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FDA Draft Guidance for Pregnant Women: Scientific and Ethical Considerations for Inclusion in Clinical Trials
https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM603873.pdf

This draft guidance addresses the complex ethical issue of balancing maternal and fetal safety with need for clinical trial data on chronic disease or acute illness during pregnancy. FDA recommends and UK applies Subpart B protections and requirements for research in pregnant women. The investigator addresses the Subpart B protections in the IRB application.

The draft guidance also provides the following guidelines for sponsors (or investigators) in designing trials that minimize risks:

For Postmarketing (FDA-approved drugs):

- Adequate nonclinical studies (including studies on pregnant animals) have been completed and
- There is an established safety database in nonpregnant women from clinical trials or preliminary safety data from the medical literature and/or other sources regarding use in pregnant women and one of the following:
  - Efficacy cannot be extrapolated and/or
  - Safety cannot be assessed by other study methods

For Premarketing studies (i.e., investigational drugs):

- Adequate nonclinical studies (including studies on pregnant animals) have been completed and
- The clinical trial holds out the prospect of direct benefit to the pregnant woman and/or fetus that is not otherwise available outside the research setting or cannot be obtained by any other means (e.g., the pregnant woman may not have responded to other approved treatments or there may not be any treatment options)