PDG Test Strip Interpretation

The manufacturer of the PDG strips was made aware of the comments concerning the residual faint line detected by 50% of participants during the pilot study. Action was taken and the test strips re-formulated following the pilot. A larger study will need to monitor participant feedback in a timelier manner and have a clear process in place for participants to use when unsure of how to interpret strip results. The process should consider the need for daily photo logs of strip results, online high quality photo / video examples in addition to paper references for participant to use as aids in strip interpretation, instructions on when to repeat testing, when to contact research staff, and documentation.

Online Diary and Instructions

An online diary system for participants who have access to computer or cell phone technology would help ensure the completion and accuracy of diaries in a timelier manner and eliminate the need for all data entry to be completed at the end of the participant's involvement in the study, which occurred in the pilot study. Supply inventory and the documentation of faulty strips could be easily recorded allowing for research staff to easily monitoring study supply needs and manufacturing issues. Day to day diary compliance monitoring would assist research staff in identifying participants who might need additional encouragement and would help staff with contact schedules and logistics. Providing additional space on the diary to allow participants to record extra details that they feel was relevant to the study was feedback received from the pilot study.

The Addition of Vaginal Ultrasound

It was clear from participant feedback received at the end of the pilot study that the inclusion of vaginal ultrasound would deter some people from participating in a larger study. Logistic of adding another procedure to the study protocol schedule and the anxiety concerning the invasive nature of the procedure were the primary reasons given for not participating. To combat this, study staff would need to be educated on the procedure and be able to answer questions and alleviate fears and anxiety utilizing videos and photographs as educational aids. Logistics around scheduling will need to be flexibility, with adequate compensation provided to cover parking, mileage and travel time costs. Close collaboration with a provider of this procedure would be essential. Participants would need to be assured that only one ultrasound would be required and that the timing would be based on serum progesterone confirmation of ovulation.