

**CONSENT FORM**

**Title of Research:** South-seq: DNA sequencing for newborn nurseries in the South (NIH Grant Number 2U01HG007301-05)

**Site:** Woman’s Hospital, Baton Rouge, Louisiana

**UAB IRB Protocol #:** IRB-300000328

**Principal Investigators:** Steven Spedale, 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). In order to do so, we plan to record the return of results conversations that you will have as part of this study.

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 caregivers enrolled for the clinical trial across 6 NICU sites: UAB, Children’s of Alabama, University of Mississippi Medical Center (UMMC), Woman’s Hospital, University of Louisville and Norton Healthcare (UofL). 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 5 time points: the time of consent, return of results (ROR) appointment, 1-month post-ROR, 4-months post-ROR, and 4.5-months post-ROR. Each survey 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 a 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:

- o 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, you will be asked some of these same questions and some additional ones related to your health, your understanding of the genetics results returned, and how the results influence future 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.
- Woman's IRB, Woman's Research and Development Committee, and Woman's Health Research Department
- 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 Woman's Hospital. 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 Woman's Hospital 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.

### **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 Steven Spedale, MD, at 225-928-2555.

### **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, Woman's Hospital, 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 and AnVIL 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. Steven Spedale at 225-928-2555.

If you have questions about your rights as a research participant, or concerns or complaints about the research, you may contact, Ericka Seidemann, Human Protections Administrator at Woman's Hospital, at 225-231-5296 or [ericka.seidemann@womans.org](mailto:ericka.seidemann@womans.org).

### **Legal Rights**

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





Medical Record Number \_\_\_\_\_

**Authorization to Release Health Information from Woman's Hospital**

Patient's Name \_\_\_\_\_ Patient's Date of Birth \_\_\_\_\_  
 I hereby authorize appropriate personnel at **WOMAN'S HOSPITAL** to release my health information to, and/or allow my records to be reviewed by:

<b>Recipient(s):</b>	Study doctors, nurses, and personnel; public health agencies and government agencies as required by law; Woman's Institutional Review Board; UAB Institutional Review Board; Woman's Research and Development Committee; Woman's Hospital Research Center; NIH National Human Genome Research Institute (NHGRI)		
<b>Recipient's Address:</b>			
<b>Attention:</b>		<b>Contact Number:</b>	

**Purpose of Release**

- for Treatment at Another Facility
- for Research
- for an Interview
- for Publication, Broadcast, Online, Social Media or Other Dissemination by the hospital or media.
- Other Reasons; Specify: \_\_\_\_\_
- for Application for Insurance
- for Processing of my Insurance Claim
- for referral from GRACE program (care coordination for substance use disorder)
- for Treatment by a Physician
- Personal (at my request)

**Specify information to be released by placing a check mark in the appropriate box(es):**

Dates of Services \_\_\_\_\_

- Assessment Center Records
- Clinic Record
- Consultation Reports; Specify Doctor \_\_\_\_\_
- Demographic Information
- Diagnosis
- Discharge Summary
- Other Records; Specify \_\_\_\_\_
- Entire Record
- Entire Billing Record
- History & Physical
- Imaging Results
- Immunization Record
- Itemized Bill
- Lab Test Results
- Nurses Notes
- Operative Report
- Photograph/Video
- Physician Orders
- Physician Progress Notes

- Information Concerning Illness, surgery or events surrounding the birth of my child

**Special consent is required to release the following information. Indicate Your Authorization by placing a checkmark in the appropriate box(es). NO INFORMATION WILL BE RELEASED IF BOX IS NOT CHECKED.**

- The following substance use disorder information:  History & Physical  Medications  Demographics  Diagnosis  Discharge Summary and or Instructions  Lab Results  Orders (Physician/LIP)  Progress Notes (Physician/LIP)  Psychiatric Evaluation  Treatment Plan  Other; Please specify \_\_\_\_\_

- All Substance Use Disorder treatment records -- (Includes all alcohol, drug or other substance use disorder records maintained by the provider/treatment program, relating to the patient, including all admission forms and demographic information, medication, medical history, orders (physician/LRP), psychiatric evaluation, clinical testing information and other treatment information.)
- HIV or AIDS test results  Mental Health records/test results /diagnosis

**GENETIC TEST RESULTS—You must specify the test results to be released by checking or writing below:**

- Chromosome Analysis (specify below):
- Blood  Bone Marrow  CVS  Tissue
  - Amniotic Fluid  Urovisyon
  - Other All genetic testing results
  - Factor V Leiden  Methylenetetrahydrofolate Reductase
  - Prothrombin DNA  Her2/neu Fish for breast cancer
  - Cystic Fibrosis

**Marketing**

If I am providing authorization for marketing purposes, I understand that

- Woman's Hospital will not receive a monetary benefit from a third party for the use of my patient information.
- Woman's Hospital will receive a monetary benefit (directly or indirectly) from a third party for the use of my patient information.





Medical Record Number \_\_\_\_\_

**Authorization to Release Health Information from Woman's Hospital**

Patient's Name \_\_\_\_\_ Patient's Date of Birth \_\_\_\_\_

I hereby authorize appropriate personnel at **WOMAN'S HOSPITAL** to release my health information to, and/or allow my records to be reviewed by:

<b>Recipient(s):</b>	Study doctors, nurses, and personnel; public health agencies and government agencies as required by law; Woman's Institutional Review Board; UAB Institutional Review Board; Woman's Research and Development Committee; Woman's Hospital Research Center; NIH National Human Genome Research Institute (NHGRI)		
<b>Recipient's Address:</b>			
<b>Attention:</b>		<b>Contact Number:</b>	

**Purpose of Release**

- for Treatment at Another Facility
- for Research
- for an Interview
- for Publication, Broadcast, Online, Social Media or Other Dissemination by the hospital or media.
- Other Reasons; Specify: \_\_\_\_\_
- for Application for Insurance
- for Processing of my Insurance Claim
- for referral from GRACE program (care coordination for substance use disorder)
- for Treatment by a Physician
- Personal (at my request)

**Specify information to be released by placing a check mark in the appropriate box(es):**

<b>Dates of Services</b>	
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- Assessment Center Records
- Clinic Record
- Consultation Reports; Specify Doctor
- Demographic Information
- Diagnosis
- Discharge Summary
- Other Records; Specify
- Entire Record
- Entire Billing Record
- History & Physical
- Imaging Results
- Immunization Record
- Itemized Bill
- Lab Test Results
- Nurses Notes
- Operative Report
- Photograph/Video
- Physician Orders
- Physician Progress Notes

- Information Concerning Illness, surgery or events surrounding the birth of my child

**Special consent is required to release the following information. Indicate Your Authorization by placing a checkmark in the appropriate box(es). NO INFORMATION WILL BE RELEASED IF BOX IS NOT CHECKED.**

- The following substance use disorder information:  History & Physical  Medications  Demographics  Diagnosis
- Discharge Summary and or Instructions  Lab Results  Orders (Physician/LIP)  Progress Notes (Physician/LIP)
- Psychiatric Evaluation  Treatment Plan
- Other; Please specify \_\_\_\_\_

- All Substance Use Disorder treatment records – (Includes all alcohol, drug or other substance use disorder records maintained by the provider/treatment program, relating to the patient, including all admission forms and demographic information, medication, medical history, orders (physician/LRP), psychiatric evaluation, clinical testing information and other treatment information.)

- HIV or AIDS test results
- Mental Health records/test results /diagnosis

**GENETIC TEST RESULTS—You must specify the test results to be released by checking or writing below:**

- Chromosome Analysis (specify below):
- Blood
  - Bone Marrow
  - CVS
  - Amniotic Fluid
  - Tissue
  - Factor V Leiden
  - Prothrombin DNA
  - Urovisyon
  - Other All genetic testing results
  - Methylene tetrahydrofolate Reductase
  - Her2/neu Fish for breast cancer
  - Cystic Fibrosis

**Marketing**

If I am providing authorization for marketing purposes, I understand that

- Woman's Hospital will not receive a monetary benefit from a third party for the use of my patient information.
- Woman's Hospital will receive a monetary benefit (directly or indirectly) from a third party for the use of my patient information.

**Authorization Expiration Date or Event**

Unless otherwise revoked, this authorization will expire on the indicated date, event or condition. If an expiration date, event or condition is not specified below, this authorization will expire one (1) year from date of signature. For genetic information, the expiration date must be sixty days or less from date of signature. If no expiration date is specified, the authorization will expire sixty days from date of signature. The statement "end of research," "none," or similar language is sufficient if disclosure is for research, (except for research on genetic information) including the creation and maintenance of a research database or repository.

Expiration (Month, Day, Year / Event / Condition) 60 days from signature

**REQUIRED STATEMENTS**

I understand that:

1. Authorizing the release of this health information is voluntary and I can refuse to sign this authorization.
2. I have the right to revoke this authorization at any time (upon written notification to the Health Information Management Department at Woman's Hospital) except to the extent that Woman's Hospital has already released the health information before receipt of the revocation. For genetic information, I have the right to revoke the authorization at any time before the disclosure is actually made or when I am made aware of the details of the genetic information.
3. If the authorization is for research, the researcher may continue to use and disclose the health information collected prior to the receipt of the written revocation.
4. Woman's Hospital cannot condition treatment, payment, enrollment, or eligibility for benefits on the patient providing this authorization.
5. If the authorization is for research-related treatment, Woman's Hospital may condition the provision of research-related treatment on provision of an authorization for the use or disclosure of protected health information for such research.
6. Any release of information carries with it the potential for an unauthorized redisclosure by the Recipient and the information may not be protected by federal law.
7. The authorization shall be invalid if used for any other purpose other than the described purpose for which the disclosure is made.
8. A photocopy of this authorization may serve as an original.

Patient's Signature \_\_\_\_\_ Date \_\_\_\_\_

Personal Representative's Signature (if necessary) \_\_\_\_\_ Date \_\_\_\_\_

**Personal Representative**

If it is necessary for a personal representative to sign and date this authorization due to lack of capacity of the patient, including minority, interdiction or any other legal reason, indicate below how the person signing as representative has authority to do so:

- The **court appointed person acting for the patient**, if one has been appointed.
- An agent acting pursuant to a valid mandate, specifically authorizing the agent to make health care decisions.
- The patient's spouse not judicially separated.
- An adult child of the patient.
- Any parent, whether adult or minor, for his minor child.
- The patient's sibling.
- The patient's other ascendants or descendants.
- Any person temporarily standing in **for the parents**, whether formally serving or not, for a minor under his care and any guardian for his ward.
- Other (Please specify): \_\_\_\_\_

**For Office Use Only:**

Date copy of authorization given to patient \_\_\_\_\_

Date copy of authorization mailed to patient \_\_\_\_\_

Date records sent \_\_\_\_\_

Media of records disclosed (other than paper):  CD  Film  Other \_\_\_\_\_





Medical Record Number \_\_\_\_\_

**Authorization to Release Health Information from Woman's Hospital**

Patient's Name \_\_\_\_\_ Patient's Date of Birth \_\_\_\_\_

I hereby authorize appropriate personnel at **WOMAN'S HOSPITAL** to release my health information to, and/or allow my records to be **reviewed by**:

<b>Recipient(s):</b>	Study doctors, nurses, and personnel; public health agencies and government agencies as required by law; Woman's Institutional Review Board; UAB Institutional Review Board; Woman's Research and Development Committee; Woman's Hospital Research Center; NIH National Human Genome Research Institute (NHGRI)		
<b>Recipient's Address:</b>			
<b>Attention:</b>		<b>Contact Number:</b>	

**Purpose of Release**

- for Treatment at Another Facility
- for Research
- for an Interview
- for Publication, Broadcast, Online, Social Media or Other Dissemination by the hospital or media.
- Other Reasons; Specify: \_\_\_\_\_
- for Application for Insurance
- for Processing of my Insurance Claim
- for referral from GRACE program (care coordination for substance use disorder)
- for Treatment by a Physician
- Personal (at my request)

**Specify information to be released by placing a check mark in the appropriate box(es):**

<b>Dates of Services</b>	
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- Assessment Center Records
- Clinic Record
- Consultation Reports; Specify Doctor
- Demographic Information
- Diagnosis
- Discharge Summary
- Other Records; Specify
- Entire Record
- Entire Billing Record
- History & Physical
- Imaging Results
- Immunization Record
- Itemized Bill
- Lab Test Results
- Nurses Notes
- Operative Report
- Photograph/Video
- Physician Orders
- Physician Progress Notes

- Information Concerning Illness, surgery or events surrounding the birth of my child

**Special consent is required to release the following information. Indicate Your Authorization by placing a checkmark in the appropriate box(es). NO INFORMATION WILL BE RELEASED IF BOX IS NOT CHECKED.**

- The following substance use disorder information:  History & Physical  Medications  Demographics  Diagnosis
- Discharge Summary and or Instructions  Lab Results  Orders (Physician/LIP)  Progress Notes (Physician/LIP)
- Psychiatric Evaluation  Treatment Plan
- Other; Please specify: \_\_\_\_\_

- All Substance Use Disorder treatment records -- (Includes all alcohol, drug or other substance use disorder records maintained by the provider/treatment program, relating to the patient, including all admission forms and demographic information, medication, medical history, orders (physician/LRP), psychiatric evaluation, clinical testing information and other treatment information.)

- HIV or AIDS test results
- Mental Health records/test results /diagnosis

**GENETIC TEST RESULTS—You must specify the test results to be released by checking or writing below:**

- Chromosome Analysis (specify below):**
- Blood
  - Bone Marrow
  - Amniotic Fluid
  - CVS
  - Tissue
  - Other All genetic testing results
  - Factor V Leiden
  - Prothrombin DNA
  - Urovysion
  - Methylene tetrahydrofolate Reductase
  - Her2/neu Fish for breast cancer
  - Cystic Fibrosis

**Marketing**

If I am providing authorization for marketing purposes, I understand that

- Woman's Hospital will not receive a monetary benefit from a third party for the use of my patient information.
- Woman's Hospital will receive a monetary benefit (directly or indirectly) from a third party for the use of my patient information.

**Authorization Expiration Date or Event**

Unless otherwise revoked, this authorization will expire on the indicated date, event or condition. If an expiration date, event or condition is not specified below, this authorization will expire one (1) year from date of signature. For genetic information, the expiration date must be sixty days or less from date of signature. If no expiration date is specified, the authorization will expire sixty days from date of signature. The statement "end of research," "none," or similar language is sufficient if disclosure is for research, (except for research on genetic information) including the creation and maintenance of a research database or repository.

Expiration (Month, Day, Year / Event / Condition) 60 days from signature

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Patient's Signature \_\_\_\_\_ Date \_\_\_\_\_

Personal Representative's Signature (if necessary) \_\_\_\_\_ Date \_\_\_\_\_

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