Institutional Review Board
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DATE:	November 18, 2022
TO:	Emily Oken, MD, MPH
FROM:	Harvard Pilgrim Health Care Institutional Review Board
STUDY TITLE:	[1830598-28] Project Viva Women's Health: A longitudinal study of women's health
IRB REFERENCE #:	1830598
SUBMISSION TYPE:	Continuing Review/Progress Report
ACTION:	APPROVED
APPROVAL DATE:	November 17, 2022
EXPIRATION DATE:	November 17, 2023
REVIEW TYPE:	Full Committee Review

Thank you for your submission of Continuing Review/Progress Report materials for this research study. The Harvard Pilgrim Health Care IRB has APPROVED your submission.

This submission has received Full Committee Review based on the applicable federal regulation. Federal regulations require that certain research be reviewed at least annually. Based on the level of risk, this project requires continuing review on *an annual basis*. Please use the appropriate renewal forms for this procedure.

The IRB specifically considered (i) the risks and anticipated benefits, if any, to subjects; (ii) the selection of subjects; (iii) the procedures for securing and documenting informed consent;(iv) the safety of subjects; and (v) the privacy of subjects and confidentiality of the data. All research must be conducted in accordance with this approved submission.

Please note that any revision to previously approved materials, including adding/removing any data fields for analysis, must be approved by this office prior to initiation using the appropriate revision forms for this procedure. Only IRB approved consent forms, questionnaires, letters, advertisements, etc. may be used in your research.

Unanticipated events/problems involving risks to subjects or others and SERIOUS and UNEXPECTED adverse event(s) that occur during the course of this project must be reported in accordance with the IRB policy. Please use the appropriate event reporting forms for these procedures. All FDA and sponsor reporting requirements should also be followed. All NON-COMPLIANCE issues or COMPLAINTS regarding to this study must also be reported to the IRB.

Please retain this letter with your research records. Research records include all Institutional Review Board submissions and responses and must be kept in the principal investigator's file for a minimum of three (3) years after completion of the study. If you have questions, please contact Paula Tebeau at 617 867-4587 or Paula_Tebeau@hphc.org.