HARVARD
Human Research Protection Program

Harvard T.H. Chan School of Public Health
Office of Regulatory Affairs and Research Compliance
90 Smith Street, 3rd Floor
Boston, MA 02120
Federalwide Assurance FWA00002642

Notification of Initial Study Approval

June 8, 2020

Sonia Hernandez-Diaz
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Protocol Title:	INTERNATIONAL REGISTRY OF CORONAVIRUS EXPOSURE IN PREGNANCY (IRCEP)
Principal Investigator:	Sonia Hernandez-Diaz
Protocol #:	IRB20-0622
Funding Source:	None
Review Date:	6/8/2020
STUDY Effective Date:	6/8/2020
IRB Review Type:	Expedited
IRB Review Action:	Approved

The Institutional Review Board (IRB) of the Harvard T.H. Chan School of Public Health approved this Initial Study. This approval does not expire and you will not be required to submit an annual renewal application. However, you are responsible for submitting the following to the IRB, as applicable. Any change or update to the research must be submitted in ESTR via a Modification. Once the study is eligible for closure, a closure request must be submitted in ESTR via the Close Study activity. All reports of new information must be submitted in ESTR via the Report New Information activity. If you are unsure what to submit, contact the Harvard T.H. Chan School of Public Health IRB office for further assistance.

This approval includes the following:

- Initial Application, IRB20-0622
- IRB Protocol: IRCEP_Protocol_IRB (v2)
- Consent Form: IRCEP_consent (v5)
- Recruitment Materials: Advertisement_pictures (v1)
- Recruitment Materials: Advertisement (v1)
- Study Personnel Information: Non-Harvard-Investigator
- Study Personnel Information: IIA_IRCEP
- Study Instrument/Tools: Screening Tool (questions) (v1)
- Study Instrument/Tools: Online_questions (v1)

Additionally, the IRB has reviewed the following documents:

- Ancillary Approvals/Permissions: IRCEP_LOS_Pregistry (v1)
- Other: IRCEP_Security (v1)

The IRB is in receipt of the following:

- Foreign Language Documents:

Consent_Korean (v2)
Consent_Portuguese (v2)
Consent_Russian (v2)
Consent_Arabic (v2)
Consent_Chinese (v2)
Consent_Spanish (v2)
Consent_French (v2)
Consent_German (v2)
Consent_Italian (v2)

The IRB made the following determinations:

- Special Populations: This research meets the criteria for the inclusion of pregnant women, neonates, and/or fetuses as set forth at Subpart B of 45 CFR 46.
- Risk Determination: No greater than minimal risk
- Research Information Security Level (based on Harvard Research Data Security Policy): 4

The IRB requests the following:

- The IRB understands you will add a component to this study that will trigger the European Union (EU) General Data Protection Regulation (GDPR). Harvard investigators obtaining information protected by the EU GDPR must be in compliance with this regulation prior to receipt of data/specimens from the EEA. As a result, when you are ready, please submit a Modification to add this component to the study. Instructions can be found here: https://estrsupport.fss.harvard.edu/mod-smartform

Please contact your IRB Review Specialist, Keren-Nicole Insalaco, at (617) 432-5132 or kninsala@hsph.harvard.edu with any questions.

Sincerely,

Kimberley Serpico

Kimberley Serpico, MEd, CIP
Associate Director of IRB Operations