

Sex as a Biological Variable

CCTS Biostatistics Core

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This page includes publications and tools that our consultants have found useful. For more information on this topic, including advice about how to apply it in your research, consider [scheduling a consultation with a biostatistician](#).

While we hope this resource list serves as a helpful starting point for other researchers, we provide no guarantee of its comprehensiveness or of the accuracy or reliability of the works cited. If you have concerns or suggestions to improve this page, please [contact us](#).

Overview

Since 2016, the National Institutes of Health (NIH) has expected health researchers to consider sex as a biological variable (SABV). Applicants for NIH funding are asked to “explain how relevant biological variables, such as sex, are factored into research designs and analyses for studies in vertebrate animals and humans.”

Resources

NIH Policy

National Institutes of Health (NIH) (2015a). *Consideration of Sex as a Biological Variable in NIH-funded Research*. Notice Number: NOT-OD-15-102. <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-102.html>.

National Institutes of Health (NIH) (2015b). *Consideration of Sex as a Biological Variable in NIH-funded Research*. Additional guidance regarding NIH expectations. https://orwh.od.nih.gov/sites/orwh/files/docs/NOT-OD-15-102_Guidance.pdf.

National Institutes of Health (NIH) *Reviewer Guidance to Evaluate Sex as a Biological Variable (SABV)*. This decision tree is meant to be used as a guide, but does not encompass the entire policy. https://grants.nih.gov/grants/peer/guidelines_general/sabv_decision_tree_for_reviewers.pdf.

NIH Office of Research on Women’s Health (ORWH) (2022). *Introduction to Sex and Gender: Core Concepts for Health-Related Research*. Video. <https://orwh.od.nih.gov/career-development-education/e-learning/introduction-to-sex-and-gender-core-concepts-for-health-related-research>.

NIH Office of Research on Women’s Health (ORWH) (2023). *Sex as a Biological Variable: A Primer*. E-Learning course. Module 1: SABV and the Health of Women and Men. Module 2: SABV and Experimental Design. Module 3: SABV and Analyses. Module 4: SABV and Research Reporting. <https://orwh.od.nih.gov/career-development-education/e-learning/sabv-primer>.

NIH Office of Research on Women’s Health (ORWH) *NIH Policy on Sex as a Biological Variable*. Accessed 2023-06-30. <https://orwh.od.nih.gov/sex-gender/nih-policy-sex-biological-variable>.

Articles

Arnegard, Matthew E., Lori A. Whitten, Chyren Hunter, et al. (2020). "Sex as a Biological Variable: A 5-Year Progress Report and Call to Action". In: *Journal of Women's Health* 29.6, pp. 858-864. DOI: 10.1089/jwh.2019.8247. <https://doi.org/10.1089/jwh.2019.8247>.

Bale, Tracy L and C Neill Epperson (2016). "Sex as a Biological Variable: Who, What, When, Why, and How". In: *Neuropsychopharmacology* 42.2, pp. 386-396. DOI: 10.1038/npp.2016.215. <https://doi.org/10.1038/npp.2016.215>.

Carmody, Colleen, Charlotte G Duesing, Alice E Kane, et al. (2022). "Is Sex as a Biological Variable Still Being Ignored in Preclinical Aging Research?" In: *The Journals of Gerontology: Series A* 77.11. Ed. by David Le Couteur. Keywords: Aging research, Female, Male, Preclinical, Sex, pp. 2177-2180. DOI: 10.1093/gerona/glac042. <https://doi.org/10.1093/gerona/glac042>.

Clayton, Janine Austin (2015). "Studying both sexes: a guiding principle for biomedicine". In: *The FASEB Journal* 30.2, pp. 519-524. DOI: 10.1096/fj.15-279554. <https://doi.org/10.1096/fj.15-279554>.

Clayton, Janine Austin (2018). "Applying the new SABV (sex as a biological variable) policy to research and clinical care". In: *Physiology & Behavior* 187, pp. 2-5. DOI: 10.1016/j.physbeh.2017.08.012. <https://doi.org/10.1016/j.physbeh.2017.08.012>.

Denfeld, Quin E., Christopher S. Lee, and Beth A. Habecker (2022). "A primer on incorporating sex as a biological variable into the conduct and reporting of basic and clinical research studies". In: *American Journal of Physiology-Heart and Circulatory Physiology* 322.3, pp. H350-H354. DOI: 10.1152/ajpheart.00605.2021. <https://doi.org/10.1152/ajpheart.00605.2021>.

Dhakal, Santosh, Sabal Chaulagain, and Sabra L. Klein (2022). "Sex biases in infectious diseases research". In: *Journal of Experimental Medicine* 219.6. DOI: 10.1084/jem.20211486. <https://doi.org/10.1084/jem.20211486>.

DiMarco, Marina, Helen Zhao, Marion Boulicault, et al. (2022). "Why"sex as a biological variable" conflicts with precision medicine initiatives". In: *Cell Reports Medicine* 3.4, p. 100550. DOI: 10.1016/j.xcrm.2022.100550. <https://doi.org/10.1016/j.xcrm.2022.100550>.

Dohrn, Cathleen and Nicole C. Weitowich (2018). "Considering Sex as a Variable in Clinical Trials". In: *Applied Clinical Trials*. <https://www.appliedclinicaltrialsonline.com/view/considering-sex-variable-clinical-trials>.

Garcia-Sifuentes, Yesenia and Donna L Maney (2021). "Reporting and misreporting of sex differences in the biological sciences". In: *eLife* 10. DOI: 10.7554/elife.70817. <https://doi.org/10.7554/elife.70817>.

Goymann, Wolfgang and Henrik Brumm (2018). "Let's Talk About Sex - Not Gender". In: *BioEssays* 40.5, p. 1800030. DOI: 10.1002/bies.201800030. <https://doi.org/10.1002/bies.201800030>.

Heidari, Shirin, Thomas F. Babor, Paola De Castro, et al. (2016). "Sex and Gender Equity in Research: rationale for the SAGER guidelines and recommended use". In: *Research Integrity and Peer Review* 1.1. DOI: 10.1186/s41073-016-0007-6. <https://doi.org/10.1186/s41073-016-0007-6>.

Lee, Suk Kyeong (2018). "Sex as an important biological variable in biomedical research". In: *BMB Reports* 51.4, pp. 167-173. DOI: 10.5483/bmbrep.2018.51.4.034. <https://doi.org/10.5483/bmbrep.2018.51.4.034>.

Pape, Madeleine (2021). "Co-production, multiplied: Enactments of sex as a biological variable in US biomedicine". In: *Social Studies of Science* 51.3, pp. 339-363. DOI: 10.1177/0306312720985939. <https://doi.org/10.1177/0306312720985939>.

Richardson, Sarah S. (2022). "Sex Contextualism". In: *Philosophy, Theory, and Practice in Biology* 14.0. Keywords: sex, sex essentialism, gender, preclinical research, SABV. DOI: 10.3998/ptpbio.2096. <https://doi.org/10.3998/ptpbio.2096>.

Sudai, Maayan, Alexander Borsa, Kelsey Ichikawa, et al. (2022). "Law, policy, biology, and sex: Critical issues for researchers". In: *Science* 376.6595, pp. 802-804. DOI: 10.1126/science.abo1102. <https://doi.org/10.1126/science.abo1102>.

Waltz, Margaret, Jill A. Fisher, Anne Drapkin Lyerly, et al. (2021). "Evaluating the National Institutes of Health's Sex as a Biological Variable Policy: Conflicting Accounts from the Front Lines of Animal Research". In: *Journal of Women's Health* 30.3, pp. 348-354. DOI: 10.1089/jwh.2020.8674. <https://doi.org/10.1089/jwh.2020.8674>.

Blog Posts and Additional Resources

Barr, Elizabeth and Sarah Temkin (2022). *Gender as a Social and Cultural Variable and Health*. <https://orwh.od.nih.gov/about/director/messages/gender-as-social-and-cultural-variable-and-health>.

Lauer, Mike (2015). *What Does It Mean to Consider Sex as a Relevant Biological Variable in Your NIH Grant Application?* <https://nexus.od.nih.gov/all/2015/12/11/what-does-it-mean-to-consider-sex-as-a-relevant-biological-variable-in-your-nih-grant-application/>.

National Academies of Sciences, Engineering, and Medicine (2022). *NIH Should Standardize Questions Used to Collect Sex, Gender, and Sexual Orientation Data in Studies and Surveys, Says New Report*. News release. <https://www.nationalacademies.org/news/2022/03/nih-should-standardize-questions-used-to-collect-sex-gender-and-sexual-orientation-data-in-studies-and-surveys-says-new-report>.

Rogers, Julie (2015). *Clarifications on new NIH requirement to consider sex as a biological variable*. <https://blogs.ohsu.edu/researchnews/2015/12/18/clarifications-on-new-nih-requirement-considering-sex-as-a-biological-variable/>.

Schofield, Sam (2021). This is a video from the 2021 Brain Awareness Video Contest. <https://www.brainfacts.org/brain-anatomy-and-function/anatomy/2021/sex-differences-in-the-brain-100621>.

Schubert, Kathryn G. and Margaret M. McCarthy (2021). *Biomedical Research Must Consider How Sex and Gender Influence Health*. <https://morningconsult.com/opinions/biomedical-research-must-consider-how-sex-and-gender-influence-health/>.

Scott, Stephanie F. and Michelle Benson (2018). *NIH & AHRQ: Rigor and Reproducibility Policy*. Presentation. 50 slides. Site includes links to several other resources. <https://research.columbia.edu/reproducibility-resources-and-guidelines-topic>.

Shansky, Rebecca M. (2022). *Let's Talk About Sex as a Biological Variable*. <https://www.brainfacts.org/brain-anatomy-and-function/anatomy/2022/lets-talk-about-sex-as-a-biological-variable-091222>.

Sheth, Anandi (2020). *Disseminating the Findings: Including the Discussion of SABV in Publications*. PowerPoint presentation, 26 slides. <http://score.emory.edu/documents/AnandiSheth.pptx>.

Society for Women's Health Research (SWHR) (2020). *An Official Position Statement of the Society for Women's Health Research*. https://swhr.org/swhr_resource/position-statement-inclusion-of-sex-as-a-biological-variable-in-research/.

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