CONSENT FORM

Title of Research:	South-seq: DNA sequencing for newborn nurseries in the South (NIH Grant Number 2U01HG007301-05)
Site:	Children's Hospital 200 Henry Clay Ave., New Orleans, LA 70118
UAB IRB Protocol #:	IRB-300000328
Principal Investigators:	Jessica Patrick-Esteve, MD
Sponsor:	NIH National Human Genome Research Institute (Contact: Lucia Hindorff PhD, MPH)

For Children (persons under 18 years of age) participating in this study, the term "You" addresses both the participant ("you") and the parent or legally authorized representative ("your child").

Purpose of the Research

We are asking you to take part in a research study. The purpose of this research study is to use whole genome sequencing (WGS), looking at your DNA, to identify the genetic cause of conditions like those observed in your child. For individuals with rare, undiagnosed diseases and their families, this experimental genetic test may provide information about what is causing the disease or condition. This information may be beneficial to your family in directing your child's health care, medical treatments, and your family planning decisions. Educational tools about your child's condition may also become available with a confirmed genetic diagnosis.

In addition, due to the limited number of genetic counselors available to support patients that may benefit from WGS, we will be comparing two results delivery methods: genetic counselors (standard of care), and healthcare providers (e.g. neonatologists and neonatology nurse practitioners) who undergo specific genetics results delivery training. In this clinical trial, we aim to demonstrate that both delivery methods are equivalent (i.e. there is no difference between the two methods).

Due to the experimental nature of this research study, data generated is based upon the knowledge currently accepted in the field. As more genomes are sequenced and as sequencing techniques improve, we will be better at identifying and understanding extremely rare variants (rare changes in DNA). In doing this, we will also improve and we will learn more about how certain variants may cause disease. For this reason, we plan to store samples for future research.

There will be approx. 1500 newborn participants enrolled for WGS and 800 parents and/or caregivers enrolled for the clinical trial across 5 NICU sites: UAB/Children's of Alabama, University of Mississippi Medical Center (UMMC), Woman's Hospital, University of Louisville and Norton Health (UofL) and Children's Hospital New Orleans. Samples will also be collected from biological mothers and fathers (up to 2,250 individuals), when available, so that we can use their samples to determine inheritance of any variants we find in their child. We also hope to include a diverse group of participants so we

are planning to offer this test to all populations, especially those underrepresented in science and genomic research such as African Americans and those from rural areas.

Explanation of Procedures

If you agree to join the study, you are agreeing to:

- Give us permission to collect a blood sample for DNA analysis
    - Adults will give approximately 8mL (approx. 1.6 tsp) of blood that will be drawn from the arm.
    - Newborns will give no more than the maximum amount allowed for their body weight according to the Children's Of Alabama guidelines.
- Give us permission to fully analyze your DNA (or other related material, like RNA or protein) and determine the health significance of your genetic results.
- Allow us to return health information to you that we feel may be important to your child's health or other biological relatives.
- Allow key study personnel to access your child's personal medical records to aid in analysis. Study personnel may collect information about the child's symptoms, health history, medications/treatments, etc.
- Provide key study personnel with information about your child's health history, pregnancy and birth history, information about your health and that of other family members, if you know it, etc. Study personnel will not access your medical record. They will only have access to the information that you choose to share with them.
- Allow us, if you so choose, to return genetic results that are not related to your child's condition but are medically important for other reasons.
- Answer survey questions at the time of consent, return of results (ROR), 1-month post ROR, 4-months post ROR, and 4.5-months post ROR that will take approximately 20-35 minutes to complete.

You will be asked to take part in two clinic visits here in the nursery or at the outpatient clinic. During the first visit, you will be asked to enroll in the study and give a blood sample (1.5hrs) and during the second visit you will receive the results of your child's DNA test either by a genetic counselor or a trained healthcare provider (1.5-2hrs). The return of results visit can either take place in-person or over the phone. A certified letter with results will be sent to those who do not participate in either in the in-person or phone ROR appointment.

More than one parent/guardian/caregiver of a child receiving WGS can participate in the study. It is important that anyone participating in the survey portion of the study be present at ROR and complete every survey.

Collecting samples from both biological parents increases the chances of identifying genetic variation in your child that might be causing his or her symptoms. However if both parents are not available, we can still analyze eligible patients and potentially find valuable information. In cases where we enroll family members, our DNA test can identify whether a person is the biological parent or not. We will not tell you or your family members if we find out that one or both parents

are not biologically related to the child, however we are less likely to discover diagnostic information about your condition without both biological parents.

Your blood samples will be labeled with a unique code (coded) and sent to researchers at the HudsonAlpha Institute for Biotechnology, a non-profit genetics research center located in Huntsville, AL. Some relevant, health information will also be given to the research staff, and coded with a unique study identifier, to aid in their analysis.

We will use state-of-the-art technologies to generate large amounts of information about the DNA from you and your child. A group of experts, including medical doctors and researchers, will use scientific findings and genetic databases to help decide what genetic information may be important to the health of your child. The sequence of all results believed to be medically relevant or important to your child's or your own health will be validated at HudsonAlpha Clinical Services Laboratory in Huntsville, AL or another independent clinical laboratory. We expect the entire DNA analysis process to take 2-4 months.

We do intend to perform analysis of each sample within our budgetary and technical means. If we are unable to analyze your samples you will be notified within 6 months of enrollment and sample collection. There is no cause for concern if you are told that we could not complete the analysis and provide you with results.

Return of results is at the discretion of the clinicians and researchers involved with this study. If they identify results that may impact your child's health, they may return those results to you. You will be scheduled for an appointment to discuss these findings with a genetic counselor or trained healthcare provider. Only a subset of results believed to be important to your child's medical care or those in line with the goals of this study will be reported to you. We will not provide you with all of the genetic information that we generate. At your results appointment, you may be provided with information regarding:

- Primary findings - These findings will include information about a variant(s) (DNA change) that may potentially be the reason for your child's phenotype (symptoms) or condition.
    - Most children will not receive a primary finding (or diagnosis). If no diagnosis is found, we will tell you. Even if we do not find a genetic diagnosis, your condition may still be the result of a change in your DNA that we are currently unable to identify.
    - If you receive a genetic diagnosis, this may not change your child's prognosis or medical treatment. However it may help you and your doctor to better understand the cause of your child's condition and the risks of similar conditions affecting your biological children.
- Secondary findings – These findings may be reported to any study participant and may include any genetic changes that might impact your health or the health of your current or future children. These may include:
    - Whether there are any changes in your DNA that could put you at a higher risk for developing a disease unrelated to your child's condition in the future, such as cancer or heart disease.

1. Some of these diseases may be medically useful and some may not be medically useful. We will not return results that are not medically useful.
2. Some of these diseases will appear in childhood and others will appear when you are an adult.

- Carrier status – In the event that we discover that your child's symptoms are caused by a recessive genetic condition where he or she inherited one variant (DNA change) from each parent, we may provide information about whether or not you are a "carrier" for a genetic change that may be passed on to your biological children.

We will arrange for a genetic counselor or a trained healthcare provider to discuss the results of the test with you. Educational materials will also be made available to you to help you better understand any results that you may or may not receive as part of this study.

You will be actively enrolled in this study for up to one year however we may continue to access your medical record for up to 5 years. We plan to use coded information from our medical record to determine the impact of whole genome sequencing and genetic diagnosis on medical care. After you receive the results of the genetic test, you may be contacted by your physician or key study personnel to check on you or to ask follow-up questions. Your DNA samples may be stored indefinitely for future research unless you choose to withdraw from the study. Please note that participation in this study is voluntary and you may withdraw from this study at any time.

You will also be presented with a baseline survey at the time of enrollment that you can complete online using Genome Gateway. The survey will ask you questions about basic demographics, how you feel about your child's health and your experience in the hospital, how well you understand medical terms, math and genetics. After you receive results from this testing, you will be asked some of these same questions and some additional ones related to your health, your understanding of the genetic results returned, and how the results influence future life planning at 1-month post ROR, 4-months post ROR, and 4.5 months post ROR.

Risks and Discomforts

The risks of drawing blood include pain, bruising, lightheadedness, and fainting. Infection at the site of the needle stick is a rare side effect. These are the same risks you face any time you have a blood test.

The main concerns associated with genetic testing are anxiety, depression, or other forms of emotional distress that may result from receiving genetic information about the suspected cause of your child's condition. This is especially true for those diseases that are not treatable or preventable. Though some treatments have been shown to help individuals with certain genetic conditions, there is no "cure" for most.

When performing genetic testing, it may be discovered that family relationships are not as predicted. For example, a child might not be biologically related to his/her father, or two people who are married might turn out to be biologically related. These findings will not be disclosed as part of this study.

In some cases, you may receive information about your carrier status and/or changes in your DNA that may impact your health. These findings will only be returned if they were inherited by your child who is enrolled in this study and suspected to contribute to their condition. Genetic changes in children that affect development may be inherited from one or both parents, even if the parents appear to be healthy. This information may affect the way you view or evaluate yourself or your family. It may also influence, or generate anxiety about, future family planning decisions.

It is also important to keep in mind that you and your biological relatives have similar DNA sequences. This means that genetic information about your child may also have implications for your relatives if the variation was inherited.

You may be referred to an additional physician or clinic for further testing or advice depending on the type of genetic information we generate from your sample. If you experience psychological distress or other difficulties, we can also refer you to an appropriate resource for care and/or support.

There may be unforeseeable risks associated with receiving genetic information and the potential decisions, actions, or inactions that may be required in response to that information. Please consider this carefully and ask any questions that you may have before deciding whether or not to participate in this study.

It is important that you consider the risks and uncertainties of this research study that make it different from traditional medical testing.

We will make sure that the information that you are given is as accurate as possible to the best of our ability. We will use the best standards, practices, and technologies available to researchers. However, the technologies available to analyze DNA and our knowledge of how DNA affects health are changing rapidly. They are also subject to much uncertainty. Some DNA changes that are important to health may be missed, and other DNA changes that are not important may be incorrectly identified as if they are important. There are also moral and ethical questions about using genetic information on which scientific and medical communities have not yet reached a consensus. Therefore, we do NOT guarantee that our test will have the same levels of completeness, accuracy, or standardization associated with more traditional medical tests.

Before offering your consent to participate in this research study, please consider all of the risks associated with:

- The return or possible lack of return of results;
- Whether our interpretation of those results is accurate;
- How you and/or your family will choose to act upon or not act upon the information or lack of information.

Benefits

You may not benefit directly from taking part in this study. However, your participation may lead to new discoveries that help to advance medical research and improve patient care, especially, but not only, newborn patient care in the future. Your participation in this study may help to make health care and access to health care broader and more representative.

You may find out if there is a change in your child's DNA that has altered their development. You might also find out if this change could affect future biological children.

A genetic diagnosis may help you connect with other families in the community who face similar medical problems. While unlikely, it is possible that a genetic diagnosis may point your doctor to a better medical and/or educational treatment.

You may discover that you or your child are at an increased risk for developing other diseases and that information may be of medical benefit.

None of the above benefits are guaranteed, and it is expected that many participants will not receive specific information that is relevant to their health.

Alternatives

This is not a treatment study. Your alternative is not to participate in this research study.

Confidentiality

Information obtained about you for this study will be kept confidential to the extent allowed by law. However, research information that identifies you may be shared with people or organizations for quality assurance or data analysis, or with those responsible for ensuring compliance with laws and regulations related to research. They include:

- the UAB Institutional Review Board (IRB). An IRB is a group that reviews the study to protect the rights and welfare of research participants.
- Louisiana State University Health Sciences Center-New Orleans IRB
- Children's Hospital New Orleans IRB
- the NIH National Human Genome Research Institute (NHGRI)
- the Office for Human Research Protections (OHRP)

The information from the research including your child's clinical information, family history, and genetic variants may be published for scientific purposes; however, your identity will not be given out to anyone outside of the clinical team involved with the study.

Your consent form will be placed in your child's medical record at Children's Hospital New Orleans. This may include either a paper medical record or electronic medical record (EMR). An EMR is an electronic version of a paper medical record of your care within this health system. Your child's EMR may indicate that you and your child are enrolled in this study and provide the name and contact information for the principal investigator.

Results of research tests or procedures that have been clinically validated (i.e. Sanger reports) may be placed in your child's medical record. All information within your medical record can be viewed by individuals authorized to access the record.

Information relating to this study, including your name, medical record number, date of birth and social security number, may be shared with the billing offices of Children's Hospital New Orleans so costs for clinical services can be appropriately paid for by either the study account or by your insurance.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

A federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and some employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that we get from this research.
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

Be aware this federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance, nor does it protect you against genetic discrimination by some employers.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Louisiana law prohibits discrimination in employment or insurability based on your genetic information. Your genetic information is considered your property and no insurer or employer may obtain genetic information or a DNA sample without first obtaining your written consent. (LA Statute RS22:1023 and RS23:368).

Voluntary Participation and Withdrawal

Whether or not you take part in this study is your choice. There will be no penalty if you decide not to be in the study. If you decide not to be in the study, you will not lose any benefits you are otherwise owed. You are free to withdraw from this research study at any time. Your choice to leave the study will not affect your relationship with any institution participating in this study.

In the event that you chose to withdraw from the study:

- No further genetic information from the study will be reported to you.
- Your blood samples will be destroyed.
- You will not be contacted to provide new information, additional samples, or participate in additional studies related to this project.
- If the analysis of your DNA has been completed, this information will be retained for the study.

If you would like to withdraw from the study, please contact Dr. Patrick-Esteve at 504-896-9418.

Cost of Participation

There will be no cost to you for taking part in this study. The blood draw, genomic sequencing and analysis, and genetic counseling related to this study will be provided to you at no cost during the study period.

After you receive your research results, you may decide with your doctor or your child's doctor to get more testing. The costs of your standard medical care or any services rendered in response to a genetic finding identified by this research project will be billed to you and/or your insurance company in the usual manner. This type of follow-up medical testing will be considered part of your clinical care, and will not be paid for by the research study.

Payment for Participation in Research

Participation in this study is voluntary and $50 will be provided for each survey completed for a total of $300 for your completion of all 6 study-related surveys. Ask the study staff about the method of payment that will be used for this study (e.g., check, cash, gift card, direct deposit); payment may take up to 4 weeks to process.

Payment for Research-Related Injuries

UAB, UMMC, HudsonAlpha, UofL, Children's Hospital New Orleans/LSUHSC-NO, and NIH/NHGRI/sponsors of this research project have not provided for any payment if you are harmed as a result of taking part in this study. If such harm occurs, treatment will be provided. However, this treatment will not be provided free of charge.

Significant New Findings

The study doctor or study staff will tell you if new information becomes available that might affect your choice to stay in the study. Please note that HudsonAlpha may, but is not required to, reanalyze your sample or report any new findings after results have been returned.

Storage of Specimens for Future Use

As part of this study, we would like to store some of the blood and DNA specimens collected from you and your child for validation of variants (to determine if a variant was inherited from a parent, etc.) identified by this project and for future research relevant to rare disease or other genetic disorders. The future research may be conducted by the study doctor or by other researchers that obtain IRB approval for their research. The specimens will be labeled with a code that only the study doctor can link back to you. Results of any future research will not be given to you or your doctor. The specimens obtained from you in this research may help in the development of a future commercial product. There are no plans to provide financial compensation to you should this occur. You do not have to agree to allow your specimens to be stored in order to be part of this study.

You may at any time withdraw from the study and request that your specimens be removed from storage and not be used for future research. If you decide you want your specimens removed, you may contact Dr. Bruce Korf at 205-934-9411. Once the request is received, and if your samples have not already been used for other research, they will be destroyed. If you do not make such a request, your specimens will be stored indefinitely or until used.

Initial next to your choice below:

___ I agree to allow my specimens to be kept in the HudsonAlpha CSL and used for future genetics research.

___ I do NOT agree to allow my specimens to be kept and used for future research.

Genomic Data Sharing (GDS)

We consider the privacy of your information to be of high priority and will take a variety of steps to ensure that privacy. However, it is important for researchers to share some of the information that they learn from studying human samples. We will never share personally identifiable information, like names and addresses, with anyone outside of the research study. However, parts of your information may be shared.

Some of your genetic information, limited to a very small subset that will not cause privacy loss risks to you, may be published in scientific journals or other unrestricted-access public venues to encourage sharing of the knowledge that may be learned by analyzing your DNA and DNA from other individuals. This could include information about your child's symptoms, their age, and any genetic findings that we discover.

We may share coded lists of the DNA differences that we identify in public genetic databases. These databases gather genetic information from large groups of people and are pooled together such that no specific participant can be identified.

There is a very small chance that some commercial value may result from the use of your donated samples or genetic information. If that happens, you will not receive a share in any profits.

Unless you opt out, we may submit your complete genomic data along with some of your coded health information to an NIH-designated Data Repository such as dbGAP (http://www.ncbi.nlm.nih.gov/gap) , AnVIL (https://anvilproject.org/), or another controlled access database. Access to dbGAP is only available to qualified researchers at qualified institutions who have agreed to abide by certain privacy safeguards, obligating them, both legally and ethically, to protect your privacy and to maintain information confidentiality. However, since your genetic information is unique to you, there is a small chance that someone could trace your information back to you. This risk is very small, but may grow in the future. Some risks and benefits are listed below:

Risks: The risk of sharing your genomic data is that someone could link the information stored in the databases back to you. If your information suggests something about your health such as increased risk for disease, it could be misused. For example, it could be used to make it harder for you to get or keep a job or insurance or be used to discriminate against you or your family. There may also be other unknown risks. As stated above (confidentiality section of this form), there are federal protections against the misuse of your data (i.e. the Genetic Information Nondiscrimination Act, GINA).

Benefits: There is no direct benefit to you from sharing your genomic data with NIH-designated repositories, however allowing researchers to use your data may lead to a better understanding of how genes affect health which may help other people in the future.

Initial next to your choice below:

___ I agree for my genetic and other relevant study data, such as health information, to be shared with NIH-designated repositories such as dbGAP and AnVIL in a coded form for future research or analysis

___ I do NOT agree for my genetic and other relevant study data, such as health information, to be shared with NIH-designated repositories such as dbGAP and AnVIL in a coded form for future research or analysis

Contact For Future Research

As new research opportunities are identified, the researchers may wish to perform additional tests on fresh samples or invite eligible participants to enroll in new studies. We would like permission to contact you in the future, however this is not a requirement to participate in this study. A separate consent form will be obtained if you wish to participate in future research.

Initial next to your choice below:

___ You have permission to contact me about new research opportunities that may interest me.

___ You do NOT have permission to contact me about new research opportunities.

Secondary Findings

One unanimous decision to receive or not to receive secondary findings must be made by each participant family. Because parental samples are only used for confirmation of variation identified in the child's whole genome sequence for this project, only those secondary findings identified in the child will be confirmed in the parental samples. Participant families may opt to receive this information, if available. If a family chooses to do so, information about an identified secondary finding will be included in the child's medical record. Nothing will be placed in the parent's medical record.

Initial next to your choice below:

___ We (child and parent(s), if enrolled) would like to receive information about secondary findings.

___ We (child and parent(s), if enrolled) would NOT like to receive information about secondary findings.

Questions

If you have any questions, concerns, or complaints about the research or a research-related injury including available treatments, please contact Dr. Bruce Korf at 205-934-9411 or Dr. Patrick-Esteve at 504-896-9418.

If you have questions about your rights as a research participant, or concerns or complaints about the research, you may contact, Dr. Patrick-Esteve, at Children's Hospital, 200 Henry Clay Ave., New Orleans, LA 70118, jpatri@lsuhsc.edu, 504-896-9418. You may also contact the Chancellor of the LSU Health Sciences Center of New Orleans at (504) 568-4801 and Dr. Druby Hebert, Chairman of the Children's Hospital New Orleans IRB, at 504-899-9511.

Legal Rights

You are not waiving any of your legal rights by signing this consent form.

Signatures

Your signature below indicates that you have read (or been read) the information provided above and agree to have your child participate in this study. You will receive a copy of this signed consent form.

Your signature below indicates that you have read (or been read) the information provided above and agree to participate in this study. You will receive a copy of this signed consent form.

_____

Name of Proband Child (printed)

_____

Signature of Parent or Legally Authorized Representative Date

Mother/Father/Caregiver

_____

Name of Parent Participant (printed) Relationship

_____

Signature of Parent Participant Date

Mother/Father/Caregiver

_____

Name of Parent Participant (printed) Relationship

_____

Signature of Parent Participant Date

_____

Signature of Person Obtaining Consent Date

In this research study, one consent form may be used to waive consent for the infant and capture informed consent of both parents; however, a separate HIPPA Authorization form will be completed for each participant.

Waiver of Assent

The assent of _____ (name of child/minor) was waived because of:
Age _____ Maturity _____ Psychological state of the child _____

LOUISIANA STATE UNIVERSITY HEALTH SCIENCES CENTER

At New Orleans (LSUHSC-NO) and CHILDREN'S HOSPITAL

INSTITUTIONAL REVIEW BOARD/ADMINISTRATIVE REVIEW COMMITTEE

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AUTHORIZATION FOR USE AND DISCLOSURE OF PROTECTED HEALTH INFORMATION FOR RESEARCH PURPOSES – Proband

Title of Research Project: **South-seq: DNA sequencing for newborn nurseries in the South**

Name of Sponsor: National Institutes of Health (NIH) National Human Genome Research Institute
If applicable IRB Number: N/A

Principal Investigator: Jessica Patrick-Esteve, MD IRB or Protocol Number: new / ARC #new

I hereby request and authorize the LSUHSC-NO and/or Children's Hospital to use and disclose protected health information from the record(s) of:

Patient's Name/Address:

_____

Birth Date: ____/____/____

Specifically, I request and authorize any part of my health information relevant to the research project, identified above and in the Informed Consent document, to be used and/or disclosed to the Principal Investigator identified above or his/her designee, in connection with the research project. (NOTE: The following sentence may be deleted if not appropriate): I understand that this may include information relating to: Human Immunodeficiency Virus ("HIV") infection or Acquired Immunodeficiency Syndrome ("AIDS"); treatment for or history of drug or alcohol abuse; and/or mental or behavioral health or psychiatric care.

I specifically authorize the use and disclosure of the following PHI:
(Please provide a detailed description of the particular data and period of time you are requesting)

__X___Complete health record(s) for date(s) of service from date of birth to 5 years after study enrollment, which may contain all of the documents listed below, as well as other notes or documents relating to my treatment or hospitalization.
_____History and physical exam _____
_____Hospital Inpatient Records _____

_____Clinic/Outpatient Records_____
_____ Consultation reports _____
_____Laboratory test results_____
_____Radiology Reports_____
_____Pathology Reports_____
_____Discharge Summary_____
_____Progress Notes_____
_____Photographs, videotapes_____
_____X-Ray films/images, digital or other images_____
_____Diagnosis and Treatment Codes_____
_____Complete billing record_____
_____Other: _____

I understand that copies of the records indicated above will be:

- Used by employees of LSUHSC-NO and/or Children's Hospital including treatment providers, and/or other members of its workforce.

- Disclosed to LSUHSC-NO and/or Children's Hospital, government officials or government agencies, such as the Food and Drug Administration study sponsors, study monitors, or others responsible for oversight of the research project.

- Sent to collaborating researchers outside LSUHSC-NO and/or Children's Hospital if and to the extent indicated in the attached Informed Consent document(s).

I understand that by signing this form, I am allowing LSUHSC-NO and/or Children's Hospital and their researchers to use or disclose my health information in connection with the attached Informed Consent and for the purpose of the research that is described in the Informed Consent. For example, the researchers may need the information to verify that I am eligible to participate in the study, or to monitor the results, including expected or unexpected side effects or outcomes. Other University/Hospital and government officials, safety monitors, and study sponsors may need the information to ensure that the study is conducted properly. Also, I understand that my health information may be disclosed to insurance companies or others responsible for my medical bills in order to secure payment.

I understand that any privacy rights not specifically mentioned in this Authorization are contained in the Notice of Privacy Practices that I received or will receive from the Principal Investigator or at the facility that I attend.

I understand that I may revoke this authorization at any time, except to the extent that LSUHSC-NO and/or Children's Hospital has already relied on the authorization, by sending or transmitting of a facsimile, a written notice to the contact person listed in the attached Informed Consent document(s).

I understand that if my information already has been included in a research database or registry as described in the attached Informed Consent document(s), LSUHSC-NO and/or Children's Hospital considers itself to have relied on it, and therefore my information will not be removed from those repositories. Unless otherwise revoked, I understand that this authorization (_X_) will not expire or (___) will expire upon {date or event}_____. I understand that if I do not sign this form, I will not be able to participate in the above research study or receive the study-related interventions, but that LSUHSC-NO and/or Children's Hospital cannot otherwise condition treatment on my signing this form.

While the research study is in progress, my right to access any research records or results that are maintained by the facility may be suspended until the research study is over. If my access is denied, I understand that it will be reinstated at the end of the research study.

I understand the information disclosed by this authorization may be subject to re-disclosure by the recipient and no longer be protected by the Health Insurance Portability and Accountability Act. The LSUHSC and/or Children's Hospital facilities, their employees, officers, and physicians are hereby released from any legal responsibility or liability for disclosure of the above information to the extent indicated and authorized herein.

I UNDERSTAND THAT THIS AUTHORIZATION SUPERSEDES ANY CONTRARY INFORMATION IN ANY OTHER DOCUMENTS I HAVE SIGNED RELATED TO THE ATTACHED STUDY.

Signature of Patient or Patient's Legal Representative:_____
Date:___/___/___

Printed Name of Legal Representative (if any):
_____

Representative's Authority to Act for Patient (e.g., relationship to patient):
_____

Verification of Representative's Authority: ( ) viewed driver's license ( ) viewed Power of Attorney ( ) viewed other_____ (specify)

LOUISIANA STATE UNIVERSITY HEALTH SCIENCES CENTER

At New Orleans (LSUHSC-NO) and CHILDREN'S HOSPITAL

INSTITUTIONAL REVIEW BOARD/ADMINISTRATIVE REVIEW COMMITTEE

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AUTHORIZATION FOR USE AND DISCLOSURE OF PROTECTED HEALTH INFORMATION FOR RESEARCH PURPOSES – Biological Mother

Title of Research Project: **South-seq: DNA sequencing for newborn nurseries in the South**

Name of Sponsor: National Institutes of Health (NIH) National Human Genome Research Institute
If applicable IRB Number: N/A

Principal Investigator: Jessica Patrick-Esteve, MD IRB or Protocol Number: new / ARC #new

I hereby request and authorize the LSUHSC-NO and/or Children's Hospital to use and disclose protected health information from the record(s) of:

Patient's Name/Address:

_____

Birth Date: ____/____/____

Specifically, I request and authorize any part of my health information relevant to the research project, identified above and in the Informed Consent document, to be used and/or disclosed to the Principal Investigator identified above or his/her designee, in connection with the research project. (NOTE: The following sentence may be deleted if not appropriate): I understand that this may include information relating to: Human Immunodeficiency Virus ("HIV") infection or Acquired Immunodeficiency Syndrome ("AIDS"); treatment for or history of drug or alcohol abuse; and/or mental or behavioral health or psychiatric care.

I specifically authorize the use and disclosure of the following PHI:
(Please provide a detailed description of the particular data and period of time you are requesting)

__X___Complete health record(s) for date(s) of service from study enrollment to 5 years after study enrollment, which may contain all of the documents listed below, as well as other notes or documents relating to my treatment or hospitalization.
_____History and physical exam_____
_____Hospital Inpatient Records_____
_____Clinic/Outpatient Records_____
_____ Consultation reports _____

_____Laboratory test results_____
_____Radiology Reports_____
_____Pathology Reports_____
_____Discharge Summary_____
_____Progress Notes_____
_____Photographs, videotapes_____
_____X-Ray films/images, digital or other images_____
_____Diagnosis and Treatment Codes_____
_____Complete billing record_____
_____Other: _____

I understand that copies of the records indicated above will be:

- Used by employees of LSUHSC-NO and/or Children's Hospital including treatment providers, and/or other members of its workforce.

- Disclosed to LSUHSC-NO and/or Children's Hospital, government officials or government agencies, such as the Food and Drug Administration study sponsors, study monitors, or others responsible for oversight of the research project.

- Sent to collaborating researchers outside LSUHSC-NO and/or Children's Hospital if and to the extent indicated in the attached Informed Consent document(s).

I understand that by signing this form, I am allowing LSUHSC-NO and/or Children's Hospital and their researchers to use or disclose my health information in connection with the attached Informed Consent and for the purpose of the research that is described in the Informed Consent. For example, the researchers may need the information to verify that I am eligible to participate in the study, or to monitor the results, including expected or unexpected side effects or outcomes. Other University/Hospital and government officials, safety monitors, and study sponsors may need the information to ensure that the study is conducted properly. Also, I understand that my health information may be disclosed to insurance companies or others responsible for my medical bills in order to secure payment.

I understand that any privacy rights not specifically mentioned in this Authorization are contained in the Notice of Privacy Practices that I received or will receive from the Principal Investigator or at the facility that I attend.

I understand that I may revoke this authorization at any time, except to the extent that LSUHSC-NO and/or Children's Hospital has already relied on the authorization, by sending or transmitting of a facsimile, a written notice to the contact person listed in the attached Informed Consent document(s).

I understand that if my information already has been included in a research database or registry as described in the attached Informed Consent document(s), LSUHSC-NO and/or Children's Hospital

considers itself to have relied on it, and therefore my information will not be removed from those repositories. Unless otherwise revoked, I understand that this authorization (_X_) will not expire or (___) will expire upon {date or event}_____. I understand that if I do not sign this form, I will not be able to participate in the above research study or receive the study-related interventions, but that LSUHSC-NO and/or Children's Hospital cannot otherwise condition treatment on my signing this form.

While the research study is in progress, my right to access any research records or results that are maintained by the facility may be suspended until the research study is over. If my access is denied, I understand that it will be reinstated at the end of the research study.

I understand the information disclosed by this authorization may be subject to re-disclosure by the recipient and no longer be protected by the Health Insurance Portability and Accountability Act. The LSUHSC and/or Children's Hospital facilities, their employees, officers, and physicians are hereby released from any legal responsibility or liability for disclosure of the above information to the extent indicated and authorized herein.

I UNDERSTAND THAT THIS AUTHORIZATION SUPERSEDES ANY CONTRARY INFORMATION IN ANY OTHER DOCUMENTS I HAVE SIGNED RELATED TO THE ATTACHED STUDY.

Signature of Patient or Patient's Legal Representative:_____
Date:___/___/___

Printed Name of Legal Representative (if any):
_____

Representative's Authority to Act for Patient (e.g., relationship to patient):
_____

Verification of Representative's Authority: ( ) viewed driver's license ( ) viewed Power of Attorney ( ) viewed other_____ (specify)

LOUISIANA STATE UNIVERSITY HEALTH SCIENCES CENTER

At New Orleans (LSUHSC-NO) and CHILDREN'S HOSPITAL

INSTITUTIONAL REVIEW BOARD/ADMINISTRATIVE REVIEW COMMITTEE

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AUTHORIZATION FOR USE AND DISCLOSURE OF PROTECTED HEALTH INFORMATION FOR RESEARCH PURPOSES – Biological Father

Title of Research Project: **South-seq: DNA sequencing for newborn nurseries in the South**

Name of Sponsor: National Institutes of Health (NIH) National Human Genome Research Institute
If applicable IRB Number: N/A

Principal Investigator: Jessica Patrick-Esteve, MD IRB or Protocol Number: new / ARC #new

I hereby request and authorize the LSUHSC-NO and/or Children's Hospital to use and disclose protected health information from the record(s) of:
Patient's Name/Address:
_____

Birth Date: ____/____/____

Specifically, I request and authorize any part of my health information relevant to the research project, identified above and in the Informed Consent document, to be used and/or disclosed to the Principal Investigator identified above or his/her designee, in connection with the research project. (NOTE: The following sentence may be deleted if not appropriate): I understand that this may include information relating to: Human Immunodeficiency Virus ("HIV") infection or Acquired Immunodeficiency Syndrome ("AIDS"); treatment for or history of drug or alcohol abuse; and/or mental or behavioral health or psychiatric care.

I specifically authorize the use and disclosure of the following PHI:
(Please provide a detailed description of the particular data and period of time you are requesting)

__X___Complete health record(s) for date(s) of service from study enrollment to 5 years after study enrollment, which may contain all of the documents listed below, as well as other notes or documents relating to my treatment or hospitalization.
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_____ Consultation reports _____
_____Laboratory test results_____

_____Radiology Reports_____
_____Pathology Reports_____
_____Discharge Summary_____
_____Progress Notes_____
_____Photographs, videotapes_____
_____X-Ray films/images, digital or other images_____
_____Diagnosis and Treatment Codes_____
_____Complete billing record_____
_____Other: _____

I understand that copies of the records indicated above will be:

- Used by employees of LSUHSC-NO and/or Children's Hospital including treatment providers, and/or other members of its workforce.

- Disclosed to LSUHSC-NO and/or Children's Hospital, government officials or government agencies, such as the Food and Drug Administration study sponsors, study monitors, or others responsible for oversight of the research project.

- Sent to collaborating researchers outside LSUHSC-NO and/or Children's Hospital if and to the extent indicated in the attached Informed Consent document(s).

I understand that by signing this form, I am allowing LSUHSC-NO and/or Children's Hospital and their researchers to use or disclose my health information in connection with the attached Informed Consent and for the purpose of the research that is described in the Informed Consent. For example, the researchers may need the information to verify that I am eligible to participate in the study, or to monitor the results, including expected or unexpected side effects or outcomes. Other University/Hospital and government officials, safety monitors, and study sponsors may need the information to ensure that the study is conducted properly. Also, I understand that my health information may be disclosed to insurance companies or others responsible for my medical bills in order to secure payment.

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I understand that I may revoke this authorization at any time, except to the extent that LSUHSC-NO and/or Children's Hospital has already relied on the authorization, by sending or transmitting of a facsimile, a written notice to the contact person listed in the attached Informed Consent document(s).

I understand that if my information already has been included in a research database or registry as described in the attached Informed Consent document(s), LSUHSC-NO and/or Children's Hospital considers itself to have relied on it, and therefore my information will not be removed from those

repositories. Unless otherwise revoked, I understand that this authorization (_X_) will not expire or (___) will expire upon {date or event}_____. I understand that if I do not sign this form, I will not be able to participate in the above research study or receive the study-related interventions, but that LSUHSC-NO and/or Children's Hospital cannot otherwise condition treatment on my signing this form.

While the research study is in progress, my right to access any research records or results that are maintained by the facility may be suspended until the research study is over. If my access is denied, I understand that it will be reinstated at the end of the research study.

I understand the information disclosed by this authorization may be subject to re-disclosure by the recipient and no longer be protected by the Health Insurance Portability and Accountability Act. The LSUHSC and/or Children's Hospital facilities, their employees, officers, and physicians are hereby released from any legal responsibility or liability for disclosure of the above information to the extent indicated and authorized herein.

I UNDERSTAND THAT THIS AUTHORIZATION SUPERSEDES ANY CONTRARY INFORMATION IN ANY OTHER DOCUMENTS I HAVE SIGNED RELATED TO THE ATTACHED STUDY.

Signature of Patient or Patient's Legal Representative:_____
Date:___/___/___

Printed Name of Legal Representative (if any):
_____

Representative's Authority to Act for Patient (e.g., relationship to patient):
_____

Verification of Representative's Authority: ( ) viewed driver's license ( ) viewed Power of Attorney ( ) viewed other_____ (specify)