

Research Ethics Digest Discussion Guide

Thank you for reading the October 2022 issue of *Research Ethics Digest*. You may use this Discussion Guide as a starting point to plan a professional development meeting for your IRB members, or to deepen your own understanding of the articles it contains.

Barbara E. Bierer, Laura G. Meloney, Strategies to optimize inclusion of women in multi-national clinical trials, *Contemporary Clinical Trials*, Volume 117, 2022, 106770, ISSN 1551-7144, <https://doi.org/10.1016/j.cct.2022.106770>.

(<https://www.sciencedirect.com/science/article/pii/S1551714422000969>)

Overview

Despite improvements over the last two decades in the inclusion of women as participants in clinical trials, women are still underrepresented in trials for some therapeutic areas that impact this population the greatest, such as cardiovascular disease. This underrepresentation affects clinical care, clinical trial study design and data analysis, and can impact overall public confidence in research. In addition to highlighting several potential root causes for underrepresentation of women in research, this article examines key elements of study design that, if examined closely and developed with inclusion and diversity in mind, may lead the way to significant scientific understanding and potent advances in clinical care.

Background and Further Reading

- Eudocia Lee, Patrick Wen, Gender and sex disparity in cancer trials, *ESMO Open*. 2020; 5(4). <https://doi.org/10.1136/esmoopen-2020-000773>.
- L. Filbey, M.S. Khan, H.G. Van Spall. Protection by inclusion: increasing enrollment of women in cardiovascular trials. *Am. Heart J. Plus* (2022), p. 100091 <https://doi.org/10.1016/j.ahjo.2022.100091>.
- Kumar A, McCullough L. Cerebrovascular disease in women. *Therapeutic Advances in Neurological Disorders*. 2021;14. doi:10.1177/1756286420985237

Discussion Questions

- The authors highlight several reasons why the representation of women in clinical trials is important, including their observation that public confidence in research depends on the ability of the public to identify with the enrolled population. Why is it important for the general public to relate to, or identify with, the enrolled population of a given study?
- In what ways are clinicians' "hands tied" when attempting to interpret data from predominantly male research subjects when diagnosing female patients?

- Why do women continue to be underrepresented in trials in certain therapeutic areas and in certain geographies? Describe the types of barriers to participation in research that women are facing. How can the IRB play a role in closing this gap?

Facilitation Tips:

- These discussion questions may be used for individuals, small groups, or in larger groups, to help actively learn the material presented in the article as well as provide a stimulus for further thinking.
- In group settings, a designated facilitator will be helpful to guide discussion. The facilitator does not need to be an expert on the topic.
- The facilitator and participants should read the article in advance.
- Begin the discussion session by introducing the participants to one another, if necessary, and sharing general thoughts about the article topic.
- The facilitator should then lead the group in considering the discussion questions. Read one question and allow quiet time for participants to think. Encourage discussion by directly asking individuals, especially quieter ones, to share their responses. In large groups it can be helpful to break into smaller groups or pairs, which then share their thoughts.
- The facilitator should be an active listener, restating a comment or question for the group if clarification is needed. They can help the group to stay on topic and encourage further discussion by asking probing or follow-up questions. “Does everyone agree with that?”, “I heard Jane say [this]. Does anyone want to suggest an alternative?”, and “What other possibilities can we consider?”, are all good questions to ask.
- The facilitator can summarize the discussion occasionally or ask a participant to synthesize what they’ve heard. This is particularly useful to wrap up the discussion at the end.