OMB No. 0990-0263
Approved for use through 5/6/2021

Protection of Human Subjects
Assurance Identification/IRB Certification/Declaration of Exemption
(Common Rule)

Policy: Research activities involving human subjects may not be conducted or supported by the Departments and Agencies adopting the Common Rule (56FR28003, June 18, 1991) unless the activities are exempt from or approved in accordance with the Common Rule. See section 101(b) of the Common Rule for exemptions. Institutions submitting applications or proposals for support must submit certification of appropriate Institutional Review Board (IRB) review and approval to the Department or Agency in accordance with the Common Rule. Institutions must have an assurance of compliance that applies to the research to be conducted and should submit certification of IRB review and approval with each application or proposal unless otherwise advised by the Department or Agency.

1. Request Type	2. Type of Mechanism	3. Name of Federal Department or Agency and, if known, Application or Proposal Identification No.
[X] ORIGINAL [ ] CONTINUATION [ ] EXEMPTION	[X] GRANT [ ] CONTRACT [ ] FELLOWSHIP [ ] COOPERATIVE AGREEMENT [ ] OTHER: In House	Office on Women's Health, United States Department of Health and Human Services ASTWH220105-01
4. Title of Application or Activity 2024-25 Mothers' Support and Health in Pregnancy and Parenting (MotherSHIPP)		5. Name of Principal Investigator, Program Director, Fellow, or Other Katy Kaplan, MSEd, PhD (Univ of DE)

6. Assurance Status of this Project *(Respond to one of the following)*

[X] This Assurance, on file with Department of Health and Human Services, covers this activity:
Assurance Identification No. FWA00003616, the expiration date 6/7/2028 IRB Registration No. _IRB00000032_____

[ ] This Assurance, on file with *(agency/dept)*_____, covers this activity.
Assurance No._____, the expiration date_____ IRB Registration/Identification No._____*(if applicable)*

[ ] No assurance has been filed for this institution. This institution declares that it will provide an Assurance and Certification of IRB review and approval upon request.

[ ] Exemption Status: Human subjects are involved, but this activity qualifies for exemption under Section 101(b), paragraph_____.

7. Certification of IRB Review (Respond to one of the following IF you have an Assurance on file)

[X] This activity has been reviewed and approved by the IRB in accordance with the Common Rule and any other governing regulations.
by: [X] Full IRB Review on 4/2/24 and/or [X] Expedited Review on 7/8/24
[ ] If less than one year approval, provide expiration date _____

[ ] This activity contains multiple projects, some of which have not been reviewed. The IRB has granted approval on condition that all projects covered by the Common Rule will be reviewed and approved before they are initiated and that appropriate further certification will be submitted.

8. Comments
N/A

9. The official signing below certifies that the information provided above is correct and that, as required, future reviews will be performed until study closure and certification will be provided.	10. Name and Address of Institution Philadelphia Department of Public Health 1101 Market Street, Suite 1320 Philadelphia, PA 19107
11. Phone No. *(with area code)* 12. Fax No. *(with area code)* 13. Email: Frank.Franklin@Phila.Gov	
14. Name of Official Frank A. Franklin, PhD, JD, MPH	15. Title Deputy Health Commissioner/Chairperson
16. Signature Frank Franklin (Jul 16, 2024 12:40 EDT)	17. Date Jul 16, 2024

Executive Summary

Description of intent and methodology of study

The purpose of this study is to create stronger supports for pregnant and postpartum women with substance use disorders (SUD) and mental health conditions. The goals of Mothers' Support and Health in Pregnancy and Parenting (MotherSHIPP) Study are to:

1. Test the effectiveness of the MotherSHIPP app designed for Apple and Android devices that provides mobile education on pregnancy, postpartum, parenting, and substance use and mental health recovery. Use of the MotherSHIPP app will be paired with access to a Recovery Advocate who is a mother with lived experience with SUD who will provide virtual peer support through individual and group sessions.
2. Examine if the use of the MotherSHIPP app with peer support improves health outcomes for pregnant and parenting people with SUD and mental health conditions.

Description of Philadelphia Department of Public Health, Department of Behavioral Health or other City Department involvement

The MotherSHIPP Grant was awarded to the City of Philadelphia's Department of Behavioral Health and disAbility Services (DBHIDS) as a pass through to Community Behavioral Health (CBH). CBH is contracted by DBHIDS as the Medicaid Behavioral Health Managed Care Organization in Philadelphia County. The Principal Investigator for the study has transitioned from a position at CBH to the University of Delaware, where she continues as PI for this study.

Participants will be referred to the study using CBH's Clinical Based Care Management (CBCM) program which operates in several obstetrics/gynecology clinics through Philadelphia County. However, any Medicaid-eligible person that meets the eligibility criteria for the study can participate. Information about the MotherSHIPP Study will be disseminated through the networks of providers and programs that support individuals with behavioral health conditions and/or during the pregnancy and postpartum time frame.

Duration of study:

The duration of the study varies based on gestational age at enrollment for each participant. Since participants can enroll between 13 weeks of pregnancy through 2 weeks postpartum, the length of time in the study could be as long as 10 months, or as short as 3 months if enrolled within 2 weeks postpartum.

Risks to subjects:

Risks associated with this study are minimal. Breach of confidentiality is a risk; however, all possible steps will be taken to protect private identifiable information and restrict access to only authorized study team members. The questionnaire asks about topics that may be distressing or triggering. We have attempted to minimize this risk by detailing what topics will be covered before participants begin the questionnaire. Participants do not have to answer a question if they

don’t want to, or they can discontinue their participation in the study at any time. If the subject appears to need crisis assistance, suicide or domestic violence, researchers will provide national hotline numbers. After the interview, the research assistant would get in touch with the Principal Investigator to see if further action.

Numbers of participants: We plan to enroll 120 pregnant/postpartum women, over the age of 18, during a 9–12-month period.

Contact information for Principal Investigator

Name: Katy Kaplan, M.S. Ed, PhD
Department/Center: Center for Community Research/Service
Contact Phone Number: 302-831-0362
Email Address: katykap@udel.edu

Other Investigators:

Name: Sara L. Kornfield, Ph.D.
Department/Center: University of Pennsylvania, Center for Women's Behavioral Wellness
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2024-25 Certification Form UNSIGNED 070924

Final Audit Report 2024-07-16

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