



HARVARD

Human Research Protection Program

Harvard T.H. Chan School of Public Health
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Notification of Modification / Update Approval

June 16, 2020

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Protocol Title: INTERNATIONAL REGISTRY OF CORONAVIRUS EXPOSURE
IN PREGNANCY (IRCEP)
Principal Investigator: Sonia Hernandez-Diaz
Protocol #: IRB20-0622
Submission #: MOD20-0622-01
Funding Source: None
Review Date: 6/16/2020
MOD Effective Date: 6/16/2020
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 Modification / Update.

This approval includes the following:

- Modifications as described in MOD20-0622-01
 - Revised Research Protocol – To reflect that the study have been extended to EU participants.
 - Additional Study Materials – A copy of the GDPR consent supplement (to be provided to EU participants in addition to the standard consent form) have been uploaded to the ESTR record.
- IRB Protocol: GDPR_IRCEP_Protocol (v2)
- Consent Form: GDPR_consent (v1)

Please contact me at (617) 432-5132 or kninsala@hsph.harvard.edu with any questions.

Sincerely,

Keren-Nicole Insalaco
Sr. IRB Review Specialist