BRONSON	Affix Patient Label
	Patient Name: Date of Birth:

Informed Consent For Pediatric
Anorectal Manometry (ARM) with or without Sedation

This information is given to you so that you can make an informed decision about your child having **Anorectal Manometry (ARM) with or without Sedation.**

Reason and Purpose of the Procedure:
Anorectal manometry is used in infants and children with stooling problems. It tests the relaxation of the muscles which help to control bowel movements. These are called sphincters. It can also test how well the child senses fullness of the rectum. This is how the body knows it is time to have a bowel movement. A tube with a balloon on its end is inserted into the rectum. The balloon is slowly inflated to create a feeling of stool in the rectum. A computer shows how well the sphincter muscles are working.

Your child may be given some medication to relax him/her during the procedure. Most children are able to tolerate the procedure, and are able to cooperate with the doctor's requests without difficulty.

Benefits of this procedure:
Your child might receive the following benefits. Your doctor cannot promise your child will receive any of these benefits. Only you can decide if the benefits are worth the risk.

- Helps the doctor diagnose specific medical conditions, so treatment can be started.
- Allows the doctor to test the coordination of the rectal muscles. Your child can be taught exercises to help with rectal muscle coordination.

Risks of procedure:
No procedure is completely risk free. Some risks are well known. There may be risks not included in the list that your doctor cannot expect.

Risks of this procedure:

- **Rectal Bleeding.** This can be due to irritation from the tube insertion. Medication may be needed.
- **Infection.** Your child may need antibiotics.
- **Perforation.** This is a small hole or puncture. This can occur in the rectum. Your child may need surgery to repair**.**
- **Reactions to the oral sedation.** Your child may have hives or a rash. He/she may have hyperactivity. Sometimes a severe reaction can occur and cause breathing problems. Emergency medications and equipment are kept readily available should this happen.

Information on Moderate Sedation:
Your child will be given medicine in an IV to relax him/her. This medicine will also make your child more comfortable. This is called "moderate sedation". Your child will feel sleepy. He/she may sleep through parts of the procedure. We will monitor your child's heart rate and blood pressure. We will also monitor their oxygen level. If your child's heart rate, blood pressure or oxygen levels fall outside the normal range, we may give medications to reverse the sedation. We may not be able to reverse the sedation. We may need to support their breathing. Even if your child has a NO CODE status, they:

- may need intubation to support their breathing.
- may need medications to support their blood pressure.

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We will re-evaluate your child's medical treatment plan and NO CODE status when sedation has cleared their body.

General Risks of this Procedure:

- Small areas of the lungs may collapse. This would increase the risk of infection. This may need antibiotics and breathing treatments.
- Clots may form in the legs, with pain and swelling. These are called DVT's or deep vein thrombosis. Rarely, a part of the clot may break off and go to the lungs. This can be fatal.
- Bleeding may occur. If excessive your child may need a blood transfusion.
- Reaction to the anesthetic. The most common reactions are nausea and vomiting. In rare cases, death may occur. The anesthesiologist will discuss this with you.

Risks Associated with Obesity:

Obesity is linked to an increased risk of infections. It can also lead to heart and lung complications and clot formation.

Risks Specific to Your Child:

_____
_____
_____
_____

Alternative Treatments:

Other choices:

- Do nothing. You can decide not to have the procedure.

If You Choose Not to Have this Treatment:

- Your child may continue to have problems with constipation or stool leakage.

General Information:

- During the procedure your child's doctor may need to perform more or different procedures than you agreed to.
- During the procedure your child's doctor may need to do more tests or treatment.
- Tissues or organs taken from the body may be tested. They may be kept for research or teaching. I agree the hospital may discard these in a proper way.
- Students, technical sales people and other staff may be present during the procedure. My child's doctor will supervise them.
- Pictures and videos may be done during the procedure. These may be added to my child's medical record. These may be published for teaching purposes. My child's identity will be protected.

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By signing this form I agree:

- I have read this form or had it explained to me in words I can understand.
- I understand its contents.
- I have had time to speak with my child's doctor. My questions have been answered.
- I want my child to have this procedure**: Anorectal Manometry with or without Sedation:** _____
- I understand that my child's doctor may ask a partner to do the surgery.
- I understand that other doctors, including medical residents or other staff may help with surgery. The tasks will be based on their skill level. My child's doctor will supervise them.

Provider: This patient may require a type and screen or type and cross prior to surgery. IF so, please obtain consent for blood/product.

Parent Signature_____ Date:_____ Time:_____

Relationship: □Parent □Closest relative (relationship) _____ □Guardian

Interpreter's Statement: I have translated this consent form and the doctor's explanation to the patient, a parent, closest relative or legal guardian.

Interpreter:_____ Date_____ Time:_____

Interpreter (if applicable)

For Provider Use ONLY:

I have explained the nature, purpose, risks, benefits, possible consequences of non-treatment, alternative options, and possibility of complications and side effects of the intended intervention, I have answered questions, and parent has agreed to procedure.

Provider signature:_____ Date:_____ Time:_____

Teach Back

Parent shows understanding by stating in his or her own words:

____ Reason(s) for the treatment/procedure: _____

____ Area(s) of the body that will be affected: _____

____ Benefit(s) of the procedure:_____

____ Risk(s) of the procedure: _____

____ Alternative(s) to the procedure:_____

Or

____ Parent elects not to proceed: _____ (parent signature**)**

Validated/Witness:_____Date:_____Time:_____