

Report 46: Appropriate reporting and analysis of sex differences in environmental research

Convener: Martha Nolan

Brief History: Historical challenges to the inclusion of both sexes in research from basic to human studies. And the lack of reporting of sex in research

Discussion Highlights: Not enough is being done even now. There is a need to do a better job of analyzing – report even no difference. We know sex differences exist and are biologically significant – so how do we make single sex studies rare or require justification even in animals since anyone who tries to follow it up in the other sex hits problem of not being novel or unique.

Focus on women needs to not be so significantly on reproductive health. Expand to lung, autoimmune, cardiovascular, metabolic and other organs and systemic issues. Reproductive organs are only a part of women or men's health. Discussion brought up emphasis on toxicants and xenobiotics not just endogenous E2 and timing of exposure affects disease outcomes (fetal development).

Is regulatory science adequate to identify sex differences? Are the protocols effective? Appropriate? Out of date? Can NIEHS help to improve the quality of this work? Refine/improve the toolbox? Justify inclusion of additional animals needed?

Recommendations:

- Research should be adequately powered to detect sex differences (or justify why not) in both animal and human research. Give weight to sex difference at granting mechanism – recognizing cost factor upfront.
- Make identification/evaluation of sex differences in a study (animal and human) a valid/important specific aim for NIEHS funded research. Communicate to study sections and provide incentives.
- Get beyond reproductive organs (beyond plumbing) to other organs or systems. Include life stages such as puberty as a critical window as well as other significant age points.
- Sex differences research transcends NIEHS and should involve other institutes in a collaborative/integrated approach. NIEHS lead/encourage effort internal to NIH and externally to other regulatory agencies on addresses sex differences in environmental science.
- NIEHS should give value to studies where sex differences is an end point

Discussion Participants: Paul Howard, Mary Lee, Grace LeMasters, Edward Levin, Health Patisaul, William Schrader