

Questions to Address

- What are the country-specific regulations and guidelines that must be considered in discussions about pregnant women as research participants? Are there other laws (other than those governing research) that must also be considered?
- What role, if any, do international guidelines (e.g., CIOMS) and/or regulations (including U.S.) have in your deliberations?
- What has been your experience with previous trials involving pregnant women? How did you think about questions regarding the risks and benefits?
- What do you see as the most significant ethical concerns about or barriers to conducting an intervention trial with pregnant women? Are there particular areas of confusion or conflict for Ethics Committees and Institutional Review Boards?