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| Description: IRB | **Confidentiality Agreement for Coded Biologic Specimens and/or Data** |

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| Please provide contact information for a representative who can answer any questions that the IRB might have concerning this submission:  This box is for IRB use ONLY.   |  |  | | --- | --- | |  |  | | |
| Name: |  |
| Position: |  |
| E-mail: |  |
| Phone #: |  |
| Pager #: |  |
| 2nd Contact: | name + e-mail or phone # |
| Group: |  |

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| Form Instructions:   * Submit the signed form as part of your myIRB submission to the IRB office. You must include copies of all paperwork including any relevant IRB approvals or consent forms. * Submissions that do not meet our Submission Acceptability Standards will be returned to the PI. Visit <http://irb.ufl.edu/irb01/forms.html><http://irb.ufl.edu/wp-content/uploads/myIRB-Acceptability-Standards.pdf> for more information. * All submissions must be typed. |

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| 1. | Date: |
| 2. | Principal Investigator at UF: Mark Hudak, MD UF ID#: 1253-1950 |
| 3. | Project Title at UF: National Registry for Surveillance and Epidemiology of Perinatal COVID-19 Infection |

This form can be used in order to establish that coded/de-identified data and/or samples can be transferred between two parties in such a way as to insure that the data/samples can be considered anonymous to the researcher who receives the data/samples.

* The “collector-investigator” is the individual who originally possesses the data or samples.
* The “recipient-investigator” is the individual who will receive the coded/anonymous data or samples.

Under the terms of this agreement, the two parties agree that (1) the collector-investigator will not disclose any information that could identify who the samples belong to, AND (2) the recipient-investigator will not attempt to identify who the samples belong to.

Details of Confidentiality Agreement:

When an investigator conducts research involving biologic specimens and/or data, including images, that are obtained in an anonymous form from a collector-investigator, the recipient-investigator and the collector-investigator of the specimens and/or data agree, by signing the statements below, to maintain the confidentiality of the identities of the donor-subjects from whom the specimens and/or data were obtained.

**Collector-Investigator:**

I, the collector-investigator, affirm that (a) I have the appropriate authority to release this data/samples, and (b) I will not provide the recipient-investigator access to the identities of the donor-subjects or to information through which the identities of the donor-subjects could readily be ascertained.

Indicate what will be given to the recipient investigator:

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| data | Describe: The following data will be collected to submit into the RedCap system:  Maternal  (Age of mother, Gravidity, Race/ethnicity of mother, COVID-19 status at delivery,  Interval (days) between date of admission for delivery and date of neonatal birth, Interval (days) between first positive maternal test for SARS-COV and date of birth, Duration of maternal hospitalization (days), Final maternal disposition status, Indication for which mother was tested, (8) Indication for which mother was tested, Maternal condition immediately before admission for delivery, Required hospitalization for SARS-COV-2 before delivery (admitted and not discharged before delivery), Days of illness before delivery, Labor, Route of delivery, If labor was augmented or induced or delivery was by c-section, why?, Rupture of membranes, Duration of ROM (hours), Did mother have negative SARS-CoV-2 testing after the positive test?, Days from delivery that mother was tested and negative, Did mother receive betamethasone before delivery?, Did mother receive specific treatment for SARS-COV-2?, If yes, which medication(s) did mother receive. Maternal discharge status including cause of death if applicable.  Newborn  Gestational age at birth (to nearest completed week), Birth weight (g), Sex, Apgar at 5 minutes, Were mother and infant separated at birth?, Was the infant isolated, What were the locations at which the infant was cared for during birth hospitalization, Duration of neonatal hospitalization at your hospital (days), Final disposition status and cause of death if applicable, Neonatal signs during hospitalization, Respiratory support, Other diagnoses, Other administered neonatal intensive care, Laboratory findings from birth to discharge, Did newborn have SARS-CoV-2 testing?, If yes, check all days and specimen that were tested and were positive, Did mother provide breast milk?, If infant received mother’s own milk, either by direct breast feeding or by expression, what was viral testing status of the mother at that time, Discharge medications |
| samples | Describe: |

***A copy of the IRB approval letter and Informed Consent Form for this study that originally collected the samples/data is attached.***

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| Collector-Investigator name: |  |
| Affiliation: | UF  Non-UF – describe: |
| Signature: |  |
| Date: |  |

**Recipient-Investigator:**

I, the recipient-investigator, affirm that I will not ask the collector-investigator or accept from the collector-investigator any information that could identify the donor-subjects or any information through which the identities of the donor-subjects could readily be ascertained.

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| Recipient-Investigator name: | Mark Hudak, MD |
| Signature: |  |
| Date: |  |