PRGLAC
Summary of Responses to the Request for Information

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Request for Information

NOT-18-003

- Published February 15, 2018
- Comment period closed April 2, 2018

- 34 independent responses received
- Half represented multiple individuals or organizations
- Eight comments identical

Input Requested On…

- Pregnant women as a “vulnerable population” in regulations
- Who should consent to participation in research
- Inclusion of pregnant and lactating women in study designs
- Research on therapies used by pregnant and lactating women
- How to address reluctance to include pregnant or lactating women in research studies
- How to reach these populations, their partners, and health care providers with new information/clinical guidelines

Key Themes

- Study Design for Research on Therapies Used by Pregnant or Lactating Women
- Ethical Issues
- Issues Concerning Research on Lactation
- Communications Among Researchers, Health Care Providers, and Pregnant/Lactating Women
- Additional Issues

Study Design

- Adequate risk assessment prior to clinical research:
  - Pregnancy registries should be created/utilized
  - Predictive animal models developed
  - Breast milk repositories
  - Mathematical modeling
- Pharmacokinetic studies to confirm optimal dosing
- Presumption of exclusion should shift to inclusion
- Take advantage of opportunistic studies: gather data on pregnant and lactating women who are already taking drugs for their conditions
- Use existing studies as potential models (IMPAACT, VAMPSS)

Study Design:
other suggestions

- Engage target populations in study design
- Bring trials to the participants (home health nurses)
- Incentives: childcare, transportation, prenatal vitamins, genetic testing and counseling
- Consider trimester-specific enrollment to measure physiologic changes
- Measure drug or metabolite in breast milk to determine infant exposure
- Post-market surveillance on drugs used and data sharing

Ethical Issues

- ~~Vulnerable~~ population
- Shift presumption to inclusion
- No greater than “minimal risk”
- Maternal consent only for research participation

Issues Related to Lactation

- Research needed on maternal milk supply/treatment of inadequate production
- Milk composition in minority populations

Communications Issues

- Telling pregnant and lactating women about the value of research/risks and benefits
- Professional societies and organizations - CMEs
- Strategies:
  - Websites and social media
  - Lactation consultants in hospitals
  - Support groups

Additional Issues Raised

- Study herbal supplements used by pregnant and lactating women
- Additional treatments needed for postpartum pain and mental health issues
- Alternative therapies evaluated in scientific manner
- Consider using BPCA/PREA model for drugs used by pregnant and lactating women; other incentives for research
- Research on underlying conditions: CAH, PCOS, diabetes, optimal weight gain

Summary

Most Common Comments

- Remove pregnant women from “vulnerable” category and shift to a presumption of inclusion in research
- Only consent of pregnant woman should be required for research participation
- Opportunistic studies of drugs used by pregnant/lactating women
- Little to no research on inadequate milk supply or treatment
- Research needed on safety/efficacy of herbal supplements
- Communicate with pregnant and lactating women about research

Thanks!

- To all respondents

Questions and Discussion