NICU and Pediatric Repository

UI IRB # 201411731

USAGE AGREEMENT (Identified data/samples)

The recipient acknowledges that the conditions for use of this research material are governed by the University of Iowa Institutional Review Board (IRB) in accordance with Department of Health and Human Services regulations at 45 CFR 46. The recipient agrees to comply fully with all such conditions and to report promptly to the NICU and Pediatric Repository Principal Investigator any proposed changes in the recipient’s research project and any unanticipated problems involving risks to subjects or others. The recipient remains subject to applicable State or local laws or regulations and University of Iowa policies that provide additional protections for human subjects.

The research material provided to the recipient may be utilized only in accordance with the conditions stipulated in this Usage Agreement, as approved by the UI IRB, as follows:

* The recipient must provide an IRB approval memo to the NICU and Pediatric Repository for attachment to the NICU and Pediatric Repository IRB.
* The recipient’s IRB application should specifically describe why the recipient investigator cannot do his/her study without receiving identified samples/data.
* The recipient may not contact individuals who are collecting the material to obtain any identifying information.
* All material is identified by a code number that is assigned by the NICU and Pediatric Repository for tracking purposes.
* Subject information will be kept confidential in a locked file that can be accessed only by the recipient and NICU and Pediatric Repository and in password-protected computer files in a secure, non-public area and can only be accessed by the recipient and NICU and Pediatric Repository.
* In addition to the identified research material and/or data, at the recipient’s request, the NICU and Pediatric Repository may provide the recipient with the following information about the subject/material:

Demographic data such as gender, age, race/ethnic background; maternal health information about the pregnancy such as prenatal diagnostic tests, health conditions of the mother, prenatal medications, cervical cerclage information, labor and delivery outcomes; and neonatal outcomes such as gestational age, birthweight, complications and discharge information such as oxygen at discharge and day of life at discharge. Maternal and infant labs associated with pregnancy such as blood type, bilirubin values and sepsis lab results. Mother's medical history both her general conditions and conditions due to pregnancy such as gestational diabetes, hypertension and PPROM before labor.

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Any use of this material beyond the terms of this agreement requires prior review and approval by the University of Iowa IRB and, where appropriate, by an IRB at the recipient site, which must be convened under an application Office of Human Research Protections approved Federalwide Assurance.

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Dr. Allison Momany, Principal Investigator Date

NICU and Pediatric Repository

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Recipient Investigator Date

Recipient Investigator’s Project Title:

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