where relevant
- ✓ Methods: describes how gender will be measured or investigated in the population under study
- ✓ Recruitment method: addresses and mitigates bias
- ✓ Analysis: describes how gendered sub-groups will be compared and that the findings will be reported separately in the results section
- ✓ Implementation and knowledge translation plan: considers aspects affected by gender

Weakness:

- ✗ Conflates and/or confuses the terms sex and gender
- ✗ Reports that gender is irrelevant without adequate justification
- ✗ Fails to measure or disaggregate the results by gender when it is possible and relevant to do so

RESOURCES

[Do you know the sex of your cells?](#)

[Better science with sex and gender: Facilitating the use of a sex and gender-based analysis in health research](#)

Online learning modules: Sex and Gender in Health Research

- [Sex and Gender Considerations in Biomedical Research](#)
- [Sex and Gender Considerations in Data Collection and Data Analysis with Humans](#)