

Reviewer Guidance to Evaluate Sex as a Biological Variable (SABV)

Main points

- NIH expects that sex as a biological variable will be factored into research designs, analyses, and reporting in vertebrate animal and human studies.
- Strong justification from the scientific literature, preliminary data, or other relevant considerations must be provided for applications proposing to study only one sex.
- This decision tree is meant to be used as a guide, but does not encompass the entire policy. See [NOT-OD-15-102](#) for more information.

Does the study involve vertebrate animals or humans?¹

NO

No further consideration of SABV required; not considered a weakness

YES

Acknowledge as a **weakness** in the critique and discussion and score accordingly

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NO

YES

NO

YES

Is strong justification provided for the single sex study?³

Does the proposal demonstrate plans to report data disaggregated by sex?⁴

NO

YES

Are both sexes included in the study?

NO

Is the study intended to test for sex differences?²

YES

Is the design/analysis adequately rigorous to test for sex differences?

YES

NO

Acknowledge as a **strength** in the critique and discussion and score accordingly

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- Notes
- ¹ See FAQs on [inclusion](#), [primary cells and tissues](#), and [established cell lines](#).
 - ² See FAQs on [considering sex as a biological variable](#) and [use of males and females in basic research](#).
 - ³ See FAQ on [justification of single sex studies](#).
 - ⁴ Based on the research question and availability of relevant data, statistically powered comparisons between the sexes may not be required. Analyzing and publishing sex-based data, even in the absence of powered sex differences analyses, would permit the consideration of the influence of sex in the interpretation of study results and the appropriate generalization of research findings.