

Guidance to PIs on addressing sex as a biological variable (SABV) in animal protocols

Background: Accounting for sex as a biological variable (SABV) should begin with the development of research questions and study design. Properly addressing SABV must be included in all aspects of data collection, in the analysis of results, and in the reporting of findings.

Rationale: Consideration of sex as a biological variable may be critical to the interpretation, validation, and generalizability of research findings. Adequate consideration of both sexes in experiments and disaggregation of data by sex allows for sex-based comparisons and may inform clinical interventions. Appropriate analysis and transparent reporting of data by sex may therefore enhance the rigor and applicability of preclinical biomedical research.

Policy: 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. Further information regarding NIH expectations for the consideration of sex as a biological variable is provided at the following website:

http://orwh.od.nih.gov/sexinscience/overview/pdf/NOT-OD-15-102_Guidance.pdf

Guidance:

Applications for approval of study protocols must include a thorough delineation of how sex is factored into the research designs and analyses for studies. Strong justification from the scientific literature, preliminary data, or other relevant considerations, must be provided for applications proposing to study only one sex. For the majority of cases, where both sexes will be studied, the subject numbers must reflect those required to disaggregate the data by sex and thus allow for sex-based comparisons. Scientific justifications will be approved and/ or modifications required, by the Scientific Director prior to protocol review by ACUC.