Partners HealthCare System
Research Consent Form

Subject Identification

Parent Template
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Protocol Title: A pilot study to evaluate safety and efficacy of the hypoglossal nerve stimulator in the treatment of adolescents with Down syndrome with obstructive sleep apnea

Principal Investigator: Christopher Hartnick, MD

Site Principal Investigator: Christopher Hartnick, MD

Description of Subject Population: Children ages 10 years old to 21 years old with Down Syndrome who have moderate to severe obstructive sleep apnea after adenotonsillectomy and will undergo hypoglossal nerve stimulation implantation surgery

About this consent form

Please read this form carefully. It tells you important information about a research study. A member of our research team will also talk to you about giving permission for your child to take part in this research study. People who agree to take part in research studies are called "subjects." This term will be used throughout this consent form.

Partners HealthCare System is made up of Partners hospitals, health care providers, and researchers. In the rest of this consent form, we refer to the Partners system simply as "Partners."

If you decide to give permission for your child to take part in this research study, you must sign this form to show that you want him/her to take part. We will give you a signed copy of this form to keep.

Key Information

Taking part in this research study is up to you. You can decide not to give permission for your child to take part. If you decide to give permission for your child to take part now, you can change your mind and s/he can drop out later. Your decision won't change the medical care your child gets within Partners now or in the future.

The following key information is to help you decide whether or not to give permission for your child to take part in this research study. We have included more details about the research in the Detailed Information section that follows the key information.

Why is this research study being done?

In this research study we want to determine if the Inspire® System, a hypoglossal nerve stimulation system for the treatment of Obstructive Sleep Apnea (OSA) symptoms, can be used safely in adolescents and young adults with Down Syndrome and moderate to severe obstructive sleep apnea.

How long will your child take part in this research study?

If you decide to give permission for your child to join this research study, it will take about 12 months to complete the research study. During this time, we will ask you and your child to make at least 9 visits to **Massachusetts Eye and Ear**. Some visits will take 1-2 hours, and others will require you and your child to spend the night for a sleep study.

What will happen if your child takes part in this research study?

If you decide to give permission for your child to join this research study, the following things will happen:

Your child will complete office visits at baseline (before surgery) to determine if your child is a candidate for the nerve stimulation device. If your child is eligible and receives surgery, your child will attend office visits at 1, 2, 6, and 12 months after surgery. During these visits, the doctor will check how your child is doing with the device and will ask you how your child is sleeping by completing surveys called the *OSA-18* and the *Epworth Sleepiness Scale* questionnaires. Your child will also undergo an overnight sleep study after each visit during which the device settings may be changed and adjusted, as needed.

Why might you choose to have your child take part in this study?

While it is possible that the implanted device will help to improve your child's Obstructive Sleep Apnea symptoms, your child may not directly benefit from participating in this research study.

However, information gained from this study may help us treat people with obstructive sleep apnea in the future.

Why might you choose NOT to have your child take part in this study?

Taking part in this research study has some risks and requirements that you should consider carefully.

Important risks and possible discomforts to know about include:

1) From the surgery: pain and soreness in the surgical site, infection, numbness and tingling in the mouth or neck, etc.
2) From the device: failure to stimulate, migration or traction of pulse generator or leads, lead dislodgement, damage, or failure, failure of respiratory sensing, etc.

A detailed description of side effects, risks, and possible discomforts can be found later in this consent form in the section called "What are the risks and possible discomforts from being in this research study?"

What other treatments or procedures are available for your child's condition?

Other treatments or procedures that are available to treat obstructive sleep apnea include **c**ontinuous positive airway pressure, or CPAP, tracheotomy, or corrective surgeries for your child's jaw or throat.

If you have questions or concerns about this research study, whom can you call?

You can call us with your questions or concerns. Our telephone numbers are listed below. Ask questions as often as you want.

Christopher Hartnick, MD, is the person in charge of this research study. You can call him/her at **617-573-4206, M-F 9-5**. You can also call Vanessa De Guzman **at** 617-573-3191, **M-F 9-5** with questions about this research study.

If you have questions about the scheduling of appointments or study visits, call **617-573-4206.**

If you want to speak with someone **not** directly involved in this research study, please contact the Partners Human Research Committee office. You can call them at 857-282-1900.

You can talk to them about:

- Your rights as a research subject
- Your concerns about the research
- A complaint about the research
- Any pressure to take part in, or to continue in the research study

Detailed Information

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 your child. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Why is this research study being done?

Many people suffer from a disorder called obstructive sleep apnea, which occurs when the airway is blocked during sleep and causes difficulty breathing. By stimulating a nerve under the chin, called the hypoglossal nerve, with mild electrical stimulation, the tongue is lifted up from the back of the throat. This process can help to reopen the airway in carefully selected individuals with sleep apnea.

The Inspire® System is a hypoglossal nerve stimulation system that improves moderate to severe obstructive sleep apnea syndrome symptoms in carefully selected adults. It is FDA approved for use in the adult population. However, it is not current FDA approved for use in adolescents and young adults with Down Syndrome. This means that it can only be used in adolescents and young adults with Down Syndrome if it is prescribed off-label or if it is used in research studies such as this.

The purpose of this research study is to determine if the Inspire® System can also be used safely in adolescents and young adults 10 years to 21 years of age with Down Syndrome and moderate to severe obstructive sleep apnea. You and your child have been asked to participate in this study because your child has Down Syndrome, and moderate to severe obstructive sleep apnea which has persisted despite prior therapy.

Your child's doctor is also the person responsible for this research study, and is interested in both your child's clinical care and the conduct of this research study. You have the right to discuss this study with another person who is not part of the research team before making your decision about whether or not to be in the study.

Who will take part in this research?

We are asking you to give permission for your child to take part in this research study because your child has Down Syndrome, and moderate to severe obstructive sleep apnea which has persisted despite prior therapy.

About 50 people will take part in this research study. Participants will be enrolled from 12 hospitals, including Massachusetts Eye and Ear.

This study is supported in part by Inspire® Medical Systems, the company which manufactures the Inspire® System hypoglossal nerve stimulator being used in this study.

None of the investigators involved in this study has a financial interest in the Inspire® System.

What will happen in this research study?

It will take about 12 months to complete the research study. During this time, we will ask you and your child to make at least 9 visits. Some visits will take 1-2 hours, and others will require you and your child to spend the night for a sleep study.

If you and your child choose to participate in the study, the following procedures will take place as part of the study.

1. **Baseline visit**: Your doctor will talk to you about your child's general health and well-being, check your child's height and weight, review medications, and examine your child's tongue function (functional tongue exam). This is performed to determine if your child is likely to benefit from the device.

2. **Pre-Implant Screening:** Three additionally screening procedures will be performed to make sure your child is likely to benefit from the device.

    a. First, you will meet with the doctor who will perform the surgery (surgeon). He/she will talk with you, review your child's medications, and examine your child to determine he/she is an appropriate candidate for the surgery. They will also describe the surgery. You will also be asked to fill out short questionnaires about your child's symptoms, how sleepy he/she feels in certain situations, and how well your child feels in general. These tests are called the *OSA-18* and the *Epworth Sleepiness Scale*.

    b. Second, if your child has not had an overnight sleep study (Polysomnography or PSG) within the last 18 months, he/she will need to have one. Based on the study results, your doctor will determine if your child can proceed with the study. If your doctor recommends that you do not continue with the study, you and your child would be done with the study at this point.

        i. A PSG is an overnight sleep study which records detailed information that shows how the body responds during sleep. A technician will attach sensors to your child's body for the study which will keep track of several body functions including brain waves, heart rate, breathing rate, oxygen level, eye movement and chin movement. This information will be used to prepare a detailed report about how your child sleeps.

c. Third, your child will undergo a Drug-induced sleep endoscopy (DISE) if your child has not had DISE within the last 18 months. Based on the results of this test, the doctor may recommend that your child is a candidate for nerve stimulation device. They may also determine that your child is not a candidate for nerve stimulation device. If your child is not a candidate, you and your child are done with the study at this point.

   i. DISE is a type of study performed under sedation in the operating room. Doctors will monitor your child's heart and oxygen levels while he/she is put to sleep using medications given through an IV in a vein. After your child is asleep, a flexible camera will be placed into the nose to take pictures of your child's nose and throat. The pictures will be saved on a video camera or computer and used to help identify locations that may be contributing to your child's snoring and sleep apnea. This procedure will take approximately 1-2 hours, and your child should be able to go home the same day after you wake up.

   ii. A team of up to 3 doctors will review the results of the DISE; at least two of these doctors must agree you or your child is a good candidate for the study before moving forward. The three doctors who review the DISE are: Dr. Christopher Hartnick (Massachusetts Eye and Ear Infirmary), Dr. Ryan Soose (University of Pittsburgh Medical Center), and Dr. Raj Dedhia (University of Pennsylvania/Penn Medicine).

   iii. To facilitate this review, the DISE video will be uploaded to a secure, password protected website hosted by Inspire. Your child's name will not be associated with the video; only the date of the DISE and the hospital where the DISE was done will be listed.

3. **Surgery:** When it has been determined your child is a candidate for the study, preparation for surgery will be based on hospital standards at Massachusetts Eye and Ear Infirmary. The surgery will be performed under general anesthesia. During the surgery, 3 incisions will be made in the skin. One will be under your child's chin through which an electrode attached to a lead (wire) will be surgically implanted around one of your child's hypoglossal nerves (the nerve the controls movement of his/her tongue).

   A second incision just below one of your child's collar bones will be made to implant a stimulator under the skin. The stimulator is a small device that provides mild electrical impulses to the hypoglossal nerve.

A third incision will be made between your child's ribs to implant a pressure sensor. The wire attached to this sensor will also be connected to the stimulator. The system (the three implanted parts) will then be tested to see if it moves your child's tongue. Later on, after your child's body has healed, the implanted system will be turned on to see if it helps to open up the airway while your child sleeps to improve his/her breathing.

a. **Planned duration of stay in the hospital:** After surgery your child will be in the hospital for one or more nights based on his/her recovery.

b. **Discomfort:** When the anesthesia wears off after surgery your child will feel some mild soreness in the neck or at the incision sites. He/she will be given pain relieving medicine to relieve any discomfort, as well as a medicine to prevent infection.

c. **Postoperative X-ray:** An X-ray of the device will be performed after surgery to verify the position of the device and electrodes. Your child will be exposed to a very small dose of radiation for this procedure, similar to the levels experienced during a standard chest radiograph.

4. **Surgery Follow-up Visit:** The study team recommends that you follow up with a local ear, nose, and throat doctor one week after surgery to check that the surgical wound is healing well. We do not plan to collect any data for the study from this visit.

5. **One Month After Surgery:** Approximately one month after surgery you and your child will be seen in clinic. The doctor will speak with you about your child's general health and well-being after surgery and the implant. The doctor will examine your child's tongue and wound. You will also be asked to help fill out short questionnaires about your child's symptoms, how sleepy he/she feels in certain situations, and how well he/she feels in general. These tests are called the *OSA-18* and the *Epworth Sleepiness Scale*. The doctor will then check your child's implanted device with a computer-like machine called a programmer. This machine has a wire that the doctor will place outside your child's body and over his/her device. The doctor will then turn on the device. Your child will feel his/her tongue move or feel a mild stimulation, but the stimulation will be very weak. You and your child should tell the doctor what he/she feels from the device. The device will then be turned off. Your child will also undergo an in-lab sleep study (PSG). The device will be turned back on, and the settings will be adjusted to improve your child's sleep and make sure your child is comfortable. You will also be given a subject programmer, which is a hand-held remote control to turn on your child's implanted device when he/she goes to sleep, and to adjust the stimulation amplitude slightly (if needed), then turn off the device when your child wakes up. You will receive instructions on how to use it. Now that the stimulation device has been activated, your

child will then begin using it each night for sleep. When he/she is awake and the stimulation is on, your child should feel his/her tongue move or mild stimulation, but this should not wake him/her up when asleep. The sensation may take a few nights to get used to.

6. **Two months, 6 months, and 12 months after surgery:** You and your child will return to clinic. The doctor will talk to you about your child's general health and wellbeing, examine your child's tongue and incision sites, and ask that you and your child complete the *OSA-18* and the *Epworth Sleepiness Scale* questionnaires. The doctor will also check the performance of your child's implanted device and its settings with the physician programmer machine. Your child will also undergo an in-lab sleep study (PSG). The first half of the night will evaluate your child's sleep, and in the second half device settings may be changed and adjusted.

7. **Visits after study completion:** Even after the study has concluded, you/your child will need to see the surgeon at least once per year while the nerve stimulator remains implanted. These visits are not part of the study but they are important to make sure that the device is functioning normally and that the surrounding tissue remains healthy.

Your child will be asked to stop other therapies for his/her apnea, such as CPAP, while he/she is in the trial. If your child has a tracheotomy, doctors may want to cap the tracheotomy during the study period.

Partners has an electronic system that lets the study doctors know if your child is admitted to a Partners Hospital, or if your child visits a Partners Hospital Emergency Department. We want to make sure the study doctors know about any possible problems or side effects your child experiences while s/he is taking part in the study.

Study Information Included in Your Child's Electronic Medical Record
A notation that your child is taking part in this research study may be made in your child's electronic medical record. Information from the research that relates to your child's general medical care may be included in the record (for example, list of allergies, results of standard blood tests done at the hospital labs).

How may we use and share your child's samples and health information for other research?

The images and information we collect in this study may help advance other research. If your child joins this study, we may remove all information that identifies your child (for example, your name, medical record number, and date of birth) and use these de-identified data in other research. It won't be possible to link the information back to your child. Information may be shared with investigators at our hospitals, at other academic institutions or at for-profit, commercial entities. You will not be asked to provide additional informed consent for these uses.

Will you get the results of this research study?

No. The research study we are doing is only a stepping stone in understanding **the treatment of obstructive sleep apnea.** Therefore, no information about the results of this research study or the results of your child's individual participation in the research study will be given to you or your child's doctor. Tests done for the research using your child's samples will not be useful in directing your child's medical treatment. The results of the tests will not be placed in your child's medical record.

What are the risks and possible discomforts from being in this research study?

Participation in this study may involve risks that are currently not known.

Risks of Screening Procedures:

Risks of Drug-Induced Sleep Endoscopy	
Nose bleeding	Light-headedness
Trauma to the upper airway	Pain or irritation in the throat or nasal passage
Suspension of breathing episode	
Risks of PSG Studies	
Inability to sleep in the PSG lab	Fatigue the next day, loss of productivity
Irritation or bleeding at external electrode sites	May lead to pain or sleeplessness
Bruising or bleeding or soreness from external electrode removal	

Risks of Implantation Surgery:

The surgical scar will be approximately 2 inches long, just below the chin. Normally this scar blends in with normal creases in the neck and is not disfiguring. The electrodes and sensor should not be noticeable underneath the skin. The stimulator may cause a small lump underneath the skin below the collar bone.

Considerations for future medical care - *Noncompliance with the following postoperative precautions may have serious effects on your child's health*

Strong magnetic fields generated by magnetic resonance imaging (MRI) scanners may move the stimulation device, leads, or cause excessive stimulation**. After the device is implanted, your child will not be able to have an MRI scan of the chest, but will able to get MRI imaging of the head and extremities ONLY according to specific parameters.** Should your child require MRI imaging of the head and extremities, consult the study doctor so he/she can provide you with those specific parameters. Your child's doctor may be able to get similar information about his/her health from other available testing methods, such as CT scan, ultrasound, and X-ray, which will not interfere with the implanted device. If an MRI scan is needed of the chest, the Inspire® system must be removed surgically.

Precautions must be taken around theft and security detectors (such as those found in museums, retail stores, courthouses, and airports). The magnetic fields created by this equipment could cause the implanted device to stimulate your child's tongue. In rare cases, they could also reset the device. If this happens, your child will need to see the doctor to have the device reprogrammed.

Notify any doctor your child is seeing that he/she has an implanted device. For certain procedures (such as external cardiac defibrillators, diathermy, high output ultrasonic waves, ultrasonic scanning equipment, electrocautery and radiation therapy), equipment might be used that could interfere with your child's implanted device. It is also possible that these types of procedures could damage the stimulation system or hurt your child. However, if special precautions are taken by your child's other healthcare providers, these procedures may still be performed.

During the course of your child's life, additional implantable devices such as cardiac defibrillators or pacemakers may need to be placed. The nerve stimulator might interfere with functioning of these devices. Therefore, it is important that any doctor taking care of your child know about the nerve stimulator that is implanted. Have your child's doctor contact the investigator of this trial prior to any procedure to ensure that your child's implanted device and your child will remain safe.

A minority of OSA patients also have other neurological causes of sleep apnea, called "central sleep apnea". If improvement in your child's OSA by the implanted nerve stimulator reveals this other type of apnea, additional treatment during and after his/her hospitalization may be necessary.

Specific Risks:

Surgical and Device Related Risks	
Post-surgical pain or tenderness near incisions	Post-surgical headache, fever, or dizziness
Post-surgical throat soreness from intubation	Post-surgical nausea or vomiting
Post-surgical irritability, nervousness, confusion	Post-surgical sleep problems like insomnia or sleepiness
Post-surgical constipation	Post-surgical mild to moderate swelling, oozing, and/or bruising around the surgical incisions,
Post-surgical back pain due to lying on the table during the procedure	Depending on geography, standard uncomplicated post-implant hospitalization may be up to 36 hours.
Damage to blood vessels (e.g. erosion) in the vicinity of implant	Allergic and/or rejection response to the implanted materials
Excessive bleeding	Infection
Trauma (e.g. perforation or dissection) or damage to arteries and veins	Local irritation, infection, seroma (pocket of clear fluid under the skin, hematoma (blood outside the blood vessels), erosion, swelling
Irritation or damage to nerves near the implant	Persistent pain at the implant site
Nerve trauma	Pain, numbness or inflammation in the mouth, neck
Hypoglossal nerve trauma or damage	Strange sense of touch or burning sensation on the tongue or neck (dysesthesia)
Procedure related deterioration of pre-existing medical condition	Tongue movement restrictions
Blood thinning medications may result in complications such as excessive bleeding, clotting, or hematomas	Tongue may get larger (hypertrophy) or smaller (atrophy)
Airway constriction or obstruction	Tongue muscle twitches (Fasciculations)
Air in the chest cavity (pneumothorax)	Problems with swallowing or speaking
Damage to the lung or membrane that surrounds the lung (pleura)	Muscle stimulation of floor of mouth musculature
Death	Pneumothorax
System Related Risks	
Migration or traction of pulse generator or leads	Elevated stimulation threshold
Lead dislodgement	Failure to stimulate
Lead damage and/or failure	Implantable Pulse Generator failure

Premature battery failure	Failure of respiratory sensing
Breakage or misuse of surgical tools	Misuse of the subject programmer may result in ineffective function
Spontaneous stimulation and sensing threshold changes	Therapy may irritate a subject, wake them, or prevent them from sleeping
MRI can induce currents on implantable components, potentially causing tissue damage and tongue dysfunction	MRI may cause damage to the device
Should your child become pregnant, there may be unknown risks to the embryo or fetus	There may be risks that are not currently known at this time
Implanted parts may need to be surgically moved or removed	

Risks of using the implanted system can be minimized by following the instructions for using the Inspire® device, and by following your child's doctor's instructions.

Potential Need for More Surgery:

Battery replacement: The implanted device is powered by a battery that has an expected lifespan of 5-8 years. The lifespan of the battery will vary based on the stimulation parameters that your physician programs into your child's device. Although unlikely, the battery may deplete sooner than expected. Battery replacement is performed through a small incision at the device implant site below your child's collar bone under local anesthesia, where a numbing medication is injected into the tissue over the implant. Your child will need time to allow the incision to heal.

Repositioning or replacement of stimulation or sensing leads: If one of the implanted leads moves, the doctor may need to perform another surgery to reposition or replace the lead in order for your child to continue the device. Risks related to another surgery are described in the potential risk section (table), as well as sections on considerations for implanted device removal and potential risks associated with implanted device removal.

Considerations for Device Removal:

If your child's health should change such that he/she requires another electrical stimulation device to be implanted, your child's doctor would turn off the Inspire® system. You may choose to have the device removed, or leave it in place even though your child is not using it. You and your child will be asked to continue to follow-up with your child's study doctor until the implanted device is removed. As long as any part of the Inspire® system is implanted, your child cannot have an MRI scan of the chest.

If you and your child's doctor determine that any of the implanted devices need to be removed, the risks detailed above, along with some new risks, would apply to the removal surgery. The risks to remove a device are higher because scar tissue builds up around the implanted device, and there is a higher risk of infection from the surgery. Additional injury to the nearby nerves, blood vessels or tissues could occur.

Further additional risks include:

Potential Risks with Implanted Device Removal	
Implanted Component	**Risks**
Stimulation lead – risk of removal is increased because of scar tissue that builds up around the lead after it has been implanted in the body. This lead is around the hypoglossal nerve in the neck area.	Irritation or Injury to the nerves located in the area around the tongue and jaw
	Injury to blood vessels (arteries and veins) in the tongue, jaw and neck
	Extended recovery time
Sensing lead – risk of removal is increased because of scar tissue that builds up around the lead after it has been implanted in the body. This lead is on your side implanted between the ribs.	Irritation or injury to the lung or rib
	Collapsed lung
	Scar tissue and adhesions
	Extended recovery time
Stimulator - this is implanted in your upper chest below the collar bone.	Scar tissue and adhesions

Pregnancy Risks

Your child may not take part in the study if your child is or plans to become pregnant during the study period due to procedures that require general anesthesia. If your child is female and at least 11 years old, a urine pregnancy test will be conducted as part of the hospital's standard care before undergoing a procedure with anesthesia.

Risks of Anesthesia

Drug induced sleep endoscopy, surgical implantation, battery replacement, electrode repositioning and device implantation will be performed under anesthesia. General anesthesia can result in airway obstruction, temporary changes in heart-rate and oxygen level, and changes in behavior as medications wear off. **These risks are increased in subjects with Down syndrome**. Your child's anesthesiologist will specifically discuss these risks with you and obtain a separate consent on the day of procedures and surgeries requiring anesthesia.

What are the possible benefits from being in this research study?

While it is possible that the implanted device will help to improve your child's Obstructive Sleep Apnea symptoms, your child may not directly benefit from participating in this research study. The data collected in this study will assist with the development of future therapies for obstructive sleep apnea.

Can your child still get medical care within Partners if s/he doesn't take part in this research study, or if s/he stops taking part?

Yes. Your decision won't change the medical care your child gets within Partners now or in the future. There will be no penalty, and your child won't lose any benefits your child receives now or has a right to receive.

We will tell you if we learn new information that could make you change your mind about your child taking part in this research study.

What should you do if you want your child to stop taking part in the study?

If your child takes part in this research study, and you want him/her to drop out, you should tell us. We will make sure that your child stops the study safely. We will also talk to you about follow-up care for your child, if needed.

Also, it is possible that we will have to ask your child to drop out of the study before s/he finishes it. If this happens, we will tell you why. We will also help arrange other care for your child, if needed.

Will you or your child be paid to take part in this research study?

You will not be paid to participate in this study.

We may use your child's samples and information to develop a new product or medical test to be sold. The Sponsor, hospital, and researchers may benefit if this happens. There are no plans to pay you or your child if your samples or information are used for this purpose.

What will you have to pay for if your child takes part in this research study?

If your child participates in this research study, the cost of the Inspire® System hypoglossal nerve stimulator being used in this study and/or the cost of certain procedures performed for the purpose of this research study will be billed to your health insurance provider. You will also be responsible for any deductibles and co-payments required by your insurance company for standard treatment.

You will be notified, in advance should your health insurance provider refuse to cover certain or all of these research costs and if any of these uncovered research costs will be billed directly to you. You will be provided with a price estimate for the uncovered research costs that will be billed to you. If you decide to continue your child's participation in the research study, you will be referred to a financial counselor at the hospital to establish an acceptable payment arrangement and/or to discuss whether any financial assistance may be available to you.

If you do not have health care insurance, you will be provided with a price estimate of the research costs that will be billed to you. If you decide to continue your child's participation in this research study, you will be referred to a financial counselor at the hospital to establish an acceptable payment arrangement and/or discuss whether you would qualify for financial assistance.

For more information, please ask to speak to someone regarding the hospital's Patient Financial Assistance Program which is intended to assist low-income patients who do not have the ability to pay for their health care services.

If you choose to have your child's Inspire® system removed, you would be responsible for the cost.

What happens if your child is injured as a result of taking part in this research study?

We will offer your child the care needed to treat any injury that directly results from taking part in this research study. We reserve the right to bill your insurance company or other third parties, if appropriate, for the care your child gets for the injury. We will try to have these costs paid for, but you may be responsible for some of them. For example, if the care is billed to your insurer, you will be responsible for payment of any deductibles and co-payments required by your insurer.

Injuries sometimes happen in research even when no one is at fault. There are no plans to pay you or your child or give you other compensation for an injury, should one occur. However, you or your child are not giving up any of your legal rights by signing this form.

If you think your child has been injured or has experienced a medical problem as a result of taking part in this research study, tell the person in charge of this study as soon as possible. The researcher's name and phone number are listed in the beginning of this consent form.

If your child takes part in this research study, how will we protect your child's privacy?

Federal law requires Partners to protect the privacy of health information and related information that identifies you. We refer to this information as "identifiable information."

In this study, we may collect identifiable information about your child from:

- Past, present, and future medical records
- Research procedures, including research office visits, tests, interviews, and questionnaires

Who may see, use, and share your child's identifiable information and why they may need to do so:

- Partners researchers and staff involved in this study
- The sponsor(s) of this study, and the people or groups it hires to help perform this research or to audit the research
- Other researchers and medical centers that are part of this study
- The Partners ethics board or an ethics board outside Partners that oversees the research
- A group that oversees the data (study information) and safety of this study
- Non-research staff within Partners who need identifiable information to do their jobs, such as for treatment, payment (billing), or hospital operations (such as assessing the quality of care or research)
- People or groups that we hire to do certain work for us, such as data storage companies, accreditors, insurers, and lawyers
- Federal agencies (such as the U.S. Department of Health and Human Services (DHHS) and agencies within DHHS like the Food and Drug Administration, the National Institutes of Health, and the Office for Human Research Protections), state agencies, and foreign government bodies that oversee, evaluate, and audit research, which may include inspection of your records

- Public health and safety authorities, if we learn information that could mean harm to your child or others (such as to make required reports about communicable diseases or about child or elder abuse)
- Other: Inspire Medical Systems staff

Some people or groups who get your child's identifiable information might not have to follow the same privacy rules that we follow and might use or share your child's identifiable information without your permission in ways that are not described in this form. For example, we understand that the sponsor of this study may use your child's identifiable information to perform additional research on various products or conditions, to obtain regulatory approval of its products, to propose new products, and to oversee and improve its products' performance. We share your child's identifiable information only when we must, and we ask anyone who receives it from us to take measures to protect your child's privacy. The sponsor has agreed that it will not contact you or your child without your permission and will not use or share your child's identifiable information for any mailing or marketing list. However, once your child's identifiable information is shared outside Partners, we cannot control all the ways that others use or share it and cannot promise that it will remain private.

Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your child's identifiable information. Your permission to use and share your child's identifiable information does not expire.

The results of this research study may be published in a medical book or journal, or used to teach others. However, your child's name or other identifiable information **will not** be used for these purposes without your specific permission.

Your Child's Privacy Rights

You have the right **not** to sign this form that allows us to use and share your child's identifiable information for research; however, if you don't sign it, your child can't take part in this research study.

You have the right to withdraw your permission for us to use or share your child's identifiable information for this research study. If you want to withdraw your permission, you must notify the person in charge of this research study in writing. Once permission is withdrawn, your child cannot continue to take part in the study.

If you withdraw your permission, we will not be able to take back information that has already been used or shared with others, and such information may continue to be used for certain purposes, such as to comply with the law or maintain the reliability of the study.

You have the right to see and get a copy of your child's identifiable information that is used or shared for treatment or for payment. To ask for this information, please contact the person in charge of this research study. You may only get such information after the research is finished.

Informed Consent and Authorization

Statement of Person Giving Informed Consent and Authorization

- I have read this consent form.
- This research study has been explained to me, including risks and possible benefits (if any), other possible treatments or procedures, and other important things about the study.
- I have had the opportunity to ask questions.
- I understand the information given to me.

Signature of Subject (Consent):

I give my consent to take part in this research study and agree to allow my health information to be used and shared as described above.

_____	_____	_____
Subject	Date	Time

Signature of Parent(s)/Guardian for Child (Consent):

I give my consent for my child to take part in this research study and agree to allow his/her health information to be used and shared as described above.

_____	_____	_____
Parent(s)/Guardian #1 for Child	Date	Time

_____	_____	_____
Parent(s)/Guardian #2 for Child	Date	Time

Signature of Guardian or Authorized Representative for Adult (Consent):

I give my consent for the person I am authorized to represent to take part in this research study and agree to allow his/her health information to be used and shared as described above.

_____

Print Name (check applicable box below)

- ☐ Court-appointed Guardian
- ☐ Health Care Proxy
- ☐ Durable Power of Attorney
- ☐ Family Member/Next-of-Kin

_____ _____ _____

Signature Date Time (optional)

Relationship to Subject:_____

Assent

Statement of Person Giving Assent

- This research study has been explained to me, including risks and possible benefits (if any), other possible treatments or procedures, and other important things about the study.
- I have had the opportunity to ask questions, and my questions have been answered.

Signature of Child (Assent):

I agree to take part in this research study and agree to allow my health information to be used and shared as described above.

_____ _____ _____

Child Assent, Ages 14-17 Date Time

Signature of Adult (Assent):

I agree to take part in this research study and agree to allow my health information to be used and shared as described above.

Adult Assent, Ages 18 and over	Date	Time

Signature of Study Doctor or Person Obtaining Consent:

Statement of Study Doctor or Person Obtaining Consent

- I have explained the research to the parent(s)/guardian and child.
- I have answered all questions about this research study to the best of my ability.

Study Doctor or Person Obtaining Consent	Date	Time

Consent Form Version Date: 11/4/2019