

Human Subjects Research Regulation Perspective

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Stated Institutional Commitment to Research on Pregnant People



- > UW Human Subjects Division Standard Operating Procedures
 - “supports the policy of providing pregnant [people] with the same opportunities as nonpregnant [people] to participate in research unless the individual meets exclusionary criteria or the study poses more than minimal risk to the fetus”

Institutional Promotion of Regulatory Clarity and Consistency that Acknowledges the “Flexibility” of Subpart B

- > Web-based standard operating procedures (SOPs) and Worksheets accessible to *all*
- > Training on regulatory definitions and interpretations of “risk” for IRB staff and committee members
- > IRB staff accessibility pre-submission and during trial

A Unique Feature of the University of Washington

- > UW Human Subjects Assistance Program
 - Institutional injury compensation program offering medical and other assistance for injuries “more likely than not caused by UW-conducted research”

“The traditional narrative of ‘why we cannot’ must shift to ‘how we can’”



The Pathway Forward:
*Insights on Factors that Facilitate Research
with Pregnant Women*

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*“[W]hat I say all the time is
that...the regulations have a
path for this, let’s walk
down that path”
(NonInvestigator 4)*