NICU and Pediatric Repository

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| PI: | Allison Momany |
| IRB ID #: | 201411731 |

Project Details

I. Project Introduction

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|  | **I.1** | ***Project to be reviewed by:*** |
|  |  | IRB-01 |

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|  | **I.2** | ***Project Title:*** |
|  |  | NICU and Pediatric Repository |

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|  | **I.3** | ***Short Title (optional):*** |
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|  | **I.4** | ***Provide a short summary of the purpose and procedures of the study proposed in this IRB application.**** ***DO NOT include information on studies not proposed in this application.***
* ***Use LAY terminology only. This must be easily understandable by IRB community members and nonscientists.***
* ***DO NOT cut and paste technical abstracts from funding applications that may not be understood by a general audience.***
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|  |  | The purpose of this study is to allow for samples that are collected for research projects to be placed in a central repository of biological specimens (ie. Human blood, saliva, feces, urine) and derived products (ie. DNA, RNA). These samples are and will be linked to medical records to study conditions of pregnancy and the newborn by researchers including the principal investigators that co-direct the repository (Dr. John Dagle and Dr. Allison Momany). Many specimens are collected for medical reasons, are left-over, and would normally be discarded. However, some participants may be asked to provide a blood or saliva sample if leftover blood is not available or if specific sample collection procedures are needed (ie. use of a specific sample to get plasma or treating the sample immediately to stabilize RNA). Some participants may be recontacted later for additional samples.Outside investigators (from this University or other Universities) who wish to utilize samples and/or data from the NICU and Pediatric Repository will have the option to either 1) accept coded data and samples (no access to personal identifiers). In this case, they will not need IRB approval and will sign a data usage agreement. OR 2) request identified data. In this case, the investigator will be required to obtain and submit to the NICU and Pediatric Repository proof of IRB approval for their project.Data and samples from four existing studies of preterm birth and complications of prematurity, Disease Variability in the Newborn (199911068), Premie Study (200506792), Metabolics of Pregnancy (201112755) and Persistent Pulmonary Hypertension in the Newborn - Genetic Variation (200307031), will be shared with this study. These studies were closed upon approval of this IRB. The principal investigators (Dr. Dagle and Dr. Momany) will continue to use these specimens and new specimens collected directly under the repository for their ongoing funded research of preterm birth and complications of prematurity. |

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|  | **I.5** | ***Specify your research question(s), study aims or hypotheses (do not indicate "see protocol")*** |
|  |  | The aims of this study are to:1) collect and store biological specimens and their derivatives from NICU and pediatric patients and their families.2) link the collected specimens to medical records data.3) make stored samples and health information available to researchers to study conditions of pregnancy and the newborn. |

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|  | **I.6** | ***Background and significance and/or Preliminary studies related to this project.(do not indicate "see protocol")*** |
|  |  | Repositories are important resources for advancing genetic and genomic research and the translation of this research into health improvements. Many institution-wide comprehensive repositories such as the one proposed here have recently been developed both in the US and throughout the world. This repository will serve as a research resource for many researchers and will help to expedite the research process to promote the translation of research to medicine. |

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|  | **I.7** | ***Literature cited / references (if attaching a grant or protocol enter N/A).*** |
|  |  | N/A |

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II. Research Team

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|  | **II.1** | ***Principal Investigator*** |
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| **Name** | **E-mail** | **College** |
| --- | --- | --- |
| Allison Momany | allison-momany@uiowa.edu | Carver College of Medicine |

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|  | **II.2** | ***Team Members*** |
|  |  | **UI Team Members**

| **Name** | **E-mail** | **College** | **Contact** | **Key Prsn** | **UI COI** | **VAMC COI** | **Consent Process Involvement** | **Deactivated** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Allison Momany, PHD | allison-momany@uiowa.edu | Carver College of Medicine | Yes | Yes | No |  | Yes | No |
| Sandra Arnold, MSN, DNP , RN | sandra-arnold@uiowa.edu | Carver College of Medicine | No | No | No |  | Yes | No |
| Jennifer Bermick, MD | jennifer-bermick@uiowa.edu | Carver College of Medicine | No | Yes | No |  | Yes | No |
| Stephania Cavallaro Moronta, MD | stephania-cavallaromoronta@uiowa.edu | Carver College of Medicine | No | No | No |  | Yes | No |
| Brenda Coulter, RN | brenda-coulter@uiowa.edu | Carver College of Medicine | No | No | No |  | Yes | No |
| John Dagle, MD, PHD | john-dagle@uiowa.edu | Carver College of Medicine | Yes | Yes | No |  | Yes | No |
| Heath Davis, Informatics, BS, MS | h-davis@uiowa.edu | Carver College of Medicine | No | No | No |  | No | No |
| Parker Harlow, High School | parker-harlow@uiowa.edu | College of Public Health | No | No | No |  | Yes | No |
| Sydney Jellison, BS | sydney-jellison@uiowa.edu | Carver College of Medicine | No | No | No |  | Yes | No |
| Samuel Knoshaug, Health & Human Physiology, BA | samuel-knoshaug@uiowa.edu | Carver College of Medicine | No | No | No |  | Yes | No |
| Emese Kovacs, BA | emese-chmielewski@uiowa.edu | Graduate College | No | No | No |  | No | No |
| Gretchen Larson, High School | gretchen-larson@uiowa.edu | College of Liberal Arts and Sciences | No | No | No |  | Yes | No |
| Patrick McNamara, MB, BCh | patrick-mcnamara@uiowa.edu | Carver College of Medicine | No | Yes | No |  | No | No |
| Jeffrey Murray, MD | jeff-murray@uiowa.edu | Carver College of Medicine | No | Yes | No |  | No | No |
| Paige Nelson, BA | paige-nelson@uiowa.edu | College Lib Arts and Sciences | No | No | No |  | Yes | No |
| Kelli Ryckman, PHD | kelli-ryckman@uiowa.edu | College of Public Health | Yes | Yes | No |  | No | No |
| Donna Santillan, BA, BS, PHD | donna-santillan@uiowa.edu | Carver College of Medicine | No | Yes | No |  | No | No |
| Mark Santillan, MD | mark-santillan@uiowa.edu | Carver College of Medicine | No | Yes | No |  | No | No |
| Bailey Schrimper, MSN | bailey-schrimper@uiowa.edu | Carver College of Medicine | No | No | No |  | Yes | No |
| Amy Stanford, Postdoc, MD | amy-stanford@uiowa.edu | Carver College of Medicine | No | No | No |  | No | No |
| Maria Thurow, BA | maria-thurow@uiowa.edu | Carver College of Medicine | No | No | No |  | Yes | No |
| Nancy Weathers, BBA | nancy-weathers@uiowa.edu | Carver College of Medicine | Yes | No | No |  | Yes | No |

**Non-UI Team Members**

| **Name** | **Institution** | **Location** | **FWA** | **Role** | **DHHS** | **Contact** | **Key Prsn** | **UI COI** | **VAMC COI** | **Consent Process Involvement** | **Email** |
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| Nothing found to display. |

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|  | **II.3** | ***The Principal Investigator of this study is:*** |
|  |  | Fellow or Research Scholar |

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|  | **II.3.a** | ***Select the mentor or faculty advisor:*** |
|  |  | John Dagle |

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|  | **II.6** | ***Identify the key personnel. The system will automatically designate the PI and all faculty members on the project as “key personnel.” For information about other team members who should be designated as “key personnel” please click on the help information.*** |
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| **Name** | **Is Key Personnel** |
| --- | --- |
| Allison Momany, PHD | Yes |
| Sandra Arnold, MSN, DNP , RN | No |
| Jennifer Bermick, MD | Yes |
| Stephania Cavallaro Moronta, MD | No |
| Brenda Coulter, RN | No |
| John Dagle, MD, PHD | Yes |
| Heath Davis, Informatics, BS, MS | No |
| Parker Harlow, High School | No |
| Sydney Jellison, BS | No |
| Samuel Knoshaug, Health & Human Physiology, BA | No |
| Emese Kovacs, BA | No |
| Gretchen Larson, High School | No |
| Patrick McNamara, MB, BCh | Yes |
| Jeffrey Murray, MD | Yes |
| Paige Nelson, BA | No |
| Kelli Ryckman, PHD | Yes |
| Donna Santillan, BA, BS, PHD | Yes |
| Mark Santillan, MD | Yes |
| Bailey Schrimper, MSN | No |
| Amy Stanford, Postdoc, MD | No |
| Maria Thurow, BA | No |
| Nancy Weathers, BBA | No |

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|  | **II.5** | ***Select research team member who is the primary contact for study participants.*** |
|  |  | Nancy Weathers |

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III. Funding/Other Support

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|  | **III.1** | ***Funding Sources*** |
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| **Source Entered as Text** | **DSP Link** | **Type** | **Source** | **Grant Title** | **Name of PI on Grant** |
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| Source is entered as text no |  | Departmental / PI Discretionary |  |  |  |

\* new source name |

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|  | **III.3** | ***Does any member of the research team have a financial conflict of interest related to this project according to the***[***Conflict of Interest in Research***](http://coi.research.uiowa.edu/)***policy? If yes, please indicate which members below.*** |
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| --- | --- |
| **Name** | **Has Conflict of Interest** |
| Allison Momany, PHD | No |
| Sandra Arnold, MSN, DNP , RN | No |
| Jennifer Bermick, MD | No |
| Stephania Cavallaro Moronta, MD | No |
| Brenda Coulter, RN | No |
| John Dagle, MD, PHD | No |
| Heath Davis, Informatics, BS, MS | No |
| Parker Harlow, High School | No |
| Sydney Jellison, BS | No |
| Samuel Knoshaug, Health & Human Physiology, BA | No |
| Emese Kovacs, BA | No |
| Gretchen Larson, High School | No |
| Patrick McNamara, MB, BCh | No |
| Jeffrey Murray, MD | No |
| Paige Nelson, BA | No |
| Kelli Ryckman, PHD | No |
| Donna Santillan, BA, BS, PHD | No |
| Mark Santillan, MD | No |
| Bailey Schrimper, MSN | No |
| Amy Stanford, Postdoc, MD | No |
| Maria Thurow, BA | No |
| Nancy Weathers, BBA | No |

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IV. Project Type

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|  | **IV.1** | ***Do you want the IRB to give this project*** |
|  |  | Regular (expedited or full board) review |

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|  | **IV.2** | ***Enter the date you will be ready to begin screening subjects/collecting data for this project. (If you do not have a specified date, add "upon IRB approval")*** |
|  |  | 1/1/2015 |

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|  | **IV.3** | ***Are you requesting a***[***waiver of informed consent/authorization***](https://hso.research.uiowa.edu/ui-investigator%E2%80%99s-guide)***(subjects will not be given any oral or written information about the study)?*** |
|  |  | Yes, but only for some of the subjects |

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|  | **IV.5** | ***Describe the different study populations (subjects who are and are not giving consent)*** |
|  |  | UIHC Moms and babies provide samples that are only available within a specific, limited time frame, such as the cord blood at the time of delivery or fecal matter/urine from the newborn; or other clinical samples and study data, which would otherwise be discarded or opportunity lost. These samples are time-sensitive and need to be properly stored/recorded, and additional time is needed for consent to be given. It is not possible to approach all potential subjects for consent prior to collection of these unique samples, and so these potentially important samples could be lost to the study. Samples collected as part of UIHC clinical care or samples that can be collected non-invasively such as discarded cord blood/fecal matter/urine may be collected for this study and stored for up to nine months without consent due to the sensitive time after delivery and respect for the family. Because some of the babies from whom these samples are taken may be quite ill, it is difficult and potentially upsetting to approach the parents about the use of these samples during the first week of life when the samples are collected. Premature babies can have many health complications which take months to stabilize and approaching families during this stressful time is not a good option. If the subject is approached and declines study enrollment, then the stored samples will be discarded. If the subject is enrolled in the study, then normal study procedures and sample processing would commence.Minor mothers are an important part of this study since we know mother's age is a factor in the health of the newborn. Since some mothers are not quite 18 and unable to consent for themselves, we ask that their parents’ consent be waived so they may participate in the study. Minor mothers would need to sign the consent for themselves and their child(ren).Other family members (ie. fathers, siblings) of UIHC deliveries will be consented when first approached about the study.Pediatric subjects and their families approached in a clinical setting will be consented at the time of initial introduction to the study.Should the subject reach adulthood during the life of the study, samples for these subjects which we have current interaction with when they turn 18 will be re-consented. All other subjects turning 18 (which we do not have current interaction with) will be included in the study by this waiver of consent since it is not reasonable to re-consent people after many years have passed.Samples and data collected under four studies, Disease Variability in the Newborn (IRB #199911068), Premie Study (IRB #200506792), Metabolics of Pregnancy (IRB #201112755) and Persistent Pulmonary Hypertension in the Newborn - Genetic Variation (IRB #200307031), will have their consent waived under this study. Their consent was obtained in their original studies respectively it is not reasonable to re-consent people after many years have passed and from whom we may not have updated contact information. |

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|  | **IV.6** | ***Will subjects be provided with additional pertinent information after participation?*** |
|  |  | No |

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|  | **IV.8** | ***Indicate type of study (check all that apply)*** |
|  |  | * Other - Repository for the study of genetic and clinical information regarding factors influencing pregnancy and the health of the newborn.
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|  | **IV.9** | ***List the earliest (beginning) date the data you wish to review were created:*** |
|  |  | 1/1/1999 |

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|  | **IV.10** | ***List the latest (ending) date the data you wish to review were created:*** |
|  |  | ongoing |

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|  | **IV.11** | ***Indicate sources of your data or specimens (check all that apply)*** |
|  |  | * UIHC (UI Health Care) or a UIHC Hybrid Covered Entity records/specimens - biological samples and associated data collected before study consent is obtained
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|  | **IV.11.a** | ***Select all Private Identifiable Information (PII) or Protected Health Information (PHI) accessed and used for this study (select all that apply)*** |
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| Identify types of PHI accessed |
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| **Type of PHI** | **UIHC data source** |
| Name |  |
| Street address |  |
| City |  |
| County |  |
| Precinct |  |
| Zip code |  |
| Geocodes smaller than state |  |
| Date of birth, ages > 89 years of age |  |
| Diagnosis dates |  |
| Procedure dates |  |
| Admission or discharge dates |  |
| Telephone numbers |  |
| Fax numbers |  |
| E-mail addresses |  |
| Social Security number |  |
| Medical record number |  |
| Health plan beneficiary or account numbers |  |
| Certificate/license numbers |  |
| Vehicle identifiers and serial numbers or license numbers |  |
| Device identifiers or serial numbers |  |
| Web URLs |  |
| Internet Protocol (IP) address numbers |  |
| Biometric identifiers including finger/voice prints |  |
| Full face photographic images or any comparable images |  |
| None of the above |  |

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|  | **IV.12** | ***List ALL of the variables, including any identifiers not previously entered or links to identifiers you plan to obtain/use for purposes of this study. (The information accessed should be the minimum data variables necessary for performing the desired analysis.)*** |
|  |  | Subjects for whom consent is temporarily waived due to collecting and holding samples until subject can be approached, minor mothers and those enrolled in studies 199911068, 200506792, 200307031 and 201112755, will have approximately 350 variables extracted from medical charts including: demographic data such as address, dob, race/ethnic background, occupation, education, other measures of SES; maternal health information about the pregnancy such as prenatal diagnostic tests, due date information, health conditions of the mother, prenatal medications, cervical cerclage information, labor and delivery outcomes; and neonatal outcomes such as birth information, complications and discharge information are collected from the UIHC chart or other medical record from the institution providing care to the subject. Maternal and infant labs associated with pregnancy will also be collected such as blood type, bilirubin values and sepsis lab results. Mother's medical history both her general condidtions and conditions due to pregnancy will also be collected. This data will be kept on secured servers with only approved research team members having access.Only data (as described above) and specimens that were collected PRIOR to aging up will continue to be used after the subject has turned 18, unless the subject is reconsented. |

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|  | **IV.13** | ***A minimal risk study is a study in which the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.Explain why this study involves no more than minimal risk to subjects or to their privacy.*** |
|  |  | The data collected from medical records exists for routine clinical care; no additional data will be generated. Samples collected are already being collected as part of UIHC clinical care. These samples, or a portion leftover after lab processing, would otherwise be discarded. Should the subject reach adulthood, samples will be used in the same way as when the subject was a minor. Since we do not update contact information, re-consenting the subject aging up would be difficult if not impossible. |

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|  | **IV.14** | ***Explain why this consent waiver will not adversely affect the subject's rights and welfare.*** |
|  |  | There is no additional risk to the patient beyond normal clinical care. The stored samples will not be used unless consent is signed. Subjects from studies 199911068, 200506792, 200307031 and 201112755 have already signed a consent agreeing to sharing their data with other researchers. Should the subject reach adulthood during the life of the study, the samples will be used in the same way as when the subject was a minor. There is no additional risk to the patient when they turn 18. |

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|  | **IV.15** | ***Explain why it is impracticable (not possible) to conduct this research without a waiver of consent/waiver of authorization.*** |
|  |  | The desired samples/data are time-sensitive & need to be properly stored/recorded, and additional time is needed for consent to be given. In addition, because some of the babies from whom these samples are taken may be quite ill, it will be difficult & potentially upsetting to approach the parents about the use of these samples immediately. Should the subject reach adulthood, re-consenting would be difficult and impractical due to cost & sharing of the data/samples with other researchers. |

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|  | **IV.16** | ***Will you be accessing any medical records or medical information, or do any of the data you plan to access meet the federal regulatory definition of***[***protected health information (PHI)***](http://hso.research.uiowa.edu/hipaa-privacy-rule-waiver-sample)***?*** |
|  |  | Yes |

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|  | **IV.17** | ***Explain why it is impracticable (not possible) to conduct this research without access to and use of protected health information.*** |
|  |  | We need access to the patient's medical record information in order to properly identify, label and store the sample. The information will not be used until after consent is obtained. Should the subject reach adulthood, no additional medical information will be obtained. |

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|  | **IV.18** | ***Describe your plan to protect any subject and/or specimen identifiers from improper use and disclosure. (Identifiers include but are not limited to names, addresses, dates directly related to the subject [such as birth date, date of admission/discharge, date of clinic visit/procedure/diagnosis], social security number, medical record number, pathology accession number, or other account numbers, etc.)*** |
|  |  | Once a sample is collected, a coded ID number will be assigned and personal identifiers will be removed. Personal identifiers will be kept in a study database, which is password protected and limited to research team members. The sample will be labeled with the coded ID and stored in the Momnay/Dagle Lab. Should the subject reach adulthood, sample ID numbers and data security will not change. |

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|  | **IV.19** | ***Describe your plan to destroy subject identifiers at the earliest opportunity consistent with the conduct of the research, or explain the health or research justification for retaining subject identifiers.*** |
|  |  | Once consent is obtained the samples will be processed using our standard protocols. If consent is not obtained within nine months then the sample/data will be discarded and personal information will be removed from the study database. Identifiers will be kept for minor mothers and subjects from studies 199911068, 200506792, 200307031 and 201112755. Should the subject reach adulthood, subject identifiers will continue to be kept in a secure password protected database. |

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V. Other Committee Review

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|  | **V.1** | ***Does this project involve any substance ingested, injected, or applied to the body?**** ***Do not answer yes, if the involvement includes a device, wire, or instrument***
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|  |  | No |

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|  | **V.2** | ***Are any contrast agents used for any purpose in this study?*** |
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|  | **V.9** | ***Will any subject be asked to undergo a diagnostic radiation procedure (including radiographic, nuclear medicine, DEXA)?*** |
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|  | **V.14** | ***Will any subject be asked to undergo a radiation therapy procedure (including external beam therapy, brachytherapy, or nuclear medicine therapy)?*** |
|  |  | No |

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|  | **V.20** | ***Does this project involve the deliberate transfer of recombinant or synthetic nucleic acid molecules, or DNA or RNA derived from recombinant or synthetic nucleic acid molecules, into one or more human research participant?*** |
|  |  | No |

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|  | **V.21** | ***Will any portion of this project be conducted in the CRU, or does it use any CRU resources?*** |
|  |  | No |

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|  | **V.22** | ***Will this project use:**** ***any resource/patients of the Holden Comprehensive Cancer Center***
* ***involve treatment, detection, supportive care, or prevention of cancer***
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|  |  | No |

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|  | **V.25.a** | ***Will the study involve any of the following activity at UI Health Care, even if subjects or their insurance will not be billed for the item or service, and regardless of the study funding source (including studies with departmental or no funding)?**** ***Procedures, tests, examinations, hospitalizations, use of Pathology services, use of clinic facilities or clinical equipment, or any patient care services, including services conducted in the Clinical Research Unit; or***
* ***Physician services or services provided by non-physicians who are credentialed to bill (ARNPs, Physician Assistants, etc.)***
 |
|  |  | No |

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|  | **V.26** | ***The study involves Department of Nursing Services and Patient Care nursing, nursing resources or evaluates nursing practices at UI Health Care.*** |
|  |  | No |

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|  | **V.27** | ***Will the study involve the use of the I-CTMS (OnCore) for clinical trial data management? Select yes if any or all of the following apply:**** ***Any study required to register subjects in EPIC are encouraged to use the I-CTMS***
* ***Best practice is to use the I-CTMS for any new study that involves subject tracking or sponsor invoicing***

***Note: This question is for non-oncology studies only. For oncology studies use existing HCCC OnCore processes by selecting V.22*** |
|  |  | No |

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VI. Subjects

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|  | **VI.1** | ***How many adult subjects do you expect to consent or enroll for this project?*** |
|  |  | 6000 |

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|  | **VI.2** | ***What is the age of the youngest adult subject?*** |
|  |  | 18.0 |

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|  | **VI.3** | ***What is the age of the oldest adult subject?*** |
|  |  | 99.0 |

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|  | **VI.4** | ***What is the percentage of adult male subjects?*** |
|  |  | 40 |

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|  | **VI.5** | ***What is the percentage of adult female subjects?*** |
|  |  | 60 |

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|  | **VI.6** | ***How many minor subjects do you expect to consent or enroll for this project?*** |
|  |  | 3000 |

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|  | **VI.7** | ***What is the age of the youngest minor subject?*** |
|  |  | 0.0 |

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|  | **VI.8** | ***What is the age of the oldest minor subject?*** |
|  |  | 17.9 |

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|  | **VI.9** | ***What is the percentage of minor male subjects?*** |
|  |  | 50 |

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|  | **VI.10** | ***What is the percentage of minor female subjects?*** |
|  |  | 50 |

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|  | **VI.11** | ***Will any of the minors enrolled be in foster care or Wards of the court?*** |
|  |  | No |

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|  | **VI.13** | ***Describe EACH of your subject populations**** ***Include description of any control group(s)***
* ***Specify the Inclusion/Exclusion criteria for EACH group***
 |
|  |  | Minor subjects are newborn infants born or transferred to the UIHC Neonatal Intensive Care Unit (NICU), newborns/infants/children being seen in a clinic or another unit such as the high-risk follow-up clinic or the mother and baby nursery, or newborns/infants/children who are identified by a colleague as appropriate for this study such as offspring of mothers enrolled in other studies during pregnancy through OB/GYN. All minor siblings and cousins may be invited to enroll in the study.Adult subjects are the parents of the infant(s), and their extended family members; with a focus on first and second degree relatives of the infant or parent. Family members of specific interest are the maternal grandparents, and any maternal aunt (and the biological father) who also had a premature infant. We will include mothers of any age, as age may factor in many conditions of pregnancy is important in condition related to the health of the child. |

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|  | **VI.14** | ***Provide an estimate of the total number of subjects that would be eligible for inclusion in each of your study populations (include your control population if applicable)*** |
|  |  | There will initially be many more eligible subjects than the research team will be able to approach. It is unclear exactly how many pediatric patients are seen at UIHC yearly, however, in 2012, UIHC reported 5,157 total pediatric patient admissions and 106,193 outpatient visits. Many, but not all of these will be eligible to participate in the NICU and Pediatric Biobank. |

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|  | **VI.15** | ***Describe how you will have access to each of your study populations in sufficient number to meet your recruitment goals.*** |
|  |  | Subjects are made up mostly of the infants and their families who are admitted to the hospital by birth or transferred to any of the UIHC hospitals and clinics including the NICU. Also, infants/children and their families who are in other units or clinics may be identified to a research team member as a potential recruit such as colleagues enrolling for other studies related to pregnancy and health of the child. |

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|  | **VI.16** | ***Do you plan to recruit/enroll non-English speaking people?*** |
|  |  | No |

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|  | **VI.18** | ***Do you propose to enroll any of the following in this study as subjects?**** ***Employee of the PI or employee of a research team member***
* ***Individual supervised by PI or supervised by member of research team***
* ***Individual subordinate to the PI or subordinate to any member of the research team***
* ***Student or trainee under the direction of the PI or under the direction of a member of the research team***
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|  |  | No |

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|  | **VI.20** | ***Will subjects provide any information about their relatives?*** |
|  |  | Yes |

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|  | **VI.21** | ***Describe in detail how this information will be obtained. NOTE: The collection of identified data about family members makes the family member a subject in the study. This would require a consent process with the family member or a request for waiver of consent to collect these data. See the Research Guide for more information.*** |
|  |  | Women who have children will be the primary contact for recruitment of families for this study. Because we are interested in the maternal and child health we may be asking these women about their family history of pregnancy complications. A complete three-generation family history may be obtained asking about pregnancy and neonatal outcomes. A research team member associated with this study may obtain the family history in-person from mothers who have a child enrolled in this study. |

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|  | **VI.22** | ***List the data to be collected about subject relatives including the names of any surveys, questionnaires etc. to be used. Attach data collection tools under the Relative/Proxy Data Collection Instruments category.*** |
|  |  | Interview tools may be used to collect family information, which is then used to create or modify the family pedigree and establish the family history of prematurity and pregnancy complications. During the interview, the adult female subject is asked about her children, siblings and parents. She is asked to provide their gender and whether they were born prematurely and similar questions. |

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|  | **VI.23** | ***Will anyone (other than the subject) provide you with information about the subject (e.g. proxy interviews)?*** |
|  |  | No |

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|  | **VI.26** | ***Is this project about pregnant women?*** |
|  |  | Yes |

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|  | **VI.27** | ***Will this project involve fetuses?*** |
|  |  | No |

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|  | **VI.28** | ***Does this project involve adult subjects who may be incompetent or have limited decision-making capacity on initial enrollment into the study?*** |
|  |  | No |

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|  | **VI.32** | ***Does this project involve subjects whose capacity to consent may change over the course of the study?*** |
|  |  | No |

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|  | **VI.37** | ***Does this project involve***[***prisoners as subjects***](https://hso.research.uiowa.edu/ui-investigator%E2%80%99s-guide)***?*** |
|  |  | No |

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VII.A. Project Description (A)

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|  | **VII.A.1** | ***Where will project procedures take place (check all that apply)?*** |
|  |  | * U.S. off-campus - For families that are not doing follow-up visits at the clinic, but virtually: After talking to parent about the study, a consent may be sent by mail and completed at their home (this would only be done to use leftover samples already collected).
* UIHC - Labor and delivery, nurseries, mother/baby unit, neonatal high-risk follow-up clinic, other UIHC inpatient units and outpatient clinics
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|  | **VII.A.2** | ***Is this project also being conducted by other researchers at their own sites (e.g. a multi-site collaborative project)?*** |
|  |  | No |

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VII.B. Project Description (B)

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|  | **VII.B.1.** | ***Does this project involve any of the following (Check all that apply):*** |
|  |  | **Interventional** – Includes **Clinical (or Treatment) trial**, **Physiology intervention/study**, **Behavioral intervention/study**, **Diagnostic Trial**.**Observational****Expanded Access** – A process regulated by the Food and Drug Administration (FDA) that allows manufacturers to provide investigational new drugs to patients with serious diseases or conditions who cannot participate in a clinical trial. Examples of expanded access include non-protocol access to experimental treatments, including protocol exception, single-patient IND, treatment IND, compassionate use, emergency use, continued access to investigational drug, and parallel track ([ClinicalTrials.gov](http://prsinfo.clinicaltrials.gov/definitions.html#StudyType) & [FDA](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.21)).**Registry** – The collection and maintenance of data (not including biologic samples) in which: (1) the individuals in the registry have a common or related condition(s), and/or (2) the individuals in the registry are interested in being contacted for future studies by investigators other than those listed in Section II of this project.([UI Guide](http://hso.research.uiowa.edu/ui-investigator%E2%80%99s-guide))**Repository** – The collection, storage, and distribution of human biologic samples and/or data materials for research purposes. Repository activities involve three components: (i) the collection of data and/or specimens such as blood, tissue, saliva, etc.; (ii) the storage of data or specimens, and data management function; and (iii) the sharing of data/specimens with recipient investigators other than the original investigators. (paraphrased from [OHRP](http://www.hhs.gov/ohrp/))**Other** |

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|  | **VII.B.11** | ***Is there a separate, written protocol that will be submitted in addition to this IRB New Project form? (Note: a grant application is not considered to be a protocol)*** |
|  |  | No |

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VII.C. Project Description (C)

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|  | **VII.C.1** | ***Does this project involve any***[***research on genes or genetic testing/research***](https://hso.research.uiowa.edu/ui-investigator%E2%80%99s-guide)***?*** |
|  |  | Yes |

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|  | **VII.C.2** | ***What information will be obtained from the DNA samples?*** |
|  |  | The samples in the NICU and Pediatric Repository may be used in a wide range of studies, including genetic studies. Due to the long-term nature of repositories, it is not possible to predict all of the tests that researchers may want to utilize in the future, since many of them may not exist at this time. Currently, any testing that identifies DNA, RNA, or protein sequence, quantity, whole genome sequencing or epigenetic status may be used. Other genetic methodologies may be identified in the future and these may be utilized by researchers who utilize the NICU/Pediatric repository as well. |

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|  | **VII.C.3** | ***What data will be stored with the DNA samples? (e.g., identifiers, code numbers linked to identifiers, diagnoses, other clinical information, etc.)*** |
|  |  | DNA samples will be linked by ID numbers to demographic data such as name, address, DOB, race/ethnic background; maternal exposure information (infection, drugs, alcohol, tobacco); family health history (pedigree), minimum of three generation pedigree focusing on health of the mother during pregnancy and her newborn infant or child. |

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|  | **VII.C.4** | ***Will subjects be able to request at a later time that samples be destroyed?*** |
|  |  | Yes |

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|  | **VII.C.5** | ***Where will the DNA and any associated information be stored?*** |
|  |  | In the laboratory of Dr. Dagle and Dr. Momany (former Murray lab), 2182 Med Labs, University of Iowa. Samples and associated data may also be sent to, analyzed and stored with collaborating centers with IRB approval. Samples and associated de-identified data may also be sent and analyzed by collaborating centers or core facilities that provide specific services such as DNA sequencing or metabolic profiling. |

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|  | **VII.C.6** | ***Describe the mechanisms for maintaining confidentiality at the storage location.*** |
|  |  | Samples are stored with only a coded ID so that they are not readily identified. Access to the storage facilities are restricted to members of the research team. |

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|  | **VII.C.7** | ***Could the DNA and/or associated information be shared in the future with other researchers?*** |
|  |  | Yes |

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|  | **VII.C.8** | ***Describe the procedure for sharing:*** |
|  |  | We may share de-identified samples and data with other research investigators without prior IRB approval. A usage agreement will be signed for UI researchers and a Confidentiality Agreement will be signed for non-UI researchers. It remains our intent to be able to link genotype and phenotype data regardless of where samples are analyzed. The Momany/Dagle Lab will maintain a coded link between local data and that shared with collaborators. Collaborating researchers requesting identifiers would need IRB approval for their individual study. |

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|  | **VII.C.9** | ***Will the subjects have the option of receiving any DNA testing results?*** |
|  |  | No |

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|  | **VII.C.11** | ***Is the laboratory that will be performing the DNA testing CLIA certified?*** |
|  |  | No |

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|  | **VII.C.12** | ***Will the DNA samples be destroyed at the conclusion of the study?*** |
|  |  | No |

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VII.D. Project Description (D)

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|  | **VII.D.1** | ***Check all materials/methods that will be used in recruiting subjects (you will need to attach copies of all materials at the end of the application):*** |
|  |  | * Referral from colleague - Referral of a specific infant/family from another unit or clinic in the hospital.
* E-mail -
* Letter -
* Existing Registry/database - Subjects may be identified using the High Risk/Vermont Oxford Infant Database, the Disease Variability in the Newborn (DVIN) repository (199911068), the Premie repository (200506792), and Metabolic of Pregnancy Repository (201112755). All databases are UI based. Leftover sample may be shared from the following UI studies: Targeted metabolic profiling to predict major morbidity in very small preterm newborns (202003669), PROMPT Genetics (202108397), The PREMISE Study (202112094), Understanding Immune system development (202012208).
* Brochures -
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|  | **VII.D.1.a** | ***Will any of the materials/methods below be used by researchers (or their colleagues) to recruit subjects into this study?**** ***the potential subject is a patient OR***
* ***use of any information considered to be Protected Health Information (PHI) OR***
* ***review of patient/clinic records be used in recruiting subjects***
 |
|  |  | Yes |

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|  | **VII.D.1.b** | ***Describe source of records*** |
|  |  | Electronic Medical Records (EPIC) will need to be accessed to determine potential subjects, in this case very preterm babies. |

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|  | **VII.D.1.c** | ***Select all Private Identifiable Information (PII) or Protected Health Information (PHI) accessed and used for this study (select all that apply)*** |
|  |  |

| Identify types of PHI accessed |
| --- |
| **Type of PHI** | **Data source** |
| Name |  |
| Street address |  |
| City |  |
| County |  |
| Precinct |  |
| Zip code |  |
| Geocodes smaller than state |  |
| Date of birth, ages > 89 years of age |  |
| Diagnosis dates |  |
| Procedure dates |  |
| Admission or discharge dates |  |
| Telephone numbers |  |
| Fax numbers |  |
| E-mail addresses |  |
| Social Security number |  |
| Medical record number |  |
| Health plan beneficiary or account numbers |  |
| Certificate/license numbers |  |
| Vehicle identifiers and serial numbers or license numbers |  |
| Device identifiers or serial numbers |  |
| Web URLs |  |
| Internet Protocol (IP) address numbers |  |
| Biometric identifiers including finger/voice prints |  |
| Full face photographic images or any comparable images |  |
| None of the above |  |

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|  | **VII.D.2.a** | ***List ALL of the variables, including any identifiers not previously entered or links to identifiers you plan to obtain/use for purposes of this study. (The information accessed should be the minimum data variables necessary for performing the desired analysis.)*** |
|  |  | To identify potential subjects, the following fields will be accessed in EPIC: Subject name, DOB, Parents' names, gestational age, primary language spoken by parents, congenital diagnoses. |

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|  | **VII.D.3** | ***Describe why you could not practicably recruit subjects without access to and use of the information described above*** |
|  |  | We would not know who to approach otherwise. |

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|  | **VII.D.4** | ***Describe why you could not practicably obtain authorization from potential subjects to review their patient or clinic records for recruitment purposes.*** |
|  |  | We would not know who to approach for authorization if we did not first identify them. |

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|  | **VII.D.5** | ***Describe plans to protect the identifiers from improper use or disclosure*** |
|  |  | All identifiers will be maintained in a password protected database so that only members of the research team have access. |

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|  | **VII.D.6** | ***Describe plans to destroy identifiers at the earliest opportunity consistent with conduct of the research*** |
|  |  | Identifiers of those who were approached will be maintained in a password protected database so that we know who has already been approached. Identifiers of those who are not approached will be destroyed after the scheduled visit. |

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|  | **VII.D.7** | ***Does the research team agree that the requested information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the study, or for other research for which the use or disclosure of the requested information would be permitted by the HIPAA Privacy Rule*** |
|  |  | Yes |

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|  | **VII.D.8** | ***Will a member of the research team discuss the study with the subject in person prior to the subject agreeing to participate?*** |
|  |  | Yes |

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|  | **VII.D.9** | ***Describe the physical location where the consent process will take place:*** |
|  |  | Research team members will discuss participation with the potential subject in clinic rooms or other private or semi-private areas in the hospital/clinic area that will protect the privacy of the potential participant. In the case of virtual visits, the discussion will take place by phone or zoom and an e-consent will be emailed. The consent will be electronically signed at the subject's home via Redcap. In the case of e-consent, the subject will have the option to email or call someone from the research team for discussion/clarification if they have questions or concerns. |

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|  | **VII.D.10** | ***Will a member of the research team discuss the study with the subject by phone prior to the subject agreeing to participate?*** |
|  |  | Yes |

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|  | **VII.D.11** | ***Describe:*** |
|  |  | When reconsenting minors that have turned 18, a phone call may be made to describe the study and review the elements of the consent after the subject has expressed interest in the study. Up to two follow-up phone calls will be made to this same subject group if consents and/or kits have not been returned. Our consent signature page allows for consent even if no direct contact with a subject occurs. A research team member is available to discuss the study with a subject (minor turning 18)should they have questions. In the case of virtual visits, the discussion will take place by phone or zoom and an e-consent will be emailed. The consent will be signed at the subject's home. In the case of e-consent, the subject will have the option to email or call someone from the research team for discussion/clarification if they have questions or concerns. The consent process will take place in the subject's home. There is nothing to send back in the case of e-consent. |

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|  | **VII.D.12** | ***Who will be involved in the***[***consent process***](https://hso.research.uiowa.edu/ui-investigator%E2%80%99s-guide)***(including review of consent document, answering subjects' questions)?*** |
|  |  |

| **Name** | **Consent Process Involvement** |
| --- | --- |
| Allison Momany, PHD | Yes |
| Sandra Arnold, MSN, DNP , RN | Yes |
| Jennifer Bermick, MD | Yes |
| Stephania Cavallaro Moronta, MD | Yes |
| Brenda Coulter, RN | Yes |
| John Dagle, MD, PHD | Yes |
| Heath Davis, Informatics, BS, MS | No |
| Parker Harlow, High School | Yes |
| Sydney Jellison, BS | Yes |
| Samuel Knoshaug, Health & Human Physiology, BA | Yes |
| Emese Kovacs, BA | No |
| Gretchen Larson, High School | Yes |
| Patrick McNamara, MB, BCh | No |
| Jeffrey Murray, MD | No |
| Paige Nelson, BA | Yes |
| Kelli Ryckman, PHD | No |
| Donna Santillan, BA, BS, PHD | No |
| Mark Santillan, MD | No |
| Bailey Schrimper, MSN | Yes |
| Amy Stanford, Postdoc, MD | No |
| Maria Thurow, BA | Yes |
| Nancy Weathers, BBA | Yes |

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|  | **VII.D.15** | ***Check all materials that will be used to obtain/document informed consent:*** |
|  |  | * Consent Document
* Consent Summary (or Key Information Sheet)
* Assent Document
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|  | **VII.D.16** | ***Are you requesting a***[***waiver of documentation***](https://hso.research.uiowa.edu/ui-investigator%E2%80%99s-guide)***of consent (either no subject signature or no written document)?*** |
|  |  | No |

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|  | **VII.D.19** | ***Before the subject gives consent to participate are there any screening questions that you need to directly ask the potential subject to determine eligibility for the study?*** |
|  |  | No |

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|  | **VII.D.25** | ***After the subject agrees to participate (signs consent), are there any screening procedures, tests, or studies that need to be done to determine if the subject is eligible to continue participating?*** |
|  |  | No |

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|  | **VII.D.27** | ***Discuss how much time a potential subject will have to agree to consider participation and whether or not they will be able to discuss the study with family/friends before deciding on participation.*** |
|  |  | The potential subject can have as much time as needed to consider participation. If they do not want to decide that day, they can take home the consent form and choose to be approached again at a future visit. |

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|  | **VII.D.28** | ***How long after the subject agrees to participate do study procedures begin?*** |
|  |  | Study procedures can begin as soon as the participant has agreed to participation. |

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|  | **VII.D.29** | ***Provide a description of the enrollment and consent process for adult subjects**** ***Describe each study population separately including control population***
* ***Include when recruitment and consent materials are used***
* ***Use 3rd person active voice “The Principal Investigator will identify subjects. For example, the principal investigator will identify potential subjects, the study coordinator will discuss the study with subjects over the telephone and schedule the first study visit, etc...”***
* ***Describe the steps that will be taken by the research team to minimize the possibility of coercion or undue influence during the consent process***
 |
|  |  | Individuals are screened by a research team member for basic demographic and eligibility criteria including gestational age, birth weight and complications of the pregnancy. Infants and their parents and siblings may be invited to participate in the study. If other family members are expected to visit the hospital and the mother thinks they would like to participate, a consents and spit kits may be left in the room for them. The family members may then decide if they would like to participate. If they have questions, a contact number of a research team member will be made available to answer those questions. The research team member will return a day or two later to collect the consents and spit kits after the family members have made their decision to participate or not. Attempts to contact/consent other family members at home will not be made. When a parent is approached by a research team member, they are given a copy of the Consent Summary document and Informed Consent Document. The researcher will review the elements of consent with them and answers any questions. They can take as much time as needed to review the consent to minimize coercion.If the family is not in the subject's room at the time a research team member attempts to approach them, a flyer (see 'Biorepository Study Flyer' attached) may be left in the subject's room. On the flyer is a QR code and link to a Redcap consent summary and e-consent. (URL for e-consent: https://redcap.icts.uiowa.edu/redcap/surveys/?s=HN4MXWHA44EDM49M). The flyer also gives them the name of a team member should they have any questions or want to discuss the study before consenting. For families that receive a flyer, a follow-up phone call or email will be sent (see 'Follow-up of Interest After Leaving Flyer' and 'Follow-up of Interest Final Attempt' attached) up to two times asking if they are interested in the study and/or if they have any questions. If the family indicates they are not interested, no further contact is made. This method of approaching families will only be used if the subject's left over biological sample is the only sample being obtained and only the subject's chart will be accessed for clinical information. If other family members' samples are wanted, the protocol outlined in paragraph 1 will be implemented.Often, families are enrolled in other NICU studies that have collected biospecimens. If it has been determined that there is leftover sample in other studies that are IRB approved to share samples with other studies, the family may be contacted via email to see if they will consent to the biorepository and allow their baby's leftover sample be added to the biorepository. See 'Email for Econsent to biorep to use leftover sample for those enrolled in other studies' attached. There is no follow-up if the family decides not to consent to the biorepository.Occasionally, the best time to approach a family may be after the baby's discharge from an inpatient unit, during a follow-up clinic visit. This is accomplished by tracking families after discharge and noting their scheduled clinic appointments. The family is approached by a research team member in the clinic at their regularly scheduled appointment. In the case of virtual follow-up visits, the study/consent discussion will take place by phone and a consent will be mailed. A cover letter, two consents and consent summary documents (one copy for the subject to keep for their records) and a self-addressed, stamped envelope will be sent to the subject(s). Should the subject(s) agree to participate, they will send the signed consent in the supplied envelope. If the consent is not returned, no follow-up attempts will be made. The consent will be signed at the subject's home and sent back should they chose to participate. If the subject choses not to participate or does not wish to be contacted again, they can communicate their request via the contact number/email in the cover letter and/or choose to not send back the consent.Occasionally, only one parent accompanies the subject to a clinic visit. In this case, a separate consent, consent summary document and DNA kit may be sent home for the parent not at the visit. The at-home parent will have the option to participate. A padded self-addressed, stamped mailer will be sent with the kit and consent for the parent at home or it may be brought back at the next clinic visit. If the consent is not returned, no follow-up attempts will be made. The consent will be signed at the subject's home and sent back should they chose to participate. If the subject chooses not to participate or does not wish to be contacted again, the parent can communicate their request via the contact number/email in the cover letter and/or choose to not send back the consent.Families may also be referred by a colleague from other studies, such as those that follow women during pregnancy. The colleague would make the team aware of the potential subject and the research team would contact the potential subject and invite them to be in the repository, in this case, upon the birth of her child. The subject would be given as much time as they need to decide if they would like to be part of the repository. Once these families are referred to us we will wait until delivery at which time we will approach her to ask if she is interested in the repository. No data will be collected prior to consenting the mother after the birth of her child.For family members physically in hospital when approached by a research team member, one consent will be used for parent(s) and up to three minor children. In the case of multiple births, all children will be consented. On this consent, there are areas for the mom and/or dad to print and sign their name(s) when consenting for themselves to be in the study. Minor children name(s) will be printed on the consent and minors 13-17 years of age will also sign the consent. Children 7-12 will sign an assent, not the consent. Either parent may consent for their child(ren) and complete this by signing the consent a second time below their children's names. For families that have more than three minor children, a second consent will be used following the process described above. The research team member obtaining the consent will record the family id number on the consent page. This is a unique family identifier created by the lab. This number will also be placed on the samples to keep personal identifiers from being on the samples.In rare cases we may need to ask for more sample from a subject that has turned 18 since their initial enrollment (no longer a minor). A research team member will attempt to contact the subject by letter (see 'Letter to reconsent minors turning 18.docx') to ask for another sample, explaining that because of the number of studies relating to pregnancy and the newborn, more sample would further studies. If the subject agrees to provide more sample (i.e. they send letter back), a research team member will contact them via the phone number/email that the subject provided on the contact letter. The research team member will discuss the repository and review the elements of consent. Consent forms and consent summary documents will be mailed to potential subjects to review, sign and return. A second copy of the consent and consent summary documents will be provided for the subject to keep for their records. If agreeable with the subject, biological sample kits will be sent to the subject at the same time as the consent document. A self-addressed stamped envelope will be provided for the mailing of the consent and saliva sample. A consent document unique to this population will be used ('Adults Previously Enrolled as Minors'). A cover letter will accompany the saliva kits and consents (Cover.Letter.for.Samples.Re-Consent.Minors.Turning18). There are checkboxes on the signature page of the consent document indicating whether consent was obtained somewhere other than the UI; if so, then no research study member will sign the form. After two weeks, if the kits and/or consents are not returned, 2 follow up phone calls/emails will be made one week apart to remind the subject to send the consent and/or kits. If consent is never obtained but the sample is sent back, the sample will be destroyed. If the subject chooses not to provide an additional sample, they can mark this option on the contact letter and send it back. If there is no response to the initial letter, no further contact attempts will be made. |

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|  | **VII.D.30** | ***Describe how you will obtain the consent of the parents or legal guardians for child/minor subjects in this study**** ***Describe each study population separately including control population***
* ***Include when recruitment and consent materials are used***
* ***Use FIRST person, and provide detail as to order of events***
* ***Describe the steps that will be taken by the research team to minimize the possibility of coercion or undue influence during the consent process***
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|  |  | For family members physically in hospital when approached by a research team member, one consent will be used for parent(s) and up to three minor children. In the case of multiple births, all children will be consented. On this consent, there are areas for the mom and/or dad to print and sign their name(s) when consenting for themselves to be in the study. Minor children name(s) will be printed on the consent and minors 13-17 years of age will also sign the consent. Children 7-12 will sign an assent, not the consent. Either parent may consent for their child(ern) and complete this by signing the consent a second time below their children's names. For families that have more than three minor children, a second consent will be used following the process described above. The research team member obtaining the consent will record the family id number on the consent page. This is a unique family identifier created by the lab. This number will also be placed on the samples to keep personal identifiers from being on the samples.Occasionally, the best time to approach a family may be after the baby's discharge from an inpatient unit, during a follow-up clinic visit. This is accomplished by tracking families after discharge and noting their scheduled clinic appointments. The family is approached by a research team member in the clinic at their regularly scheduled appointment. In the case of virtual follow-up visits, the study/consent discussion will take place by phone with a parent and a consent will be mailed. A cover letter, two consents (one copy for the subject to keep for their records) and a self-addressed, stamped envelope will be sent to the subject's parent. Should the subject's parent agree to have their child participate, they will send the signed consent in the supplied envelope. If the consent is not returned, no follow-up attempts will be made. The consent will be signed at the subject's home and sent back should they chose to participate. If the subject choses not to participate or does not wish to be contacted again, the parent can communicate their request via the contact number/email in the cover letter and/or choose to not send back the consent.If the researcher keeps missing the family, a flyer may be left in the subject's room or handed out at a clinic visit. The flyer has a QR code and link to an e-consent where a parent will consent for the minor subject. (see 'Biorepository Study Flyer' attached) Siblings, except in the case of multiples, will not be consented via e-consent. This will be done in cases where only the subject's leftover biological sample and clinic data is being obtained. The flyer gives them the name of a team member should they have any questions or want to discuss the study before consenting. For families that receive a flyer, a follow-up phone call or email will be sent (see 'Follow-up of Interest After Leaving Flyer' and 'Follow-up of Interest Final Attempt' attached) up to two times asking of they are interested in the study and/or if they have any questions. If the family indicates they are not interested, no further contact is made.If the family is enrolled in other NICU studies that have collected biospecimens and there is leftover sample in other studies that are IRB approved to share samples with other studies, the family may be contacted via email to see if they will consent to the biorepository and allow their baby's leftover sample be added to the biorepository. See 'Email for Econsent to biorep to use leftover sample for those enrolled in other studies' attached. There is no follow-up if the family decides not to consent to the biorepository.Families will have as long as they desire to decide whether they want to be in the study or not. |

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|  | **VII.D.31** | ***What are the plans for the assent process for children/minors in this study? (You may choose more than one procedure if you have different child populations in your study)*** |
|  |  | * Children/minors will sign an assent or consent document -
* No assent procedure because some or all of the children/minors do not have the capability to assent or their capability is so limited that they cannot reasonably be consulted to provide assent -
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|  | **VII.D.36** | ***Provide a detailed description and rationale for each of the procedures chosen above and describe the child/minor populations to which they apply in your study.*** |
|  |  | Infants and young children are too young to sign anything, therefore children under the age of 7 will not assent.Children aged 7-12 will sign an Assent document, as well as be consented by their parent on the main consent document.Children aged 13-17 will sign the main consent document along with their parent. |

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|  | **VII.D.37** | ***Does the study include any form of deception (e.g., providing participants with false information, misleading information, or withholding information about certain study procedures)?******Examples:**** ***Procedure includes a cover story that provides a plausible but inaccurate account of the purposes of the research.***
* ***Participants will be provided with false information regarding the particular behaviors of interest in the research.***
* ***Procedures include a confederate pretending to be another participant in the study.***
* ***Participants will be told that the research includes completion of a particular task, when in fact, that task will not be administered.***
* ***Study is designed to introduce a new procedure (or task) that participants are not initially told about.***
* ***If yes, a waiver of informed consent must be requested under question IV.3.***
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|  |  | No |

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VII.E. Project Description (E)

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|  | **VII.E.1** | ***Will subjects be randomized?*** |
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|  | **VII.E.3** | ***Will any questionnaires, surveys, or written assessments be used to obtain data directly from subjects in this study?*** |
|  |  | Yes |

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|  | **VII.E.4** | ***List all questionnaires, surveys, written assessments and ATTACH each one to the application. (NOTE: You are NOT prohibited from attaching copyrighted materials to this application)*** |
|  |  | Interview\_Tool\_Pregnancy\_Hx\_and\_Hx\_of\_Prematurity |

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|  | **VII.E.5** | ***Does this project involve creating any audiotapes, videotapes, or photographs?*** |
|  |  | No |

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|  | **VII.E.6** | ***Provide a detailed description in sequential order of the study procedures following the consent process - DO NOT cut and paste from the Consent Document.Describe study populations separately if they will be participating in different procedures - include CONTROL population if applicable.DESCRIBE:**** ***What subjects will be asked to do/what happens in the study (in sequential order)***
* ***The time period over which procedures will occur***
* ***The time commitment for the subject for individual visits/procedures***
* ***Long-term followup and how it occurs***
 |
|  |  | Subjects will be recruited from the University of Iowa either during their initial visit or during a follow-up appointment. Since both parents may not always be available at the hospital stay and/or follow-up visit, a parent may take home a consent/spit kit and mailer to send the sample back. Or the parent may bring the signed consent/spit kit to next appointment. Subjects will be linked to all data by ID numbers. Families are given unique family IDs and then each family member is given a unique number within their family. Data to be collected by a physician or research assistants specifically for this study may include: 1) biological samples (leftover samples will be used when possible including those leftover from IRB 202003669 where consent has been obtained), 2) family history data to create pedigree structure, and 3) demographic, maternal and child health exposures and outcomes extracted from a medical chart review and questionnaire.After obtaining proper consent, the research assistant may conduct the interview to collect family history, health habits and obtain samples where leftover samples are not available. The entire process for the subject will take about 30 minutes.Blood samples can be collected during the mother’s and child’s hospital stay or at outpatient visits. As much as possible, blood sample collection for any subject will be coordinated with other laboratory testing blood draws to minimize trauma to the subject, including use of leftover samples that would otherwise be discarded. Other biological samples will include cord blood (collected at delivery when possible), fecal samples from the baby, urine samples from the baby, and blood and/or saliva samples for DNA from family members. Some samples taken from clinical procedures performed at UIHC will be collected by study personnel and stored prior to the subject's consent, as these samples have limited availability or would have been discarded otherwise (e.g. cord blood, fecal sample, urine, leftover specimens from clinically indicated labs, etc.). Unconsented samples will be stabilized and stored in the lab, not processed or tested, until consent is obtained. Stored, unconsented samples will be discarded after nine months, or earlier if consent is declined. For subjects under four, or those who are unable to produce adequate saliva through spitting, we will collect saliva using cheek swabs.Family history information related to pregnancy related conditions may be collected during an interview, in person by a research team member. This information will be used to create a pedigree in the database.Hospital records will be reviewed and data abstracted into the study database by the PI or research assistant, and can be done simultaneously with other data collection. Over 350 variables will be extracted from medical charts including: demographic data such as name, address, DOB, race/ethnic background, occupation, education, other measures of SES; maternal health information about the pregnancy such as prenatal diagnostic tests, due date information, health conditions of the mother, prenatal medications, cervical cerclage information, labor and delivery outcomes; and neonatal outcomes such as birth information, complications and discharge information are collected from the UIHC chart or other medical record from the institution providing care to the subject. Maternal and infant labs associated with pregnancy will also be collected such as blood type, glucose monitoring, bilirubin values and sepsis lab results. Mother's medical history both her general conditions and conditions due to pregnancy will also be collected. We will access the medical record indefinitely (while IRB is open) as we may need to obtain follow-up data on children (and mothers who delivered preterm or with complications) to identify contributors to later life health risks associated with preterm birth.We will access the hospital's High Risk Infant Follow-Up/Vermont Oxford Database to collect subject characteristics and outcome data. We also access newborn screening test values available from the State of Iowa Hygienic Lab, as only the newborn screen result of positive or negative is available as part of the medical record. We would only retrieve data from these sources on subjects who were consented and enrolled in this study.Subjects may be asked to undergo non-specific lab tests, including but not limited to thyroid function tests and lipid panels. This may be an additional lab draw (1 teaspoon of blood) for subjects which we have no existing blood sample. Blood draws and tests may be performed at an UIHC private clinic or by the subject's local clinician/certified technician. Charges and shipment arrangements, if applicable, for these potential tests will be the responsibility of the study and paid by MFK or pcard.Data/samples may be SHARED WITH collaborators or a scientific repository. Collaborators use the following redcap database link to formally make a request for data and/or samples: https://redcap.icts.uiowa.edu/redcap/surveys/?s=RFENXFCL9TJKY9PW. (see SampleandDataRequest\_Biorepository Redcap attached). This Redcap asks for a project description, IRB number if applicable, and the attributes of the samples and data requested. All requests are reviewed by the Biorepository Steering Committee which meets monthly. A fee structure may be shared with the collaborators to cover the costs of supplies and labor to aliquot the samples depending on the number of samples requested. If identifiers on data and/or samples are requested, the collaborator will need IRB approval first. If de-identified data/samples are requested, no IRB approval is needed. Please refer to 'Usage and Confidentiality Agreements Table' which outline what is required in various scenarios.Samples/data will be de-identified unless the collaborator(UI) has their own IRB protocol approval to use these samples. Non-UI collaborators will only receive de-identified, coded data, with the Momany/Dagle lab retaining the link to identifiers. Any clinical or biological data obtained by collaborators using de-identified or identified data and specimens will be shared back with the NICU and Pediatric biorepository to supplement existing data, and will be available for use by other investigators using the repository. If the recipient investigator (UI or non-UI) agrees to the conditions of the 'Usage Agreement (De-identified)'(attached), the Repository PI and Recipient PI will sign the usage agreement allowing the recipient PI to use de-identified samples and data from the repository without separate IRB approval.If the recipient investigator (UI only) requesting identified samples/data agrees to the conditions of the 'Usage Agreement (Identified)' (attached), the Repository PI and Recipient PI will sign the usage agreement allowing the recipient PI to use identified samples and data from the repository, the approval memo of the recipient PI will be attached to this IRB and a change to VII.E.6 will mention the recipient investigators research project. This IRB change will allow the IRB to check the Recipient Investigator's IRB to make sure the identified samples/data can be received from the repository.For investigators at non-UI institutions, samples/data sent TO the repository will be de-identified and a 'Confidentiality Agreement (non-UI collaborator)' (attached) will be signed by both the collaborating investigator and the repository investigator. The collaborating investigator will also supply a copy of their institution's IRB approved Inform Consent Document to be kept on file with the repository investigator. Samples will be sent as DNA or the raw sample and DNA extraction will be done in the Momany-Dagle laboratory. No further IRB approval will be necessary.For investigators at UI institutions, samples/data sent TO the repository will be identified and a 'Confidentiality Agreement (UI collaborator)' (attached) will be signed by both the collaborating investigator and the repository investigator. The collaborating investigator will also supply a copy of their institution's IRB approved Inform Consent Document to be kept on file with the repository investigator. These samples must be identifiable to eliminate duplicate samples from one individual in the repository. Without the identifiers, the two samples may mistaken as being from two different subjects. Since this is a genetic based repository, the identities of the subjects is crucial. Samples will be sent as DNA or the raw sample and DNA extraction will be done in the Momany-Dagle laboratory. No further IRB approval will be necessary.A table outlining the above scenarios is attached: 'Usage and Confidentiality Agreements Table'.Subjects consented in the 'Preterm Transfusions: Brain Structure and Function Outcomes Study' (IRB #201211734, IRB approval memo attached), may also have consented samples in the biorepository. Usage Agreements have been completed to allow the sharing of identified biorepository samples and data of subjects consented in the Preterm Transfusions study.Additional follow-up to obtain more saliva samples from enrolled subjects may occur by contacting the individuals by mail or at a follow-up clinic visit. By Mail: A letter (2015.10.15 Letter to ask for additional sample.doc OR 2018.11.29 Letter to ask for additional sample) will be sent to the subject or subject's parent which asks if they would be willing to provide an additional saliva sample (approx. 1 teaspoon) by spitting in the saliva collection kit. Sponge swabs may be used for small children unable to spit. The subject can choose whether or not they wish to provide a sample. A postage paid self-addressed envelope will be provided to send back the letter. If the letter is not returned, no additional attempts to contact the subject will be made. If the letter is returned and the subject is willing to provide a sample, a spit kit and self-addressed paid envelope will be sent to the subject. If the kit is not returned in two weeks, a follow-up call/email will be made to remind the subject once a week for the next 2 consecutive weeks. If the kit is still not returned, no further attempts will be made. If the letter is returned and the subject is not willing to provide a sample, no further attempts to obtain a sample will be made. Follow-up Clinic Visit: the subject will be approached in the clinic by a research team member. The research team member will introduce themselves and remind the subject of their repository enrollment. The subject will be asked if they are willing to provide another saliva sample. If yes, the research team member will collect the spit in a spit kit. If no, the subject will be thanked and no further attempts to collect a sample will be made. Collecting additional sample from an enrolled subject would rarely be executed, but could potentially happen 1-2 times after the initial sample collection at enrollment.Follow-up that does not require additional contact with study participants such as future medical records abstractions may occur at any time.In rare cases we may need to ask for more sample from a subject that has turned 18 since their initial enrollment (no longer a minor). Saliva collection kits will be sent to the subject at the same time as the consent document. A self-addressed envelope will be provided for the mailing of the consent and saliva sample. This process will take less than an hour. After two weeks, if the kits and/or consent are not returned, 2 follow up phone calls/emails will be made one week apart to remind the subject to send the consent and/or kits. If the consent is never obtained, the sample will be destroyed. If they choose not to provide an additional sample, they can mark this option on the contact cover letter and send it back. If there is no response to the initial letter, no further contact attempts will be made.Additional follow-up that requires additional contact with subjects for new studies will occur under a new IRB approval. |

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|  | **VII.E.7** | ***Will you attempt to recontact subjects who are lost to follow-up?*** |
|  |  | No - followup is not required in this study |

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|  | **VII.E.9** | ***Will subjects be provided any compensation for participating in this study?*** |
|  |  | No |

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VIII. Risks

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|  | **VIII.1** | ***What are the risks to subjects including- emotional or psychological- financial- legal or social- physical?*** |
|  |  | The physical risk for a blood draw is pain or bruising at the site, or rarely an infection. Collecting a saliva sample may make a subjects' mouth dry for a short time.There is a risk that confidentiality may be broken. If we find evidence that someone is a carrier of a form of a gene that causes a specific disease under study, we reserve the right to consult with the IRB regarding medically significant genetic findings to determine if informing the patient is warranted. If it is determined that someone is a carrier of a form of a gene that causes a specific disease, there is a risk that they could have increased anxiety or stress, because the results may be unclear or disturbing. Once genetic information is entered into an electronic research network/data repository there is a risk that someone might be able to use the data bank information to identify an individual. |

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|  | **VIII.2** | ***What have you done to minimize the risks?**** ***If applicable to this study ALSO include:***
	+ ***How you (members of your research team at Iowa) will monitor the safety of individual subjects.***
	+ ***Include a description of the availability of medical or psychological resources that subjects might require as a consequence of participating in this research and how referral will occur if necessary (e.g. availability of emergency medical care, psychological counseling, etc.)***
 |
|  |  | To minimize risk from a blood draw, we will coordinate blood draws for research with clinical blood draws as much as possible or use leftover samples already collected. Blood samples will be collected by RNs, MDs, or certified phlebotomists.In order to maintain confidentiality, documentation will go into the subject's UIHC electronic medical record as a record of participation in the research study and as a risk reference for health care workers. The Informed Consent Document will be kept in a research file. Other security measures to protect subject identities include the use of coded files to distance research records from names and identifiers,locked storage areas, and password-protected computer files. Access to computer systems housing sensitive information will be strictly regulated. Credentials permitting access to said systems will be granted only to participating investigators and essential administrative personnel. All systems are secured from external attack through a combination of hardware and software firewalls, and are updated with necessary security patches as they become available. Related hardware and backup media are maintained in a secure environment to which only essential personnel have physical access. Limited remote access is available to qualified personnel over encrypted channels using Secure Shell (SSH) with MIT Kerberos authentication. We have obtained a Certificate of Confidentiality to provide an additional layer of data security. To minimize psychological risks only licensed health care professionals who are either part of the research team or are the subject’s personal care providers will interact with the subjects if results need to be shared with subjects or in cases where the subject has concerns or questions about the research and their involvement. Research team members will maintain a discreet and courteous demeanor while interacting with the subject family.Access to data placed in a scientific research data bank is limited to qualified medical researchers. The data bank would have its own computer security protection systems in place. Personal identifiers are removed from data that is shared with collaborators or an electronic research data bank. |

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IX. Benefits

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|  | **IX.1** | ***What are the direct benefits to the subject (do not include compensation or hypothesized results)?*** |
|  |  | There are no direct benefit for subjects to participate in this study. |

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|  | **IX.2** | ***What are the potential benefits to society in terms of knowledge to be gained as a result of this project?*** |
|  |  | Hopefully, this biobank will expedite research related to maternal and child health. |

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X. Privacy & Confidentiality

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|  | **X.1** | ***What are you doing to protect the***[***privacy***](https://hso.research.uiowa.edu/ui-investigator%E2%80%99s-guide)***interests of the subjects?*** |
|  |  | Privacy interests are protected by following the procedures set up for the study, which specify how people are contacted and the data collected. When contact with a subject occurs in the hospital, they are approached in a patient or clinic room. Care is taken to assure minimal interruptions during the study discussion. Subjects have the right to not answer any study question asked of them. |

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|  | **X.2** | ***Are you collecting the Social Security Number of any subjects for any purpose?*** |
|  |  | No |

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|  | **X.4** | ***How will information/data be collected and stored for this study (check all that apply):*** |
|  |  | * Biologic samples (blood draws, check swabs, saliva samples, tissue samples, etc.) - Samples are kept in the Momany/Dagle Lab and logged into a secure database. Logging in samples includes labeling them with coded ID numbers, which are then used for identifying samples and information created from those samples.
	+ Name - Nancy Weathers
	+ Title - Research Support Manager
	+ University Job Classification - Faculty/Staff
* Paper/hard copy records (hard copy surveys, questionnaires, case report forms, pictures, etc.) - Paper copies of study data are kept in locked files and/or locked office. Transport of hard copies is done in a manner which protects the confidentiality of the subject, such as within unmarked folders.
* Electronic records (computer files, electronic databases, etc.) - Electronic records are protected through limited access to the database and password protected programs. Electronic information is shared with the research team members on a secure, limited access shared drive.
	+ Name - Mike Frangi and Laurie Hafner-Dahms
	+ Title - System Administration and Senior IT Support Consultant
	+ University Job Classification - ITS Staff
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|  | **X.5** | ***Do the confidentiality protections indicated above allow only members of the research team to access the data/specimens?*** |
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|  | **X.6** | ***Describe*** |
|  |  | Data/samples will be shared with collaborators or a scientific repository. Samples/data will be de-identified/coded, unless a UI collaborator has their own IRB protocol approval to access this study data. Non-UI collaborators will only receive coded data, with the Momany/Dagle Lab retaining the link to identifiers. |

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|  | **X.7** | ***Does your study meet the NIH criteria for a***[***Certificate of Confidentiality***](http://grants.nih.gov/grants/policy/coc/)***or will you be applying for Certificate of Confidentiality?*** |
|  |  | Yes |

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|  | **X.8** | ***If yes, provide rationale:*** |
|  |  | Due to the genetic component of this study, we currently have a COC. |

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XI. Data Analysis

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|  | **XI.1** | ***Describe the analysis methods you will use, including, if applicable, the variables you will analyze*** |
|  |  | Analyses conducted by the principal investigators (Dr. Dagle and Dr. Momany) and their team (named as personnel on this IRB) will continue to address the aims in their funded research projects that provide infrastructure and supplies for recruitment of these subjects. This includes examining genetic, metabolic, environmental and clinical predictors of gestational age, preterm birth and complications of prematurity including patent ductus arteriosus, intraventricular hemorrhage, respiratory distress syndrome, bronchopulmonary dysplasia, retinopathy of prematurity and persistent pulmonary hypertension in the newborn. Appropriate statistical analysis methods will be used including but not limited to logistic regression, linear regression and other statistical modeling procedures.For investigators (within or outside the University of Iowa) requesting samples from the repository (and not named as key personnel on this application) there will be no analysis done under this protocol. Data given to these investigators will be de-identified and a IRB is not required or if they request identifiers they will describe their analysis plan in that application. |

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|  | **XI.2** | ***Provide the rationale or power analysis to support the number of subjects proposed to complete this study.*** |
|  |  | Since the NICU and Pediatric Repository is not directed to any particular condition, but currently focuses on the collection of samples to study the genetics of preterm birth and complications of prematurity the more samples there are, the more likely there will be enough of any one condition for secondary studies to be done. Additionally, genetic studies require thousands of samples to detect the many genes of small effect associated with these conditions. |

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XII. Future Research

|  |  |  |  |  |  |  |
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| --- | --- | --- |
|  | **XII.1** | ***Do you wish to keep any information about subjects involved with this research project so that members of the current research team may contact them in the future for your own research projects?*** |
|  |  | Yes |

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|  |  |  |
| --- | --- | --- |
|  | **XII.2** | ***Do you wish to keep any information about subjects involved with this research project so that***[***other researchers***](https://hso.research.uiowa.edu/ui-investigator%E2%80%99s-guide)***may contact them for future research?*** |
|  |  | No |

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|  |  |  |
| --- | --- | --- |
|  | **XII.3** | ***List the data or information you will keep:*** |
|  |  | Address, phone number and email will be kept on a secure database for future potential contact. Only approved research team members will have access to the database. |

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|  | **XII.4** | ***Does this project involve storing any data, tissues or specimens for future research?*** |
|  |  | Yes – contribution for future use is mandatory for participation in the study |

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