

Factors That Dissuade Sponsors and Investigators from Including Pregnant and Lactating Women in Research

The exclusion of pregnant and lactating women from clinical research is often attributed to legal liability. However, available evidence demonstrates that such liability is limited, suggesting that perceptions of liability may be more influential than real liability. Six additional dissuasive factors face individuals and organizations involved in the development, testing, oversight, approval, and marketing of medications and vaccines. These factors are sometimes termed liabilities even though they involve no legal risk because they are considered in the aggregate along with real and perceived liability. Many of the factors overlap, interact with, and affect one another; thus, mitigation strategies must take the relationships into account.



A CULTURE OF EXCLUSION

systematic underfunding of women's health research



CHALLENGES WITH RECRUITMENT AND ENROLLMENT

inadequate resources for investigators and research participants to recruit or enroll in studies



LACK OF RESEARCH EXPERTISE

limited number of trained investigators with expertise conducting research with pregnant and lactating women



REPUTATIONAL RISK

concerns for negative publicity



COST AND COMPLEXITY

unwillingness to invest time and resources to properly conduct studies with pregnant and lactating women



LACK OF FINANCIAL INCENTIVES

insufficient financial return on investment for additional research