Abstract and Background:

Pregnant women are at risk for COVID-19 infection during the current pandemic. To date, information about the different routes (transplacental, perinatal, and postnatal) and risks of transmission of this disease to newborn infants is anecdotal and not population-based. Given that SARS-COVID-2 is a respiratory virus, the risk of transplacental transmission is presumed to be very low to absent. The risk of perinatal transmission is unknown. The risk of postnatal transmission is likely to be very high if the newborn is not immediately separated from the mother, and the severity of postnatally acquired disease in the newborn is unknown.

This National Registry represents a collaboration between the American Academy of Pediatrics Section on Neonatal-Perinatal Medicine, the Vermont-Oxford Network (VON), and MedNAX (an organization of private neonatologists). It has been informed by discussion with neonatology experts at these organizations, by Dr. Karen Puopolo at the University of Pennsylvania, and by international neonatologists who are organizing similar efforts in their countries through their neonatal networks. To date, the National Registry has enrolled mother/infant dyads in which a maternal biologic specimen obtained in the interval from 14 days through 3 days after delivery test positive for SARS-CoV-2. The case report forms for these dyads have collected de-identified data on infection control practices, virological testing, maternal and infant clinical signs and symptoms, disease severity, modalities of treatment, use of breast milk, and maternal and infant outcomes. We disseminate the findings of this registry on a weekly basis to the neonatal care community. These findings are informing the community about the likelihood of perinatal transmission and the severity of disease in the newborn.

Three months since detection of the first cases of COVID-19 infection in the United States, there are increasing numbers of pregnant women who resolved a COVID-19 infection during their current pregnancy. It is also important to learn if the infants of these women are at risk for morbidity due to primary or secondary effect of SARS-CoV-2, specifically, increased risk of preterm birth, poor fetal growth, congenital anomalies, or transplacental infection.

The National Registry will offer current (n=127 as of 5/8/2020) and future (likely n > 50) participating hospitals the option to add this second set of mother/infant dyads to the registry. It is anticipated that participating hospitals may treat this as a protocol modification under the existing approval or require a new submission entirely.

Participating centers will submit only de-identified data on mother/infant dyads eligible under this addendum. Data fields will include a subset of the fields in the first proposal with the addition of data elements that will address the four questions posed above. The burden of data abstraction will be substantially less than with mother/infant dyads where the mother has active
perinatal infection with COVID-19. Data for mother/infant dyads eligible in the protocol addendum will be stored in a separate secure REDCap database.

Specific Aims:

To provide real-time cumulative information on a weekly basis concerning:

(1) The number of cases of resolved COVID-19 infection among mothers who deliver at participating hospital;

(2) The rate of preterm birth among these mothers;

(3) The distribution of weight, length, and head circumference z-scores (a function of gestational age) to provide insight about whether COVID-19 infection earlier in pregnancy influences fetal growth;

(4) The distribution of congenital anomalies identified during the initial birth hospitalization to determine whether maternal infection in the first trimester increases the likelihood of malformations;

(5) The results of any antibody testing on cord blood that might provide insight into whether fetuses are at risk for transplacental infection.

Research Plan:

The National Registry is a non-interventional study that seeks to compile de-identified data from volunteering participating sites. Data will be stored on a server at the University of Florida and protected by internal procedures. Local investigators will have “write-only” access to the databank. Cumulative descriptive data summaries will be provided to participating hospitals on a weekly basis.

There is no DSMB for this registry study.

Risks and Discomforts: Not applicable; this study involves no patient interventions.

Possible Benefits:

It is anticipated that enrollment of a large number of mother/infant dyads through 3/31/21 will provide sufficient information to inform the four outcome questions.

Conflict of Interest:

The PI has no conflicts of interest to declare.