The Children's Hospital of Philadelphia®

# INFORMED CONSENT FORM AND HIPAA AUTHORIZATION

**Study Title:** Pilot Trial of Fetoscopic Endoluminal Tracheal Occlusion (FETO) in Severe Left Congenital Diaphragmatic Hernia (CDH)

Informed Consent Name: Severe CDH

Protocol Version: 08/04/2021 Consent Version Date: 05/29/2024

NCT Number: NCT 02549820


| | | |
|---|---|---|
| **Principal Investigator:** | Holly L. Hedrick, M.D. | Telephone: (215) 590-2733 |
| **Affiliations:** | The Children's Hospital of Philadelphia,<br>Center for Fetal Diagnosis and Treatment | |
| **Emergency Contact:** | Holly L. Hedrick, M.D. | Pager: (877) 467-4067 |


You may be eligible to take part in a research study. This form gives you important information about the study. It describes the purpose of this research study, and the risks and possible benefits of participating.

If there is anything in this form you do not understand, please ask questions. Please take your time. You do not have to take part in this study if you do not want to. If you take part, you can leave the study at any time.

In the sections that follow, the word "we" means the study doctor and other research staff. The word "you" refers to you and/or your child.

## Why are you being asked to take part in this study?

You are being invited to take part in this research study because your unborn baby has been diagnosed with a severe left congenital diaphragmatic hernia (CDH). Congenital diaphragmatic hernia is a condition in which a hole in the diaphragm allows abdominal organs to move into the chest and restrict lung growth. Babies with CDH have small lungs. Fetoscopic Endoluminal Tracheal Occlusion (FETO) blocks the airway. Fluid builds and the lungs grow. Bigger lungs may improve survival.

Unborn babies diagnosed with severe CDH have a survival rate of approximately 34%. Survivors will potentially develop severe pulmonary hypoplasia and complications.

## What is the purpose of this research study?

The purpose of this research study is to determine if performing FETO surgery and FETO release (surgery to remove the balloon) works and is safe for unborn babies with left CDH.

The study is going to look at outcomes after surgery. The main outcome that we will review is survival. In addition, we will look at maternal health, pregnancy progress, newborn health, and long-term health of babies.

## How many people will take part?

Approximately 25 pregnant women will take part in this study at The Children's Hospital of Philadelphia (CHOP).

## What is involved in the study?

This study involves fetal procedures and follow-up. If you agree to participate in this study, you will receive fetal procedures for balloon insertion and balloon removal.

### How long will you be in this study?

If you agree to take part, your participation will last for approximately 2.5 years (prenatally through your child's 2nd birthday).

**What are the Study Procedures?**

If you agree to participate in the study, your medical records from your initial evaluation at Center for Fetal Diagnosis and Treatment (CFDT) will be reviewed and collected for research. Some of the procedures may be repeated several times. Tests that are part of your routine medical care will continue to be performed. Additional tests may be performed if any of your initial test results are not normal. We will be collecting information from your medical records and child's medical records after birth.

**All procedures listed will be conducted as part of the research study.**

**Screening Procedures (before surgery)**

Counseling: A team member will provide you with information about the FETO surgeries, prenatal monitoring, and management following prenatal surgery.

Beck Depression Index: Both parents will complete a brief questionnaire about depression.

Transvaginal Ultrasound: This is a type of pelvic ultrasound used to look at a woman's reproductive organs, including the cervix. Transvaginal means across or through the vagina.

**Study Procedures during Pregnancy (First Procedure until Delivery)**

***First procedure:***

Balloon Insertion: The fetal surgeon will make a small opening in the maternal skin and insert a small curved tube into the uterus. A balloon will be placed in your unborn baby's airway and inflated. The balloon can move unexpectedly or deflate. If this happens before 29 weeks 6 days, another procedure may take place to reinsert the balloon. Insertion of the balloon will be attempted up to three times. Procedure will be performed with IV sedation and loco-regional anesthesia. General anesthesia may be used as back up during the procedures. You may receive medication to relax your uterus if your

unborn baby needs to be repositioned prior to this procedure. You will receive antibiotics and medication to keep your uterus from contracting. You will be on modified bed rest for the first two weeks.
You will be discharged from the hospital 1-2 days after the surgery and will be required to stay within 30 minutes of the hospital, with a support person until you deliver. While the balloon is in place, the fetal airway is blocked. Unexpected delivery could be life-threatening if the proper systems are not in place to manage the airway. If for any reason the baby is born, the balloon must be removed immediately to allow the baby to breathe.

***Second Procedure: Balloon Removal:***

For balloon removal, you will be re-admitted to CHOP. Removal of the balloon will be with a needle puncture or similar to the insertion procedure. After removal of the balloon, you will be hospitalized for 1-2 days. You will continue check-ups as you would for your routine care along with the following:

Targeted Ultrasonography: This is a non-invasive imaging technique that uses sound waves to make pictures of the inside of the body. Ultrasounds will be performed multiple times while the balloon is in place, to monitor your progress.

Fetal Growth Surveillance: We will conduct a special kind of ultrasound, called a Doppler ultrasound, multiple times while the balloon is in place, to examine the fetal heart for defects and estimate placental blood flow. A Doppler ultrasound is a noninvasive test.

Magnetic resonance imaging (MRI): MRI is a test that uses a magnetic field and pulses of radio wave energy to make pictures of organs and structures inside the body. The MRI will not require sedation of mother or fetus. The MRI will check the position of the abdominal organs. You will have MRIs when clinically indicated.

Fetal Echocardiogram: This is a test that uses sound waves to create an image of the heart to check for congenital heart disease. Fetal echocardiogram will be performed when clinically indicated.

Physical Exams: Physical exams will be conducted multiple times throughout the study. Exams are part of routine clinical care, but will be conducted more frequently because you are in the study. The exams will include evaluation of body systems, vital signs and weight.

Blood Tests: Blood tests will be performed multiple times throughout the study. Some of the blood tests are part of routine clinical care, but some will be performed because you are participating in the study. For these tests, blood will be taken from a vein using a needle or an IV catheter.

Interviews: Throughout the study, you will be asked to report if you are taking any medications, and report if you think that anything out of the ordinary (adverse event) has happened because of the study participation.

After Delivery: Your child will be stabilized and require additional surgery to repair the diaphragm. Infants receive follow-up testing in the neonatal intensive care unit (NICU), and again at 6 months, 12 months, and 24 months of age. Your child will be asked to complete some developmental assessments at the follow-up visits that are part of the research.

## Tests and Assessments after Birth

Bronchoscopy: A procedure that allows doctors to see the breathing passages through a lighted tube. This enables the doctors to examine your child's vocal cords and windpipe (trachea). The bronchoscopy will allow the doctors to see if there is any injury to the vocal cords or trachea. The procedure will be done in the operating room under general anesthesia.

Child Development Assessment: A developmental pediatrician, pediatric nurse practitioner and developmental psychologist will evaluate your child's cognitive abilities, language development and motor skills. Parents will also be asked to complete questionnaires about their child's behavior and skills.

Parent Assessment: Parents will be asked to complete questionnaires about their stress, coping and socio-economic status. Parents will complete these questionnaires at the 12-month and 24-month visits.

Beck Depression Inventory: Will be completed by both parents within one month of delivery and at the 12-month and 24-month visits.

**Visit Schedule:**

| Visit | Purpose | Procedures |
|---|---|---|
| Visit 1, $18^0$ – $29^5$ wks | Screening visit | **Routine Care**: Standard procedures for the evaluation of CDH include an U/S, Fetal Echo, Maternal MRI<br><br>**Research:** Informed consent, review of medical records from initial evaluation, Beck Depression Inventory (completed by both parents), CDH FETO surgery counseling, Transvaginal ultrasound, Clearance for surgery. |
| Visit 2, $27^0$ – $29^6$ wks | 1st Procedure | **Research:** Physical exam, Vital signs, Blood and urine tests, review of current medications, Fetoscopic Tracheal Occlusion – Insertion of the balloon, review of adverse events |
| Visit 3, Balloon Insertion to Delivery | Weekly Check-ups to start one week after Balloon Insertion | **Weeks 28, 29, 30, 31, 32. 33 34, 35, 36, 37, 38, $39^0$ (Balloon insertion to Delivery):**<br><br>**Routine Care:** Blood and urine tests, and Biophysical profiles (starting at 34 weeks), MRI, Fetal ECHO (as clinically indicated)<br><br>**Research:** Review of medical records, targeted ultrasound and fetal growth surveillance studies, review of adverse events |
| Visit 4, $34^0$ – $34^6$ wks | 2nd Procedure | **Research:** Physical exam, Vital signs, weight, review of current medication, Blood and urine tests, clearance for surgery, Removal of balloon, review of adverse events |
| Visit 5, $37^0$ – $39^0$ wks | Delivery | **Routine Care:** Delivery<br><br>**Research:** Review of medical records, Depression questionnaire (completed by both parents) to be completed within one month after delivery |
| Visit 6, NICU | Inpatient stay Follow-up | **Routine Care:** Echocardiographic assessments, Head MRI, Audiologic exam, Chest radiograph<br><br>**Research:** Review of medical records from NICU, and bronchoscopy |

| | | |
|---|---|---|
| Visit 7, 8 and 9 | Follow Up at 6 Months, 12 Months and 24 Months | **Routine Care:** Echocardiographic assessments, Hearing exam, Lung Function Testing, Medical History and Physical Exam, Chest X-Ray (Visits 9)<br>**Research:** Child developmental assessment, Parent Questionnaires and review of medical records. |

## What are the risks of this study?

Taking part in a research study involves inconveniences and risks. If you have any questions about any of the possible risks listed below, you should talk to your study doctor or your regular doctor.

While in this study, you/your baby are at risk for the following side effects:

**Risks associated with study device (BALT balloon):**

Most severe risks

- After placement of balloon, the fetal airway is blocked. The balloon must be removed in order for the baby to breathe. If the baby is born and the balloon is not removed, the baby will not be able to breathe and will die.
- The devices used in this study are experimental; therefore, there may be other side effects we do not know about yet.
- Since the balloon is made of natural rubber latex, it is pertinent that you disclose any individual or family history of allergies to this product. This can potentially affect the fetus's response when the balloon is inserted.

**Risks associated with Balloon insertion and removal:**

The most important risks to FETO are rupture of membranes and preterm delivery.

**Maternal Risks**

The estimated risk of serious complications related to fetoscopy is less than 1%.

Potential complications of FETO include:

- Amniotic fluid leak
- Preterm Premature Rupture of Membranes (PPROM): occurs when the membrane sac holding your baby and the amniotic fluid breaks open before 37 weeks of pregnancy.
- Chorioamnionitis is inflammation of the fetal membranes (amnion and chorion) due to a bacterial infection. Infection of the membrane requires immediate delivery.
- Bleeding
- Placental abruption, when the placental lining has separated from the uterus
- Amniotic fluid embolism is when amniotic fluid, fetal cells, hair, or other debris enters the mother's blood stream and triggers an allergic reaction.
- Polyhydramnios is excess amniotic fluid in the uterus and occurs in approximately 40% of cases. This may lead to discomfort and may require an

amnioreduction. This procedure is the placement of a sterile needle into the uterus, and the excess fluid is removed. This procedure is similar to an amniocentesis. Amnioreduction is rarely required. The risks will be discussed with you and a separate consent obtained if applicable.

- Local wound infection at the insertion site occurs in less than 1% of cases and is managed by the administration of antibiotics and/or local drainage.
- Mothers may experience difficulty getting pregnant in the future.

**Medication Risks**

Possible side-effects of the drugs being used a part of research for the mother (these medications are routinely used for all fetoscopic procedures).

Medicines used to relax the uterus:

- Terbutaline: fast heart rate, flushing, tremors, restlessness
- Nitroglycerin: headache, low blood pressure, dry mouth, dizziness

Medicines used to prevent premature uterine contractions:

- Magnesium sulfate - flushing, sweating, muscle weakness, nausea and vomiting, lethargy, blurred vision, excess fluid in the lungs necessitating supplemental oxygen; indomethacin - intestinal cramping, decreased amniotic fluid production, and constriction of the fetal ductus arteriosus
  Nifedipine – low blood pressure.

Risks of Anesthesia:

- You may need general anesthesia in order to have surgery. There are very rare but serious side effects associated with general anesthesia and epidural anesthesia including: irregular heartbeat, increases or decreases in blood pressure, rare reactions to medications used in the anesthesia, and blockage of breathing passages. An extremely rare but serious complication is rapid increase in body temperature. You will have an opportunity to discuss these risks with the anesthesiologist who will review your specific anesthetic plan.

Antibiotics:

- Cefazolin (or equivalent Clindamycin if allergic) and Oxacillin: fever, itching, rash, hives, diarrhea, nausea, vomiting, severe allergic reaction

Post-op Pain Medication:

- Morphine, Remifentanil, Percocet: slow breathing rate, slow heart rate, low blood pressure, dizziness drowsiness, headache, constipation, nausea, vomiting, itching, urinary retention
- Tylenol: rash, liver injury with overuse
- Lidocaine: slow heart rate, low blood pressure, arrhythmias, dizziness, headache, anxiety, seizures, itching, nausea and vomiting, blurred vision

Other Medications:

- Sodium citrate: minor gastrointestinal discomfort

- Ranitidine: dizziness, headache, anxiety, rash, constipation, nausea, vomiting
- Betamethasone: discomfort or bruising at the injection site, sleep problems, nausea, headache, and increased sweating. There are more serious side effects from betamethasone but these are related to more prolonged use.

**Potential Fetal/Neonatal Risks**

Complications of Fetal Tracheal Occlusion: These include vocal cord injury and widening of the windpipe.

Fetal Death: CDH fetuses have increased risk of stillbirth.

Complications after Birth: Babies born with CDH have complications from the extensive treatment needed after birth. Examples that can cause serious disease are poor function of the lungs, strain on the baby's heart, difficulty growing and gaining weight, feeding problems and if premature, problems of prematurity.

Neonatal Death: In the European studies, neonatal death of 5% (5 out of 100) was related to difficulties in removal of the balloon and airway occlusion. In the current study, you will remain in Philadelphia to reduce the risk of and possibly prevent this complication.

Anesthetic Drugs: Anesthetic medications are given to the fetus for all fetoscopic procedures. You will have an opportunity to discuss these risks with the anesthesiologist who will review your specific anesthetic plan.

Vocal Cord Injury: Vocal cords may be injured by inserting and removing the balloon from the baby's airway. Vocal cord injury results in noisy breathing and feeding problems. Treatment can include feeding through a tube instead of the mouth and injections in the cords to help the baby protect the airway.

Injury to trachea: The trachea may be injured by repeated manipulations or presence of an endotracheal tube long term. Dilation of the trachea may make the airway more at risk to collapse. The tendency to collapse may need increased pressure from a ventilator and will improve as a baby gets older.

No Response: It is possible that there will be no lung growth following the occlusion procedure.

Procedure Failure: The failure rate of entering the uterus or trachea, or positioning the balloon is currently estimated to be 2%. If the baby is in a position in which the procedure cannot be performed, the fetus may be repositioned preoperatively or the surgery may be rescheduled for a later date. If the balloon becomes dislodged additional surgery may have to be done to reinsert the balloon.

**Additional Risks and Considerations:**

MRI: There are no known risks of physical harm associated with MRI.

Ultrasound: There are no known risks of physical harm associated with an ultrasound.

Blood Draws: Taking blood may cause some pain, bleeding or bruising at the spot where the needle enters the body.

Physical Exam: You may experience momentary embarrassment or discomfort. Exams will be done in closed areas to ensure privacy.

Questionnaires and Interviews: Some of the questions asked may make you uncomfortable or upset. A social worker and psychologist will be available for counseling.

Privacy and Confidentiality: As with any study that involves collection of data, there is the possibility that privacy and confidentiality may be breached. Every precaution will be taken to secure participants' personal information to ensure confidentiality and to protect participants' privacy. When your information is shared outside of CHOP, we will label it with a unique code number instead of using identifying information like names. Similarly, if you allow us to share your child's biospecimens outside of CHOP, we will label them with a unique code instead of using identifiable information.

Inconvenience: You will be required to remain in close proximity to CHOP between the FETO procedure and the balloon retrieval procedure and this may be inconvenient for the participant and/or family.

## Are there any benefits to taking part in this study?

If you agree to take part in this study, there may or may not be direct medical benefit to your baby. The investigational FETO intervention may improve survival of your fetus and it may lower the chances of serious disease in fetuses with isolated, severe CDH. However, we cannot guarantee or promise that your baby will receive any direct benefit by participating in this study. We hope the information learned from this study may help us understand more about severe left CDH and possibly benefit other patients with severe CDH in the future.

## Do you need to give your consent in order to participate?

Once you have read this form and had your questions answered, you will be asked to decide if you wish to participate. If you wish to participate in this study, you must sign this form. A copy will be given to you to keep as a record.

Taking part in a research study involves time and responsibilities. You need to follow the study doctor's instructions, keep all study appointments and follow the FETO intervention requirements as directed. Please consider the study time commitments and responsibilities as a research subject when making your decision about participating in this study.

**What happens if you decide not to take part in this study?**

Participation in this study is voluntary; you do not have to take part in order to receive care at CHOP.

If you decide not to take part or if you change your mind later, there will be no penalties or loss of any benefits to which you are otherwise entitled.

Please note that if you decide not to take part in this study, the FETO surgery will not be an option for you at CHOP.

**Can you stop your participation in the study early?**

You can stop being in the study at any time. You do not have to give a reason.

If you wish to stop participating in the study, it is important to discuss this with the study doctor first, so she can make sure that you stop safely.

Requesting withdrawal from the study after balloon placement and prior to balloon removal can result in the death of your baby if the balloon is not removed prior to delivery. Withdrawing from the study during this timeframe is against medical advice and may warrant initiation of a legal proceeding to protect your baby.

**Can the study doctor take you out of the study early?**

The study doctor may take you out of the study if:

- Your condition worsens.
- The study is stopped.
- The study devices are no longer available.
- You cannot meet all the requirements of the study.
- New information suggests taking part in the study may not be in your best interests.

**What choices do you have other than this study?**

There are options for you other than this study including:

- Not participating in this study.
- Continuing with the usual care for this condition:
  - You can choose to receive care at CHOP without having fetal surgery.
  - You can choose to return to your referring doctor and hospital to receive usual care for this condition. Even if you choose to return to the care of other physicians, Dr. Hedrick and her associates will offer whatever help they can provide to obtain the best possible care for you.
- You may discuss other options, such as terminating your pregnancy, that are available to you with your doctor.

## What about privacy, authorization for use of Personal Health Information (PHI) and confidentiality?

As part of this research, health information about you and your baby will be collected. This will include information from medical records and from the procedures, interviews, questionnaires, and tests that are described above. Laboratory test results will appear in your medical record. We will do our best to keep your and your child's personal information private and confidential. However, we cannot guarantee absolute confidentiality. Your and your child's personal information may be disclosed if required by law.

The results of this study may be shown at meetings and published in journals to inform other doctors and health professionals. We will keep your and your child's identity private in any publication or presentation.

Several people and organizations may review or receive your and your child's identifiable information. They will need this information to conduct the research, to assure the quality of the data, or to analyze the data or samples. These groups include:

- Members of the research team and other authorized staff at CHOP
- People from agencies and organizations that perform independent accreditation and/or oversight of research; such as the Department of Health and Human Services, Office for Human Research Protections;
- Groups monitoring the safety of this study, like the Data Safety & Monitoring Board (DSMB), which includes staff from both CHOP and the University of Pennsylvania;
- The Food and Drug Administration (FDA);
- Public health authorities that are required by law to receive information for the prevention or control of disease, injury or disability.

By law, CHOP is required to protect your and your child's health information. The research staff will only allow access to your and your child's health information to the groups listed above. By signing this document, you are authorizing CHOP to use and/or release your and your child's health information for this research. Some of the organizations listed above may not be required to protect your and your child's information under Federal privacy laws. If permitted by law, they may be allowed to share it with others without your permission.

There is no set time for destroying the information that will be collected for this study. Your permission to use and share the information and data from this study will continue until the research study ends and will not expire. Researchers continue to analyze data for many years and it is not possible to know when they will be completely done.

## Can you change your mind about the use of personal information?

You may change your mind and withdraw your permission to use and disclose your and your child's health information at any time. To take back your permission, it is preferred that you inform the investigator in writing.

Dr. Holly L. Hedrick
The Children's Hospital of Philadelphia
34th Street and Civic Center Blvd.
Wood Building, Room 5115
Philadelphia, PA 19104

In the letter, state that you changed your mind and do not want any more of your and your child's health information collected. The personal information that has been collected already will be used if necessary for the research. No new information will be collected. If you withdraw your permission to use your and your child's personal health information, you and your child will be withdrawn from the study.

**Additional Information**

A Data Safety and Monitoring Board, an independent group of experts, will be reviewing the data from this research throughout the study.

You will be informed if changes to the study are needed to protect your and your child's health. You will be told about any new information that could affect your willingness to stay in the study, such as new risks, benefits or alternative treatments.

## Financial Information

While you are in this study, the cost of your usual medical care – procedures, medications and doctor visits – will continue to be billed to you or your insurance.

**Will there be any additional costs?**

CHOP is providing financial support for the study. The study will cover the costs of the following:

- Follow-up appointments: Travel and lodging will be covered in order for you to return to CHOP with your baby at 6, 12, and 24 months. You will be reimbursed (paid back) for your travel and lodging costs. You will be given written guidelines describing the personal expenses that are covered by the study.

The following procedures will be billed to you or your insurance:

- Pre-operative testing in preparation for surgery, the first surgery (insertion of the balloon) and the 2nd surgery (removal of the balloon), and post-operative care.
- Standard of care medical costs (routine prenatal care and check-ups, the delivery of your baby, your post-partum care, surgery on your baby after delivery, and the care for your baby after delivery).
- You will be responsible for costs you would normally incur for regular care of a baby with CDH (including co -payments and deductibles).

Individual insurance policies vary and we will work with you and your insurance company. If you do not have health insurance or your insurance does not cover all the costs, we will discuss payment options with you.

**Will you be paid for taking part in this study?**

You will not receive any payments for taking part in this study.

**Who is funding this research study?**

The Children's Hospital of Philadelphia is providing funding for this study.

## What if you have questions about the study?

If you have questions about the study, call the study doctor, Dr. Hedrick at (215)-590-2733. You may also talk to your own doctor if you have questions or concerns.

The Institutional Review Board (IRB) at The Children's Hospital of Philadelphia has reviewed and approved this study. The IRB looks at research studies like these and makes

sure your rights and welfare are protected. If you have questions about your rights or if you have a complaint, you can call the IRB Office at 215-590-2830.

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.

## What happens if you are injured during the study?

If you are hurt or get sick from something that was done as part of this study, doctors at the clinic or hospital can arrange for emergency medical care. The Hospital does not offer financial compensation or payment for injuries due to participation in this research. No funds have been set aside to compensate you in the event of injury.

You and your insurance company will be billed for the costs of any care or injuries.

If you think you have been injured from taking part in this study, call Dr. Holly Hedrick at (215) 590-2733. She can go over things with you, let you know of resources that may be available and give you information on what you need to do.

In case of injury resulting from this study, you will not lose any legal rights by signing this form.

## Use of Data for Future Research

As part of this study, we will collect the data described above. The data will be given a unique code and will not include information that can identify you. Only the study doctors and those working with them on this study will be able to see information that can identify you.

We would like to use this information in a future study about congenital diaphragmatic hernias. If you leave the study, you can ask to have the data collected about you removed. You can also ask us to remove information that identifies you from the data. However, we may not be able to do that if the data has already been shared with another study. We will not share any identifiable data outside of CHOP.

## Use of Specimens for External Research

The Children's Hospital of Philadelphia has collaborated with Massachusetts General Hospital (MGH) to provide MGH with specimens from patients undergoing FETO intervention at CHOP. These specimens will be used in research related to congenital diaphragmatic hernia and associated disorders such as pulmonary hypoplasia. Specimens to be shared with MGH include the balloon used in tracheal occlusion and tracheal aspirate cells which would otherwise be discarded.

If you agree to allow CHOP to transfer your child's specimens to MGH, neither you nor your child will undergo any additional procedures.

Specimens will be de-identified prior to transfer and will include a unique code, rather than information that can identify you. As with any study that involves collection of data,

there is the possibility that privacy and confidentiality may be breached. Every precaution will be taken to ensure confidentiality and to protect your privacy.

Neither you nor your child will receive any results or financial benefit from future research conducted with these specimens. You may still take part in the Pilot Trial of Fetoscopic Endoluminal Tracheal Occlusion if you do not consent to the sharing of specimens.

Please indicate whether you will allow your child's specimens to be shared with MGH by putting your initials next to one of the following choices:

_____ (initials) NO, I do not consent to the transfer of my child's specimens to Massachusetts General Hospital

_____ (initials) YES, provided that my child's identity stays private, my child's specimens may be sent to Massachusetts General Hospital for use in research

## Consent to Take Part in this Research Study and Authorization to Disclose Health Information

The research study and consent form have been explained to you by:

| Person Obtaining Consent | Signature of Person Obtaining Consent<br>Date: |
|---|---|

By signing this form, you are indicating that you have had your questions answered, you agree to take part in this research study and you are legally authorized to consent to your participation, to the participation of your fetus and to that of your child after delivery. You are also agreeing to let CHOP use and share your health information as explained above. If you don't agree to our collecting, using and sharing your health information, you cannot participate in this study.

| Name of Mother | |
|---|---|
| Signature of Mother | Date |
| Name of Father | |
| Signature of Father | Date |

## After Delivery (Documentation of the Name of the Newborn Infant)

| Name of Child Subject | Date |
|---|---|

## Consent to Take Part in this Research Study and Authorization to Disclose Health Information

***For non-English speakers***

| Name of Mother | Name of Father |
|---|---|

The research study and consent form have been explained to the mother and father of the unborn child.

By signing this form, you are indicating that you have answered the mother and father's questions, they have agreed to allow their unborn infant to take part in this research study and the mother has consented to her participation. They have also agreed to let CHOP use and share their or their child's health information as explained above. If they don't agree to the collection, use and sharing of their or their child's health information, they cannot participate in this study.

| Person Obtaining Consent | Signature of Person Obtaining Consent |
|---|---|
| | Date |

**Witness/Interpreter**

By signing this form, you are indicating that

- The information in the Summary Document as well as any additional information conveyed by the person obtaining consent was presented to the subject in a language preferred by and understandable to the subject; and
- The subject's questions were interpreted and the responses of the person obtaining consent were presented in a language preferred by and understandable to the subject.
- At the conclusion of the consent conference, the subject was asked in a language preferred by and understandable to the subject if s/he understood the information in the Summary Document as well as any additional information conveyed by the person obtaining consent (including responses to the subject's questions) and responded affirmatively.

| Name of Witness/Interpreter | Signature of Witness/Interpreter |
|---|---|
| | Date |

**After Delivery (Documentation of the Name of the Newborn Infant)**

| | |
|---|---|
| Name of Child Subject | Date |