Introducing e-consents in a clinical setting

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Keywords: Electronic consent, preeclampsia

Preeclampsia (PE) is a multiorgan hypertensive-disorder in pregnancy that causes significant maternal-fetal mortality and morbidity. The diagnostics and therapeutics for PE are limited due to its unclear etiology. Using the UI Maternal Fetal Tissue Bank, our lab has demonstrated that copeptin is robustly predictive of PE. To investigate copeptin further, we developed the Rule Out Pre-Eclampsia Study (ROPE). The ROPE study recruits women admitted to Labor and Delivery for evaluation of PE. Women are admitted for PE evaluation at all hours. Research team members are not available at all times to obtain consent which limits recruitment. Our project aimed to develop an electronic informed consent (e-IC) that is compliant with the Federal Regulation for Human Research Protection and is easy to use and readily understood by study participants. After obtaining IRB approval, simulated patients were given an iPad on which to read and evaluate the e-IC using a validated questionnaire, the Quality of Informed Consent (QuIC). Based on the QuIC, the e-IC was modified and re-tested. Participants demonstrated good comprehension of the e-IC as evidence by QuIC scores ranging from 61 to 96. Based on our results, the e-IC is an effective and efficient method for the Informed Consent process.

Presented at “Complicated Maternal Fetal Medicine Cases,” the University of

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