

Attachments:

- Expedited Review Approved: IRB #612MPR19.pdf



Expedited Review Approved: IRB #612MPR19

To: Katie Morrison Lee
Institution: Mathematica
From: HML IRB
Subject: Study #612MPR19
Date: 05/26/2022

Dear Katie Morrison Lee,

The protocol **Well-Integrated Screening and Evaluation for Women Across the Nation (WISEWOMAN), 612MPR19** was assessed through an expedited research ethics review by HML Institutional Review Board. This study's human subjects' protection protocols, as stated in the materials submitted, received research ethics review approval on 05/26/2022 in accordance with the requirements of the US Code of Federal Regulations for the Protection of Human Subjects (45CFR46 & 45CFR46.110) and were expedited by (6) Collection of data from voice, video, digital, or image recordings made for research purposes (7) Research on individual or group characteristics or behavior.

You may rely on this IRB for review and continuing ethical oversight of this study. You and your project staff remain responsible for ensuring compliance with HML IRB's determinations. Those responsibilities include, but are not limited to: 1) ensuring prompt reporting to HML IRB of proposed changes in this study's design, subject risks, informed consent, or other human protection protocols; 2) investigators will conduct the research activity in accordance with the terms of the IRB approval until any proposed changes have been reviewed and approved by the IRB, except when necessary to mitigate hazards to subjects; 3) and to promptly report any unanticipated problems involving risks to subjects or others in the course of this study.

The approval of your study is valid through 06/01/2023, by which time you must submit an annual check-in report either closing the study or requesting permission to continue for another year. Please submit your report by **05/18/2023** so that the IRB has time to review and approve your report prior to the expiration date. For instructions on how to manage an approved study refer to: [How to Manage an Approved Study](#).

HML IRB is authorized by the U.S. Department of Health and Human Services, Office of Human Research Protections (IRB #00001211, IORG #0000850), and has DHHS Federal-Wide Assurance approval (FWA #00001102).

If you have any questions, please contact us at admin@hmlirb.com.

Sincerely,

A handwritten signature in black ink, appearing to read "D. Anderson".

D. Michael Anderson PhD, MPH
IRB Chair & Human Research Protections Director
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