

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

It is recommended that applicants consider accounting for sex as a biological variable in basic science, clinical, health system and population health studies where appropriate.

Situations when sex is applicable:

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

Strength:

- ✓ Clear articulation that the phenomenon, condition or disease under study has, or does not have, a different incidence or prevalence based on sex
- ✓ 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 scientifically sound 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 how sex will be accounted for and considered in the analysis plan
- ✗ Does not demonstrate a commitment to disaggregate the data by sex
- ✗ Conflates and/or confuses the terms sex and gender

Situations when sex may not be applicable:

The integration of sex as a biological variable **may not be applicable** in research involving:

- Pathogens grown *in vitro* in an acellular environment
- The pre-clinical design and application of some biomedical technologies

A reasonable explanation should inform the decision why it is not possible or relevant to account for sex as a biological variable.

RESOURCES

- [CIHR Sex and Gender Online Training Modules](#)
- [CIHR YouTube Video: Assessing Sex and Gender Integration in Peer Review](#)
- CIHR Resources for Applicants and Peer Reviewers: [How to Integrate Sex and Gender in Research](#)
- [Sex and Gender Equity in Research \(SAGER\) Guidelines](#)