

Pregnant women may participate in clinical research where the "purpose of the activity is to meet the health needs of the mother" regardless of the degree of risk to the fetus and offspring. If the purpose of the research is not to meet her health needs, she may participate only if "the risk to the fetus is minimal." The main problem concerns the broad phrase "health needs of the mother." Consider an established treatment for a disease or condition that is safe and effective for women whenever it is given, but also has a very high risk of affecting future offspring if given during pregnancy. Ethical judgment of whether the woman should be able to have the treatment during pregnancy will depend not merely on whether the treatment will affect her "health," but also on the burdens and benefits to her of having treatment during pregnancy or after. The type of benefit to her alone is not determinative, but the magnitude is. The more minor the benefits the less discretion the woman should have to accept treatment, if there is any risk beyond minimal to offspring. Such a standard requires weighing the importance to the woman of the health need in question versus the risk to offspring.