Institutional Review Board (IRB)/Independent Ethics Committee (IEC) Authorization Agreement

Name of Institution or Organization Providing IRB Review (Institution/Organization A):
FWA #: __00003616_____
Philadelphia Department of Public Health
IRB Office, Health Center #5
1900 N. 20th Street, Philadelphia, PA 19121
Phone: 215-685-0869 Fax: 215-685-0867

Name of Institution Relying on the Designated IRB (Institution B):
University of Delaware

IRB Registration #: 00000472 Federalwide Assurance (FWA) #, if any: 00004379
Address: 210 Hullihen HallNewark, DE 19716-1551
Phone:_ (302) 831-2137 Fax: 302-831-2828

The Officials signing below agree that University of Delaware (Institution B) may rely on the designated IRB for review and continuing oversight of its human subjects research described below: (*check one*)

(___) This agreement applies to all human subjects research covered by Institution B's FWA.

(__X_) This agreement is limited to the following specific protocol(s):

Name of Research Project: Mothers Support and Health in Pregnancy and Parenting (MotherSHIPP)
Name of Principal Investigator:_ Katy Kaplan, M.S. Ed, PhD,
Sponsor or Funding Agency: DHHS Women's Health Award Number: ASTWH220105-01

(___) Other (*describe*):_____

The review performed by the designated IRB will meet the human subject protection requirements of University of Delaware (Institution B)'s OHRP-approved FWA. The IRB at Institution/Organization A will follow written procedures for reporting its findings and actions to appropriate officials at Institution B. Relevant minutes of IRB meetings will be made available to Institution B upon request. Institution B remains responsible for ensuring compliance with the IRB's determinations and with the Terms of its OHRP-approved FWA. This document must be kept on file by both parties and provided to OHRP upon request.

NOTIFICATION REQUIREMENTS
University of Delaware (Institution B) shall promptly disclose to Philadelphia Department of Public Health IRB Office (Institution A) all information pertinent to the terms of the Agreement and the obligations of the disclosing party hereunder. Without limiting the generality of the foregoing, University of Delaware (Institution B) shall agree to notify Philadelphia Department of Public Health IRB Office (Institution A) of all communications to and from the FDA, Office of Human Research Protection (OHRP) and other applicable federal and state regulatory agencies regarding the research activities to which this Agreement applies and related IRB matters, including communication concerning investigators who have research activities governed by this agreement. Institution B further agrees to promptly notify the Philadelphia Department of Public Health IRB Office in writing, fax or email any below activities to which this Agreement applies:

1. Any unanticipated problems involving risks to subjects or others;
2. Any serious or continuing noncompliance with 45 CFR Part 46
3. Any suspension or terminations of the research by the sponsor; and
4. Any reports that require forwarding to OHRP, FDA or and Department or Agency Head.

Signature of Signatory Official (Institution/Organization A):

Frank Franklin (Jul 29, 2024 12:53 EDT) Date: Jul 29, 2024

Print Full Name: Frank Franklin Institutional Title: Health Commissioner/IRB Chair

Signature of Signatory Official (Institution B):

Date: July 24, 2024

Print Full Name*: Sean P. Hayes*

Institutional Title*: Interim Associate Vice President for Research & Regulatory Affairs*

2024-25 Reliance Form UDE upong PDPH - unsigned

Final Audit Report 2024-07-29

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