



Health Center Institutional Review Board
FWA00005790

PO Box 100173
Gainesville FL 32610-0173
Telephone: (352) 273-9600
Facsimile: (352) 273-9614
Email: irb@ufl.edu

DATE: 3/23/2020
TO: Mark Hudak
Pediatrics, 653-1 W 8TH ST, LRC 3RD FLOOR
JACKSONVILLE, Florida 32209
FROM: Peter Iafrate, IRB Chairman, University of Florida
Chair IRB-01

IRB#: **IRB202000804**

TITLE: National Registry for Surveillance and Epidemiology of Perinatal COVID-19 Infection

Approved as Expedited

Expires on: 3/23/2023

You have received IRB approval to conduct the above-listed research project. Approval of this project was granted on 3/23/2020 by IRB-01. This study is approved as expedited because it poses minimal risk and is approved under the following expedited category/categories:

5. Research involving materials (data, documents, records or specimens) that have been collected or will be collected solely for non-research purposes (such as medical treatment or diagnosis). Note: Some research in this category may be exempt from the regulations for the protection of human subjects as noted in 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.

Approval Includes, but is not limited to

Consent Waiver Type(s):

Full Waiver of Informed Consent

Subjects will not be informed nor will consent be sought or obtained prior to their involvement in the research (including collection of data from identifiable records or tissue)

HIPAA Waiver Type(s):

Not Applicable - No PHI collected in bank

Special notes to Investigator (if applicable):

Please note the first summary report must be submitted to the IRB prior to releasing it to the participating sites, and no report can be generated until there are at least 25 people enrolled.

Principal Investigator Responsibilities:

The PI is responsible for the conduct of the study. Please review these responsibilities described at: <http://irb.ufl.edu/irb01/researcher-information/researcherresponsibilities.html>

Important responsibilities described at the above link include:

- Using currently approved consent form to enroll subjects (if applicable)
- Renewing your study before expiration
- Obtaining approval for revisions before implementation
- Reporting Adverse Events
- Retention of Research Records
- Obtaining approval to conduct research at the VA
- Notifying other parties about this project's approval status

Study Team:

Amanda	Herndon	Other
Kimberly	Barnette	Study Coordinator

The Foundation for The Gator Nation

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