



DATE: April 4, 2022

TO: Megan Brenner, MD MS

FROM: RUHS-MC Institutional Review Board

RE: Research Study Not Subject to Continuing Review

Title of Study: Prophylactic and Resuscitative Endovascular balloon in Gynecology & Obstetrics (PREGO) Trial
IRBNet #: 1506524-3

Dear Dr. Brenner:

This is to document that on October 1, 2021, the Riverside University Health System – Medical Center (RUHS-MC) Institutional Review Board (IRB) converted the above-entitled study to adhere to the 2018 Requirements of Subpart A of 45 CFR Part 46. Specifically, §46.101(l)(4)(ii) states that “If the determination to transition is documented on or after January 21, 2019, the research shall, beginning on the date of such documentation, comply with the 2018 Requirements.” Moreover, §46.109 (f)(1) states that “Unless an IRB determines otherwise, continuing review of research is not required in the following circumstances: (i) Research eligible for expedited review in accordance with §46.110.”

Accordingly, since the RUHS-MC IRB has converted the research to adhere to 2018 Requirements of 45 CFR Part 46, and the research is eligible for expedited review, continuing review is no longer required for this study.

In lieu of a formal continuing review, the RUHS-MC IRB will conduct an “administrative check-in” to determine if the research is complete or ongoing; this is for recording-keeping purposes. The date of the next check-in is October 30, 2022 to coincide with the previous expiration date anniversary.

Please contact the IRB Office at 951-486-4098 if you need any additional information.

Sincerely,

Glen Moulton, MPH MA(Ed) CIP® CCRP®

Manager, Institutional Review Board

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