INFORMATION AND CONSENT FORM
For Adult Participants

Study Title:	A Prospective, Multi-center Registry for Patients with Short Bowel Syndrome
Study #:	TED-R13-002
Sponsor:	Shire-NPS Pharmaceuticals,Inc
Registry Doctor:	Satinder S. Gill MD
	Emeritas Research Group, LLC 19455 Deerfield Ave., Ste. 201 Leesburg, VA 20176
Telephone Number:	(703) 723-3670
After Office Hours:	Not Applicable

WHAT IS THIS REGISTRY ABOUT?

Shire-NPS Pharmaceuticals, Inc. (the sponsor) would like to collect information about the long-term safety profile of people with short bowel syndrome (SBS) who are treated with a drug called teduglutide. The purpose of this registry research study is to evaluate the long-term safety profile and clinical course for people with SBS who are treated with teduglutide in a routine clinical setting, as well as those with SBS who are not being treated with teduglutide.

The primary safety objective is to determine the occurrence of colorectal cancer in people with SBS with any remnant colon taking or having taken teduglutide. The registry will also evaluate the long-term clinical outcomes in people with SBS.

You are being asked to participate in this registry because you have SBS and you have been treated with teduglutide, or you continue to receive parenteral nutrition for at least 6 months and have not been treated with teduglutide.

If you decide to take part in this registry, your registry doctor and staff will collect information about you and your health as part of your routine medical care and provide your information to Shire-NPS Pharmaceuticals, Inc. or its designee to include in the registry. A clinical research organization specializing in these types of studies (Quintiles) has been contracted by the sponsor to collect, monitor, and analyze the data.

Because this registry is observational, there are no scheduled visits or procedures that must happen as part of your participation in the registry.

If you decide to participate in the registry, your information will be collected over a period of 10 years.

It is planned that there will be approximately 1310 people in the registry, and people of any age or gender may participate.

If you have any questions or do not understand something in this form, you should ask the registry doctor or his/her staff. You should also discuss your participation with anyone you choose in order to better understand this registry and your options.

When reading this form, please note that the words “you” and “your” refer to the person in the registry rather than to a legally authorized representative who might sign this form on behalf of the person in the registry.

WHAT ARE THE ALTERNATIVES?

This registry does not involve treatment for your condition. You may choose not to be in the registry.

WHO IS PAYING FOR THIS REGISTRY?

A company called Shire-NPS Pharmaceuticals, the sponsor of the registry, is paying for this registry.

WHAT WILL HAPPEN DURING THIS REGISTRY?

This registry will collect data regarding the clinical course and outcomes of SBS in participants who are or are not treated with teduglutide in a real-world clinical setting. If you took, are taking, or will take teduglutide in the future, information about potential side effects of teduglutide will also be collected.

Whether or not you decide to be in the registry, the regular medical care you receive from your registry doctor will not be affected in any way. You will not have any additional or different medical treatments, medical procedures, or medical tests as a result of participating in this registry. You will continue to have the medical care you would normally have.

Data collection will begin after your consent is obtained, and follow-up data will be collected approximately twice a year by your doctor for the registry.

If you sign this form, your registry doctor will collect the following information about you during your routine visits as part of your regular medical care, and it will be entered in the registry:

- Information about you such as date of birth or age, gender, ethnicity, race, employment status, and highest level of education
- Height and weight
- Smoking history and alcohol consumption
- Your SBS history
- Other significant medical history
- Significant past laboratory and gastrointestinal imaging results
- Any medications that you are currently taking or have taken in the past 12 months
- Current treatments and treatments in the past for SBS
- Your entire teduglutide exposure history

- For female participants: pregnancy history, outcome of any pregnancy, and the newborn's health status (length, weight, gender, and Apgar score [quick summary of the health of your newborn baby])
    - Information about a pregnancy and the child's health at birth may be shared with the sponsor.
- The number of times you were hospitalized, went to the emergency room, and saw a doctor in his/her office in the past 12 months and why you went
- Potential reactions to teduglutide if you are taking teduglutide

At subsequent visits for your SBS routine medical care, your registry doctor and his/her staff will collect updated medical information on the items listed above, and enter the updated information into the registry data collection system.

Male participants able to father a child:

If you are a man able to father a child and you are taking teduglutide, please tell your registry doctor if your partner becomes pregnant. Your partner will be asked for permission to collect information about the pregnancy using a separate document.

Information about a partner's pregnancy and the child's health at birth may be shared with the sponsor.

Long-term follow-up

In case your registry doctor and/or his/her staff cannot reach you during registry participation, they may consult the below-listed sources of information to find out what happened to you and report this information in the registry data collection system. It is possible that this search might include your death and its cause. For this reason, you will be asked to provide:

- Your personal and contact information (e.g., postal address, telephone number, email address, social security number)
- Contact information for another individual, such as next of kin, who would know your whereabouts and information

This contact information about you and your next of kin that is collected for the purpose of the registry will remain at the study site and will be destroyed at the end of the registry.

If a vital status database is available, it may be used by your registry doctor and his/her staff to ascertain your status in case you become unreachable at all. If your registry doctor learns of your death during the course of the registry, your registry doctor and his/her staff may attempt to find out the reason for your passing and enter this information into the registry. This is a common procedure for long-term registries.

In case you transfer your regular medical care to a new doctor, you will be asked to provide permission for the sponsor and the clinical research organization to contact your new doctor.

WILL BEING IN THIS REGISTRY HELP ME?

There will be no direct benefit to you as a result of participating in this registry. Information from this registry may help researchers and health care professionals to better understand the safety of teduglutide and the natural history of SBS. This information may help others with SBS in the future.

ARE THERE RISKS IF I AM IN THIS REGISTRY?

There are no expected medical or physical risks related to your participation in this registry. You will not change your regular medical care for this registry.

The most important non-medical risk is the unintended disclosure of your medical data. There is a risk of loss of confidentiality of your information. This registry will conform to all applicable privacy and confidentiality laws to try to minimize this risk. You will read more about the protection of your information later in this form. Please ask the registry doctor or his/her staff if you would like to know more about how your information will be protected while you are in this registry.

If the registry doctor or his/her staff learns of any new information that might change your mind about continuing in the registry, your registry doctor or staff will tell you about it.

WILL IT COST ANYTHING TO BE IN THIS REGISTRY?

It will not cost you anything to be in the registry.

The sponsor has no plans to pay any expenses related to your condition and its therapies such as teduglutide, registry doctor charges, other office visits, or other tests. You or your medical insurance provider will be responsible for all costs associated with your regular medical treatment, including any therapies.

WILL I RECEIVE PAYMENT FOR PARTICIPATING IN THE REGISTRY?

No. There will be no payment for participating in the registry.

DO I HAVE TO BE IN THIS REGISTRY?

Your participation in the registry is completely voluntary. You can decide not to be in the registry, and you can change your mind about being in the registry at any time. There will be no penalty to you, and you will not lose any benefits. The regular care you receive from your doctor will not be affected in any way.

You can stop your participation in the registry at any time by informing the registry doctor. If you decide to withdraw from the registry early, your registry doctor or his/her staff may ask you questions about your time participating in the registry.

If you withdraw your consent to participate in this registry, then no new information will be collected from you. The data collected prior to your withdrawal, including your personal and health information, may still be used for the data analysis.

If you decide to withdraw from the registry, you will be allowed to reenter the registry. You will be required to sign a new consent form. The data collected until your withdrawal will be linked to the data collected upon your reentry into the registry, and the registry doctor will collect the missing information from the time period you were not participating to the extent possible.

Your registry doctor or the sponsor can remove you from the registry at any time, for any reason, even if you want to stay in the registry. The sponsor may also choose to terminate the entire registry at any time for any reason.

What if I work for the study site or sponsor? What if I am a family member of someone who works for the study site or sponsor?

Study site/sponsor employees and their family members do not have to be in this registry. No one should influence or pressure you to be in this registry. An employee's or his/her family member's decision to be in the registry, or to leave the registry early, will not affect the employee's job or job benefits.

WHO CAN I TALK TO ABOUT THIS REGISTRY?

You can ask questions about the registry at any time. You can call the registry doctor or his/her staff at any time if you have any concerns or complaints. You should call the registry doctor or staff at the phone number listed on page 1 of this form if you have questions about the registry procedures, costs (if any), payment (if any), or if you get hurt or sick while you are in the registry.

Quorum Review reviewed this registry. Quorum Review is a group of people who review research studies to protect the rights and welfare of research participants. Review by Quorum Review does not mean that the registry study is without risks. If you have questions about your rights as a research participant, if you are not able to resolve your concerns with the registry doctor or his/her staff, if you have a complaint, or if you have general questions about what it means to be in a research study, you can call Quorum Review or visit the Quorum Review website at www.QuorumReview.com.

Quorum Review is located in Seattle, Washington.
Office hours are 8:00 AM to 5:00 PM Pacific Time, Monday through Friday.
Ask to speak with a Research Participant Liaison at 888-776-9115 (toll free).

HOW WILL MY INFORMATION BE KEPT CONFIDENTIAL, USED, AND SHARED FOR THIS REGISTRY?

This section explains who will use and share your information if you agree to be in this registry. You must authorize this use and sharing of your

information by signing this form or you cannot be in the registry. You can still be in the main registry even if you do not authorize the use and sharing of your information for the optional parts of the registry.

If you agree to participate, the registry doctor and his/her staff will collect, retain, use, and share personal and health information about you for the registry, as described in this form. The information that is important for the registry will be entered into the registry database in coded form. Coded means that no information regarding names or initials will be used, but rather only a numeric and/or alphabetic code (participant ID number), possibly with year of birth. Only the registry doctor and authorized personnel will be able to connect the code to your name. The list connecting the code with your name is kept securely by the registry site. The personal information is secured against unauthorized access. Decoding is performed only according to the conditions prescribed by applicable law or regulation.

Your information may be used and shared with these people for the following purposes:

- The registry doctor and his/her staff to conduct this research.
- The sponsor, Shire-NPS Pharmaceuticals; people who work with or for the sponsor; and other researchers involved in this registry. These people will use your information to review the results of the registry.
- Others required by law to review the quality and safety of research, including the U.S. Food and Drug Administration (FDA), Department of Health and Human Services, other government agencies in the United States and other countries, and Quorum Review.

Your information will be protected in accordance with all applicable laws related to the protection of personal data and privacy. Your study site and Shire-NPS Pharmaceuticals, Inc. shall be jointly responsible for ensuring that your information is protected. (Shire-NPS Pharmaceuticals, Inc. has appointed a company called Quintiles IMS as its “representative” in the United States to fulfill its obligations under these laws.)

After your information is shared with the people and companies listed above, the law may not require them to protect the privacy of your information.

The sponsor and those working for the sponsor may use the information collected about you during the registry to publish or present the registry results, and to submit to regulatory or health authorities. The sponsor may also use the information collected about you during the registry for other research purposes, which may include:

- Conducting retrospective reviews of the registry or the registry data;
- Evaluating other products or therapies;
- Developing a better understanding of short bowel syndrome; or
- Improving the design and efficiency of future registries or clinical studies.

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.

Your registry doctor may tell your family doctor about you taking part in the registry and ask them for medical information about you.

You can request access to your information, and you can ask the registry doctor or his/her staff what information has been recorded about you. You can request correction of any errors in the recorded information, or where information may be missing or incomplete that it be completed.

To maintain the integrity of this research, you might not have access to any information developed as part of this registry until it is completed. At that point, you generally would have access to your information.

You can cancel your authorization to use and share your information at any time by writing a letter to the registry doctor. If you cancel your authorization, you will not be able to continue in the registry. You can cancel your authorization for the optional parts of the registry and remain in the main registry.

If you cancel your authorization, the registry doctor and his/her staff will still be able to use and share your information that they have already collected.

You can ask for your information collected and used for the registry to be erased. However, it may not be able to be fully erased because of legal and

regulatory requirements. If your information cannot be fully erased, you will be informed and provided with the reasons.

This authorization to use and share your information expires in 50 years.

_____ _____

Signature of Participant or Legally Authorized Representative

Date

Thank you for reading this and considering if you will take part in this registry.

CONSENT

I have read this form, and I have been able to ask questions about this registry. The registry doctor or his/her staff has talked with me about this registry. They have answered all my questions. I voluntarily agree to be in this registry.

By signing this form, I do not give up any of my legal rights. I will get a signed copy of this consent form.

Please check either **Yes** or **No** for each option below. Your choices will not affect your participation in the main registry.

- I give permission to my registry doctor or his/her staff to collect my personal and contact information to try to locate me in case I become unreachable during registry participation.

  ☐ Yes ☐ No

- I give permission to my registry doctor or his/her staff to collect the contact details of another individual, such as next of kin, and use them in case I am unreachable during registry participation.

  ☐ Yes ☐ No

- I give permission to my registry doctor or his/her staff to use vital status databases to ascertain my status in case I become unreachable at all.

  ☐ Yes ☐ No

- If my registry doctor learns of my death during the course of the registry, I give permission to my registry doctor or his/her staff to attempt to find out the cause of my passing and enter this information into the registry.

  ☐ Yes ☐ No

- If I transfer my regular medical care to a new doctor, I give permission to my registry doctor or his/her staff to contact my new doctor.

  ☐ Yes ☐ No

_____

Printed Name of Participant

_____ _____

Signature of Participant Date

I am the legally authorized representative of the participant named above and I consent to his/her participation in this registry.

_____
Printed Name of Legally Authorized Representative

_____ _____
Signature of Legally Authorized Representative Date

I attest that the individual providing consent had enough time to consider this information, had an opportunity to ask questions, and voluntarily agreed to participation in this registry.

_____
Printed Name of Person Explaining Consent

_____ _____
Signature of Person Explaining Consent Date

WITNESS STATEMENT

As an impartial third party, I witnessed the entire consent discussion and the signature of the individual providing consent on this form.

_____
Printed Name of Witness

_____ _____
Signature of Witness Date