UTSouthwestern Medical Center

Human Research Protection Program

MEMORANDUM

DATE: December 16, 2019

TO: Researchers Utilizing UT Southwestern Institutional Review Boards

FROM: Rhonda Oilepo, MS, CIP, CHRC
Director, Human Research Protection Program
UT Southwestern Medical Center

RE: UTSW HRPP Policy on IRB Review of Pregnant Partners

Effective December 16, 2019, the University of Texas Southwestern Human Research Protection Program (HRPP) policy on the collection of outcome data about pregnant partners of study subjects has changed. The HRPP policy is that the collection of outcome data does not meet the definition of research (45 CFR 46.102) because it is not a systematic investigation designed to develop or contribute to generalizable knowledge. Accordingly, the UTSW Institutional Review Boards (IRBs) will no longer consider pregnant partners or their children to be research subjects and will not make regulatory determinations as such.

Informed consent documents may continue to inform subjects of the plan to collect data if their partner becomes pregnant. If a pregnant partner consent document is submitted to the IRB, the IRB will review and approve inclusion of pregnant women and/or their children as research subjects and will require all regulatory requirements to be met (i.e., appropriate inclusion/exclusion criteria, identification, recruitment and consenting plans must be established, and Forms K and O1 must be completed) for the IRB to make appropriate determinations.

This policy does not affect subjects who become pregnant while enrolled on a research study. These individuals are enrolled as human subjects on research studies and collection of outcome data represents research activities. The collection of outcome data must be described in the consent document and the IRB will make regulatory determinations for involvement of pregnant women and/or their children as appropriate.