Approved Template
MUST BE APPROVED
FOR SITES BEFORE USE
Dec 27, 2013
WIRB®

[Insert Institution]
INFORMED CONSENT FORM

TITLE:	A Randomized, Assessor-Blind, Multicenter, Dose-Ranging Study Comparing the Safety and Efficacy of Prepopik™ versus Polyethylene Glycol Preparation (Local Standard of Care) in Children Aged 9 Years to 16 Years
PROTOCOL NO.:	000103 WIRB® Protocol #20132048
SPONSOR:	Ferring International Center U.S., Inc. (FIPCUS)
INVESTIGATOR:	Name Address City, State Zip Country
SITE(S):	Name Address City, State Zip Country
STUDY-RELATED PHONE NUMBER(S):	Name Number(s) (24-hour number required)

Name of Subject: _____

Parents/Legal Guardian: Parents or legal guardians, who are giving permission for a child, please note: in the sections that follow the word **'you'** refers to the parent or legal guardian and 'your child' is the person being asked to participate in the study.

Invitation to Participate

We invite your child to take part in this research study. This form, called an Informed Consent Form, tells you about what will happen during the study and the risks of taking part. The form also includes other important information about the research study, including the health information we will collect. If there is anything in this form you do not understand, please ask questions.

You do not have to allow your child to take part in this study if you do not want to. If your child does take part, you can remove your child from the study at any time, for any reason.

Your child is invited to participate in a research study of a medicine called PREPOPIK®, which is a medication to clean the colon prior to colonoscopy.

Introduction

The ideal pediatric colon cleansing should be able to clean the colon safely and be accepted by children. We are doing this study because currently no bowel preparation serves the needs of all children. The goal of colon cleansing is to remove all stool from the colon so the doctor can see the inside of the colon. If the colon is not cleaned properly prior to a colonoscopy, the doctor may not be able to determine what is causing the child's problems. Inadequate colon cleaning before a colonoscopy can also extend the length of the procedure and cause more complications during the procedure. A poorly cleaned colon may require that the colonoscopy be repeated. PREPOPIK® is approved for use in the United States for adults. It is also approved for adults and children in countries outside the United States. However, PREPOPIK® is not approved for use in children in the United States. The Food and Drug Administration (FDA) requires most medications to be tested on all groups of people that may have the medication prescribed to them. Ferring Pharmaceuticals is conducting this study to meet this FDA requirement.

1. Why is your child being asked to take part in this study?

Your child is being asked to take part in this study because he/she is being scheduled to undergo a colonoscopy, which is a test that allows the doctor to look inside the colon (large intestine or bowel) using a long flexible tube, about the width of a finger, called a colonoscope. It has a camera at the tip, which allows the doctor to view the inside of the colon on a video screen. Your child will receive a colon cleansing medication in preparation for the colonoscopy.

2. What is the purpose of this research study?

The purpose of the study is to determine if PREPOPIK® is effective, safe, and tolerated in children aged 9 years to 16 years for colon cleansing in preparation for colonoscopy when compared to oral polyethylene glycol (PEG) preparation, which is currently used for colon cleansing. Your child's opinion of the colon cleansing will also be collected.

Some children will also be asked to give five additional blood samples for pharmacokinetic testing. This testing is to help understand how long the drug stays in the body and how the drug is changed or metabolized by the body. This helps to understand the best dose of the colon cleansing medication for children. If participating in the pharmacokinetic testing, your child will be required to spend the night before the colonoscopy in the hospital, in order to have the extra blood draws.

If your child takes part in this study, your child will be randomly assigned (by chance) to receive either PREPOPIK®, or PEG preparation. PEG is currently used by your doctor, and is called

local standard of care. Your child will have a 2 out of 3 chance of receiving PREPOPIK® and a 1 out of 3 chance of receiving PEG (local standard of care).

There will be approximately 75 children in the study (45 children who are 9-12 years old and 30 children who are 13-16 years old). Fifteen children (ten children aged 9-12 and five children aged 13-16) will participate in the pharmacokinetic portion of the study.

Your child's participation in the study is expected to last between 25-43 days, depending on when your child's visits are scheduled.

3. What is involved in the research study?
If you and your child agree to have your child take part in this study, the following tests and procedures will occur:

Screening Visit – Visit 1
Before or at the first official visit, called the Screening Visit, the study will be explained to you and your child by the study doctor, who is also called the investigator. After hearing about the study, you and your child will have time to think about the study, and decide if your child would like to participate. If you and your child decide to participate, you must sign this Informed Consent Form and your child must sign an assent form. Signing the consent form means that the study has been explained to you and you give permission for your child to be in the study. Signing the assent form means that your child is willing to participate in the study.

After these forms have been signed, the investigator and his/her study team members will ask questions, perform a physical exam, and take blood and urine tests. These are done to make sure that your child is healthy enough to take part in this study.

Visit 1 procedures:

The investigator and his/her study team members will:

- Ask questions and take notes on your child's medical history and medications that he/she is taking
- Measure your child's body weight and height
- Measure your child's blood pressure and pulse while laying down and standing
- Perform a complete physical examination
- Take about 7.5 mL (1 and a half teaspoons) of blood and a urine sample from your child for tests
- Perform a urine pregnancy test on girls
- Schedule the date of colonoscopy to be performed within 3 weeks from this visit
- Answer any questions you may have
- Schedule Visit 2

Visit 2 - Randomization Visit
Visit 2 takes place 10 days or less before your child's colonoscopy. At this visit, the investigator and his/her study team will make sure that your child is still able to be in the study.

Visit 2 procedures:

During this visit a study team member will:

- Ask questions and take notes on your child's medical history and medications that he/she is taking
- Measure your child's blood pressure and pulse while laying down and standing
- Perform a physical examination
- Perform a urine pregnancy test on girls ages 9 and older
- Tell you and your child which medication for colon cleansing will be used
- Give you and your child clear instructions on how and when to take the medication
- Give you the study medication or a prescription for the medication
- Take a sample of about 2.4 mL (½ teaspoon) of blood if your child is participating in the pharmacokinetic part of the study
- Ask you to sign a form stating that you and your child will not tell the doctor performing the colonoscopy which colon cleansing medication your child used or about any blood draws your child might have
- Answer any questions you may have

Day before the colonoscopy

- Your child will need to drink the medication ordered as instructed by following the directions given to you and your child by the study team during the randomization visit
- Your child should not eat solid food during the 24 hours before the colonoscopy
- If your child is participating in the extra pharmacokinetic testing, he/she will be admitted to the hospital and stay overnight

Day of Colonoscopy – Visit 3
Before the colonoscopy, a study team member will:

- Ask if your child has taken the study medication as instructed
- Ask questions to make sure that your child has not had any new health problems since the last visit and any medications that he/she is taking
- Ask about and take notes on any medications taken since the last visit
- Perform a physical exam
- Ask you and your child to give your/his/her opinion of the study medication by answering a few questions on a survey form
- Take a blood sample at 6,8,10, and 12 hours after the first dose of the study medication totaling 14.4 ml (about 3 teaspoons) of blood if your child is selected to have the additional pharmacokinetic testing
- Answer any questions you may have

After the colonoscopy

- A study team member will check your child for side effects
- Measure your child's blood pressure and pulse while laying down and standing
- Perform a physical examination to check that your child tolerated the colonoscopy without problems
- Take about 7.5 mL (1 and a half teaspoons) of blood and a urine sample for tests to make sure your child is well enough to leave the hospital
- Answer any questions you may have

Follow-up visit – Visit 4 (3-7 days after the colonoscopy)

During this visit, a study team member will:

- Check your child for side effects related to the colonoscopy and medication
- Review the list of medications your child has taken
- Ask about any new medications your child has taken
- Take about 7.5 mL (1 and a half teaspoons) of blood and a urine sample from your child for tests
- Measure your child's blood pressure and pulse while laying down and standing
- Answer any questions you may have

Follow-up call (23-33 days after the colonoscopy)

A member of the study team will call you to discuss:

- Any illnesses or issues your child has had since the last visit
- Any medication your child has taken
- Any questions or concerns you might have about your child's participation in the study

Consent to PK Blood Samples and Testing

The first 5 subjects aged 13-16 years (assigned to 1 dose packet) and the first 10 subjects aged 9-12 years (5 assigned to ½ dose packet and 5 assigned to 1 dose packet) will be asked to participate in the PK blood testing. Your child does not have to participate in the PK testing in order to be in the study.

The Sponsor would like to collect additional blood samples on Study Visit 2 and after your child has taken the study medication for testing to determine how the drug is processed by your child's body. This may help the study Sponsor to determine the safest dose in the future. You do not have to agree to the collection of these PK blood samples for your child to participate in the main study. If you elect to have these blood samples collected and tested from your child and then change your mind, you must tell the study doctor you want the Sponsor to stop testing your child's blood. The Sponsor will then destroy your child's blood samples. If the Sponsor did any testing before you changed your mind, the Sponsor will still use the test results.

Because the samples will be taken over a 12 hour period of time, your child most likely will be required to stay overnight at the study center in order to facilitate the timing of the blood draws. Subjects who follow the "Split Dose" regimen will be required to stay overnight as the first dose must be taken between the hours of 5:00 PM and 9:00 PM. Subjects who follow the "Day Before" regimen would have the option to stay overnight or go home, depending on the timing of the first study drug administration.

If asked, do you agree to allow the collection of blood samples from your child for PK testing?
[select one of the following options by recording your initials on the appropriate line]:

I agree to allow my child to participate in the PK blood testing:

_____

I do not agree to allow my child participate in the PK blood testing:

_____

4. What are the risks of taking part in this research study?
Taking part in a research study may involve risks or "side effects."

The most common side effects found in other large studies with PREPOPIK® in children are nausea, headache, and vomiting, experienced by less than 1 percent of people taking PREPOPIK®. Patients have also complained of abdominal cramps and a sore rectum. Mild dehydration has also occurred. Some patients have had changes in the sodium, potassium and magnesium levels in their blood.

The most common side effects found with the standard of care, polyethylene glycol (PEG) preparations are nausea, bloating and abdominal fullness and were experienced by half the people who took the medication. Abdominal cramps, vomiting and rectal soreness also occurred for some people.

The risks associated with blood sampling for laboratory tests may include your child having pain or discomfort at the site of the blood test, feeling light headed or faint, developing a bruise at the site of the blood draw and rarely developing a skin infection.

You should talk about these risks with the study doctor. There may be other side effects we do not know about yet. We may give your child other medicines to make any side effects less serious or to make them feel better.

Are there risks if my child becomes pregnant or fathers a child during the study?
Your child should not participate in this study if she is pregnant, planning on becoming pregnant during the study, or is breastfeeding. The potential side effects to an unborn or breastfed child are not known at this time. Some drugs cause females to have their babies prematurely (early) or to have babies with birth defects.

If your child is female and sexually active she must agree to use a medically acceptable method of birth control. The study doctor will talk to you and her about birth control methods she must use during the study.

If your child should become pregnant while participating in the study, you or your child must notify the study doctor or study staff immediately. If your child becomes pregnant, she will have to withdraw from the study. The study doctor may ask for information about her pregnancy and the birth of the baby.

If your child's partner thinks she is pregnant during the study or within 28 days after your child has stopped taking study drug, you or your child should tell your study doctor immediately. The study doctor may ask your child's pregnant partner to provide her consent to collect information about her pregnancy and the birth of the baby.

Your child's health is important to us. We will talk to you if we need to make changes to the study to protect your child's health. We will also tell you if we learn of a better colonoscopy preparation here or somewhere else. You may choose for your child to have another preparation instead. This may mean that your child can no longer be a part of this study.

You will be told of new developments during the course of the study that may influence your willingness to allow your child to continue to participate in this medical research study.

5. Are there any benefits to taking part in this study?

Your child may not experience direct benefit by participating in the study. The benefits from taking part in this study may include easier colon cleansing than with the standard colon cleansing, but we cannot guarantee these benefits. The information we learn, however, may benefit children requiring a colon cleansing medication in preparation for a colonoscopy in the future.

6. What happens if you decide not to have your child take part in this study?

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

Participation in this study is voluntary; your child does not have to take part in order to receive care at [Insert Institution where study is taking place]. If you decide not to have your child take part, or if you change your mind, there will be no penalties or loss of any benefits to which your child is otherwise entitled. Your child's current and future medical care at [Insert Institution where study is taking place] will not be affected by your decision.

An alternative to participating in this study is to continue with your child's colon cleansing as ordered by [Insert Institution where study is taking place's] standard of care. This includes

cleaning the colon by using the currently approved Polyethylene Glycol (PEG) medication. Your doctor will discuss the benefits and risks of the alternative colon cleansing with you and your child.

7. Will confidential information be collected as part of this study?

Yes, we need to collect health information about your child in order to conduct this study. This includes information from their medical records and from the procedures, interviews and tests that are part of this research. Routine clinical laboratory tests performed as part of this study will appear in your child's medical record. We will do our best to keep your child's personal information private and confidential. However, we cannot guarantee absolute confidentiality. Your child's personal information may be disclosed if required by law.

In order to protect your child's health information, we will give their information a unique code if we have to share it with others outside of [Insert Institution]. The key to this code will be kept in the study doctor's office.

There is a chance that some people or other organizations we need to share your child's health information with may not have to follow the same privacy laws as [Insert Institution]. These other people or organizations may share your information with someone else and then the privacy laws the Hospital must obey may no longer protect your child's information.

We will use your child's information only for the needs of this study and to evaluate the study results. The following groups of people at [Insert Institution] may have access to your child's information: the research team, the Hospital's ethics committee (Western Institutional Review Board® (WIRB®)) and other Hospital staff.

We may share information about your child with the following groups of people in a way that your child could be identified: The sponsor (Ferring International Pharmascience Center U.S., Inc.), its representatives and collaborators of the Sponsor, the Food and Drug Administration (FDA) and other government agencies involved in the oversight of this research.

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

Information, that does not include personally identifiable information, concerning this clinical trial has been, or will be submitted, at the appropriate and required time, to the government-operated clinical trial registry data bank, which contains registration, results, and other information about registered clinical trials.

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.

The information collected about your child as part of this study will be retained for at least 15 years or until the study is completed, whichever is longer. At that time, the research information will either be destroyed or all the information that identifies your child will be removed from the study results and the key destroyed. Any information collected as part of the study and put into your child's medical records will be kept permanently.

8. What if your child wants to leave the study after he/she begins?

Your child may choose to leave the study at any time or you may ask that your child's health information not be used. If you ask that we no longer collect your child's health information, your child will have to leave the study. If you do decide to withdraw your child, we ask that you contact Dr. [Insert PI Name] at [phone number].

Even if you take back your permission for us to use your child's information, we may still use the information about your child that we collected before your child left the study. We do this because the FDA requires us to report what happens to everyone who starts the research study, not just those who stay in it.

The study doctor or sponsor may stop or take your child out of the study at any time and for any reason. Some of the reasons the doctor may take your child out of the study include:

- The study is stopped
- New information suggests taking part in the study may not be in your child's best interest

9. Will there be any costs to you?

You or your health insurance may be billed for any medical costs during the study if the costs would have happened even if your child was not in the study. You will not be charged for the laboratory tests performed for the purposes of this study.

You will not be charged for the cost of the PREPOPIK®. You will not be charged any fees or expenses related to this study, but other expenses for surgery and hospitalization will be charged as usual.

10. Will you be paid for taking part in this study?

You will receive up to $ [XX] for each completed study visit to help pay for things like parking expenses and travel expenses to the clinic. If your child completes the study, you will receive up to a total of $ [XX].

11. Who is funding this research study?

This study is supported by funding provided by Ferring International Pharmascience Center U.S., Inc. Ferring is a drug company that is seeking to obtain US approval for PREPOPIK® in children. This medication has been approved for use in the United States by the Food and Drug Administration (FDA) for adults. Ferring is giving money to [Insert Institution] for some of the costs of the study.

The results of the study will be reported to Ferring International Pharmascience Center U.S., Inc. If the study shows that the drug may be useful in children nine to sixteen years of age, this would benefit Ferring International Pharmascience Center U.S., Inc. financially. Please ask the principal investigator, [Insert PI Name and Title], or study coordinator, if you have any questions about how this study is funded.

12. What if you have questions about the study?

If you have any additional questions about your child's participation in the study, if at any time you feel your child has had a research-related injury or a reaction to the study drug, or if you have questions, concerns, or complaints about the research, you may call [Insert PI Name/Title and Phone Number].

This study has been approved by a special group at [Insert Institution] called Western Institutional Review Board (WIRB). WIRB looks at research studies like these and makes sure your child's rights and welfare are protected. You can talk to a person in this group if you have questions about your child's rights as someone taking part in a research study or if you have questions, concerns, input or complaints about the study.
You may contact WIRB at:

Western Institutional Review Board® (WIRB®)
1019 39th Avenue, SE Suite 120
Puyallup, Washington 98374-2115
Telephone: 1-800-562-4789 or 360-252-2500
E-mail: Help@wirb.com

WIRB is a group of people who perform independent review of research.

WIRB will not be able to answer some study-specific questions, such as questions about appointment times. However, you may contact WIRB if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

You will get a signed copy of this consent form after you sign it. You may also ask to see a copy of the full study plan (protocol).

13. What happens if your child is injured during the study?

If your child is injured as a result of being in this study, you should contact [Insert PI Name], study doctor for this study, at [Insert Institution] at [Insert PI Phone Number] to arrange for the proper care and treatment. Treatment for the study-related injury will be provided for you, at no cost to you, at [Insert Institution]. However, neither [Insert Institution] nor the sponsor intend to provide financial payments or other compensation for the injury, for medical treatment received elsewhere, for loss of work, or for other expenses. There is no federal, state, or other program that will compensate you or pay for your child's medical care if they are injured because of this

study. However, by participating in this study, you are not waiving any of your child's legal rights as a subject in a research study. Your health insurance company may or may not pay for treatment of injuries as a result of your child's participation in this study.

If you believe that your child has suffered any injury as a result of participation in this research, you may either contact [Insert PI Name] at [Insert PI Phone Number] or [Insert IRB Contact Person Name] in the [Insert IRB Name] at [Insert IRB Phone Number]. They can review the matter with you, identify other resources that may be available to you and provide information on what you need to do.

Regular doctor or specialist notification option
Please indicate below whether you want us to notify your child's regular doctor or your child's specialist of his/her participation in this study.

□ Yes, I want the study doctor to inform my child's regular doctor/specialist of his/her participation in this study:

_____ _____
Name of Doctor Phone

□ No, I do not want the study doctor to inform my child's regular doctor/specialist of his/her participation in this study.

□ My child does not have a regular doctor/specialist.

□ The study doctor is my child's regular doctor/specialist.

Consent to Take Part in this Research Study

This research study and consent form has been explained to you by:

_____ _____
Investigator/Coordinator Name **Investigator/ Coordinator Signature**

By signing this form, you are saying that you have had your questions answered and you agree to have your child take part in this research study. You are also agreeing to let [Insert Institution Name] use and share your child's health information as explained above. If you do not agree to our collecting, using and sharing your child's health information, your child cannot participate in this study.

By signing this consent form, you are saying that you understand that information about the investigational drug and study is being kept confidential by the Sponsor to protect its intellectual property rights and that the information you receive in connection with participating in the study is not publicly available. You are willing to keep the information you receive regarding the investigational drug and the study confidential until the Sponsor publishes this information. If you need to discuss such information with your health care providers and immediate family members for health care purposes, you will make them aware of the confidential nature of the investigational drug and its use in this study.

Your child's participation in this study is voluntary. You do not need to sign this form. However, your child will not be in this study if you do not sign this form.

_____
Name of Authorized Representative (print)

_____ _____
Signature of Authorized Representative Date

Relation to subject: ❑ Parent ❑ Legal Guardian

Please note: a Foster Parent is not legally authorized to consent for the foster child's participation in research.

By signing this document, you are certifying that you are legally authorized to <u>consent</u> to medical care for this child.

_____ _____
Signature of Witness (if required) Date

_____
Investigator/Study Coordinator Name

_____ _____
Investigator/Study Coordinator Signature Date

HIPAA AUTHORIZATION

Federal regulations give you certain rights related to your health information. As a part of this research, the study doctor will collect and use records that contain information or data about your child's health. These records may identify your child and will be kept as confidential as possible. This is required by law. The study doctor and study staff will use this information about your child to complete this research.

When you sign this form, you are saying that you will allow the use of your child's protected health information (PHI) for this study. PHI is information that could be used to identify your child.

The information that will be collected about your child as a part of this research includes:

- Name
- Address
- Telephone number
- Birth date
- Race
- Sex
- Social security number, if applicable
- Personal and family medical history
- Medications and supplements you take (current and past)
- Information from the physical examination done by the study doctor
- Results of tests and procedures done for this study
- Other information from other doctor's offices, clinics, hospitals that is needed for the research

Information collected about your child for the research study will be kept in a research file that is separate from your child's medical chart. The study team (including the study doctor and study staff) will know your child's identity. However, they may decide to label your child's study records with your child's initials or a code assigned to it. The study doctor and study staff are the only people who would have this code and its key.

If you sign this form, you allow the study doctor to share your child's information with the following groups. They will review the study information to help make sure it is correct. They will also review how the study doctor(s) and study staff completed the study to help make sure they conducted the study correctly and safely.

- The study sponsor and the people who work with them on the study, including Novella Clinical
- The U.S. Food and Drug Administration (FDA)
- Western Institutional Review Board
- The Department of Health and Human Services
- Other government and regulatory agencies in the United States or other countries

The study doctor may also share your child's information with your health care payor to resolve your claim if your child is hurt because of being in this study. If this happens, the study doctor or the sponsor may share your child's information with their insurance carriers to resolve your insurance claim, and the study doctor may also request medical records from your other health care providers to learn more about your child's condition.

If your child's health information is reviewed by the groups and people listed above, they may need to see your child's entire medical record.

No one can promise your child's privacy will always be protected. It is possible that your child's information will be shared (re-disclosed) in a way that it would no longer be coded (as described above) or otherwise protected.

There are national and state laws that make the study doctor protect the privacy of your child's information. After the study doctor shares your child's information with the sponsor and others, the laws may no longer protect the privacy of your child's information. The sponsor or others may share your child's information with other people who do not have to protect the privacy of this information.

The study doctor or sponsor may present your child's information at meetings or in articles written about the study (publications). Your child will not be identified by name in any presentation or publication that uses your child's research or health information.

This Authorization to use and share your child's records does not have an expiration date. If you do not cancel this Authorization in writing, then the study doctor and the study staff will be able to use and share your child's records for as long as they want. The study doctor will keep this Authorization for at least 6 years.

You have a right to see and copy your child's information. However, you will not be able to see your child's study records until after all subjects have finished the study.

You may also take away (withdraw) your permission for use of your child's health information at any time. If you choose to take away your permission, you must request this in a letter to the study doctor at the address on the first page of this form.

The research study doctor will still be able to use the information collected about your child before you withdrew your permission. Information that has already been sent to the Sponsor of the research study cannot be taken back.

If you withdraw your permission after your child has entered the study, your child will be discontinued from the research study.

Even if your child leaves the study early, the study doctor and study staff will still be able to use and share your child's records as described above unless you cancel your Authorization to use and share your child's records.

If you do not give permission to use your child's health information by signing this form, your child cannot be in this research study. If you refuse to give permission, your child's medical care or the relationship with your child's health care providers will not be affected.

You do not have to sign this form. If you do not sign this form, your child cannot take part in this research study.

AUTHORIZATION
By signing this form, I allow the use or disclosure of my child's health information. I will receive a signed and dated copy of this Authorization.

For Parent/Legal Guardian of Subjects 9 to 16 Years of Age:

_____ _____
Subject's Name (Please Print) Date of Birth

_____
Parent/Legal Guardian's Name (Please Print)

_____ _____
Signature of Parent/Legal Guardian Date

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PMF
A-F
Redacted