Authorization and Informed Consent for PAtient CenTric Chronic Pancreatitis (PACT-CP) Registry

Sponsor / Study Title:	**Nestlé Health Science S.A. / "A Patient-Driven Registry for Exocrine Pancreatic Insufficiency due to Chronic Pancreatitis"**
Protocol Number:	**NES-EPI-100**
Principal Investigator: (Study Doctor)	**«PiFullName»**
Telephone:	**«IcfPhoneNumber»**
Address:	**«PiLocations»**

Why are you being asked to be part of this registry?

You are being asked to be in a national research registry study called the "PACT-CP Pancreatitis Registry: A Patient-Driven Registry for Exocrine Pancreatic Insufficiency due to Chronic Pancreatitis" because you have a condition known as pancreatitis. This form gives you information to help you decide if you want to be included in the registry and requests your authorization to use your information for the purposes set forth in this form. You should not join this registry study until all of your questions are answered.

The decision to join the registry study is completely up to you. Your decision will not change the care you are receiving from your doctor. This registry study is not designed to treat any illness or to improve your health. You should continue to be treated for your pancreatitis by your doctor.

What is the PACT-CP Pancreatitis Registry?

The PACT-CP Pancreatitis Registry is a research study to collect healthcare information on people with Exocrine Pancreatic Insufficiency (EPI) due to pancreatitis who are being treated by a gastroenterologist. If you choose to participate in the study, you will not be asked to take any special treatments or tests as part of the study. You will be asked to complete questionnaires 4 times a year for up to 5 years, and your doctor(s) will be asked to complete questionnaires 2 times a year for up to 5 years regarding your health, treatments, and symptoms related to EPI. You will be provided with an award in the form of a $25.00 eGift Card for each completed questionnaire. The information that will be collected for this study will include demographics (for example, age, gender, race, employment, etc.), medical history (including all prior and current treatments for EPI), social history, details about the EPI condition, how pancreatitis impacts daily life, mental health, and your satisfaction with your treatment.

Why is this study being done?

The purpose of this study is to learn more about EPI due to pancreatitis through routine medical care, including where improvements can be made to patient treatment based on individual needs. The impacts of EPI and pancreatitis on subjects' daily lives and overall health will be studied, as well as how doctors treat patients with EPI. Approximately 400 subjects in North America at 20 different sites are expected to participate in this study.

What information goes into the PACT-CP Pancreatitis Registry and what happens to it?

If you decide to be in this study, you will be asked to complete PACT-CP Pancreatitis Registry Questionnaires quarterly (every three months) and to attend regularly scheduled visits with your doctor.

- You will be providing information about yourself and your condition to be included in the PACT-CP Pancreatitis Registry database.
- You will be asked to answer questions about any other medical conditions you are experiencing and medications you are taking.
- It should take you less than 25 minutes to complete questionnaires every three months.
- These questionnaires will not include your first name, last name, mailing address, full date of birth, medical record number, or your social security number.
- These questionnaires will ask for information such as your age, gender, race, ethnicity, marital status, level of education, employment status and zip code.

Your doctor will also be asked to complete forms to be included in the PACT-CP Pancreatitis Registry database. Your doctor will answer questions about things such as:

- Your condition
- When you start medications
- Your laboratory findings
- Any recent hospitalizations or new or worsening medical conditions that may be related to chronic pancreatitis or medications you are taking for chronic pancreatitis

Research staff at your doctor's office will assign you a unique PACT-CP Subject ID number that will be used to enter the information from your questionnaires into the PACT-CP Pancreatitis Registry database. The information that you and your doctor provide, including treatment information and dates of events such as clinic visits, hospitalizations, when a certain medication was prescribed, and others, will be entered into the PACT-CP Pancreatitis Registry database. Your full medical record will not be included in the PACT-CP Pancreatitis Registry database.

Why are you being asked to provide Personal Information on a separate form and what will happen to that information?

On your first study visit, you will be asked to complete a separate form that asks for contact information including email address and mobile phone number (Personal Information). Both an email address and a mobile phone number will be required to be in this study. This information will be entered into a separate Personal Information database. This information will only be used to:

- Send you PACT-CP study Questionnaires
- Provide you with your eGift Cards
- Send you study reminders
- Provide you with updates or information about additional, optional research opportunities (if payment is available related to additional/optional opportunities, it will be described at the time of the survey contact)

As part of this registry, you may be asked to enter your responses to the PACT-CP Pancreatitis Registry Questionnaires directly into an electronic system. You will need to provide Personal Information (such as your email address and mobile phone number) to create a user account. Any information you provide to create this account will not be shared with or used by HealthiVibe (the organization helping to conduct this registry study).

Who will see your complete medical record or other Personal Information?

Records of your participation in this study will be kept confidential except as disclosure is permitted by law or as described in this consent and authorization form.

Your medical record is available for use by your doctor and research staff in connection with this study. The following people and groups of people may also look at and/or copy your medical records to make sure that the study is being done properly and to check the quality of the data:

- HealthiVibe's study monitors, auditors, or representatives contracted by HealthiVibe to perform quality review activities and audits.
- The Institutional Review Board (IRB), Advarra IRB, which is responsible for protecting the rights and safety of research subjects.
- Regulatory health authorities (government agencies that oversee research or are involved in trying to keep research safe), such as the Food and Drug Administration (FDA).

If information from this study is published in a medical journal or presented at scientific meetings, you will not be identified by name or any other Personal Information.

Your Personal Information may be used and disclosed only as set forth in this consent and authorization form.

Do you have to participate in the study and how do you stop participating?

Your participation in this study is voluntary. You may decide not to participate, or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits.

To withdraw participation in the PACT-CP Pancreatitis Registry, you need to notify your study doctor of your decision, using the information listed on the first page of this form. Notification can be done in writing, in person, or by telephone.

Your participation in this study may be stopped at any time by your study doctor, the sponsor or Advarra IRB without your consent for any reason, including:

- If it is in your best interest
- If you do not consent to continue in the study after being told of changes in the study registry that may affect you
- If you lose contact with the study and your doctor for an extended period of time

After your withdrawal, neither you nor your doctor will be asked to complete any more questionnaires or forms. The information already contained in the PACT-CP Pancreatitis Registry database will not be removed.

What are the risks?

There is time and effort associated with the completion of the questionnaires. There are no anticipated physical risks. There is a potential risk of a breach of confidentiality of your health information and/or Personal Information. There may be risks that are unforeseeable.

What are the benefits?

Your participation in this study will not necessarily benefit you. The information gathered during this study may help people with pancreatitis and/or EPI in the future.

Will you be paid for participating and are there any costs?
«Compensation»

Yes, you will be paid $25.00 in the form of an eGift Card for each questionnaire you complete.

There is no cost to you to participate.

What are your alternatives?

You do not have to be in this study to receive treatment for your pancreatitis**.** This research study is for research purposes only. The only alternative is to not participate in this study.

Permission to Use and Give Out Your Personal Health Information

If you decide to be in this study, the study doctor and study staff will use and share health data about you to conduct the study. Health data may include:

- Your name.
- Address.
- Phone number.
- Date of birth.
- Medical history, including test results.
- Information from your study questionnaires.

Health data may come from your study records or from existing records kept by your doctor or other health care workers.

For this study, the study staff may share health data about you with authorized users. Authorized users may include:

- Representatives of Nestlé Health Science S.A. (sponsor)
- Representatives of HealthiVibe (the organization helping to conduct the study)
- Representatives of Advarra IRB (an Institutional Review Board that reviews this study).
- The Food and Drug Administration (FDA) and other U.S. federal and state agencies.
- Governmental agencies of other countries.
- Outside individuals and companies, such as data storage companies, that work with the researchers and sponsor and need to access your information to conduct this study.
- Other research doctors and medical centers participating in this study, if applicable.

Your health data will be used to conduct and oversee the research.

What if you do not give permission to use and give out your health information or Personal Information?

By signing and dating this Authorization , you are giving permission to use and give out your information as described in this form. If you do not give your permission,

then you will not be able to be in this study. If you are not in the study, your relationship with your doctor will continue as is.

Can you cancel your permission or will it expire?

You may cancel your permission to use and disclose your health information at any time. You can do this by notifying your doctor of your decision in writing, using the contact information listed on the first page of this form. If you withdraw your permission, you will not be able to stay in this study. Information that has already been gathered may still be used and provided to others.

Unless you cancel your permission, this authorization expires 5 years from the date when it is signed and dated. Upon expiration, no additional information will be collected but information provided under this authorization may continue to be used by the sponsor. The sponsor may hold and use the information in the PACT-CP Pancreatitis Registry database indefinitely.

Is your health information protected after it has been given to others?

There is a risk that your information will be passed on to others without your permission. The sponsor of this study will take all the appropriate measures to ensure that your health information is protected and secured from unauthorized disclosure.

Statement of authorization

I have read this form and its contents were explained. My questions have been answered. I voluntarily agree to allow study staff to collect, use and share my health data as specified in this form. I will receive a signed and dated copy of this form for my records. I am not giving up any of my legal rights by signing and dating this form.

_____

Printed Name of Subject

_____ _____

Signature of Subject Date

Legally Authorized Representative, as applicable:

_____

Printed Name

_____ _____

Signature Date

_____

Authority of Legally Authorized Representative to act on behalf of Subject

Whom to contact about this study

During the study, if you have questions, concerns or complaints about the study, please contact the study doctor at the telephone number listed on the first page of this consent document.

An institutional review board (IRB) is an independent committee established to help protect the rights of research subjects. If you have any questions about your rights as a research subject, and/or concerns or complaints regarding this research study, contact:

- By mail:
  Study Subject Adviser
  Advarra IRB
  6100 Merriweather Dr., Suite 600
  Columbia, MD 21044
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00051005.

What about my legal rights?

You will not lose any of your legal rights by signing and dating this Authorization and Informed Consent.

If you agree to be in this study, you will receive a signed and dated copy of this form for your records.

What if there is new and important information that may affect my willingness to participate?

If there is new information or any significant new findings that could relate to your willingness to continue participation in the study, we will tell you. You can then decide if you still want to be in the study.

What is the purpose of a consent and authorization form?

What is an authorization and informed consent form?

An authorization and informed consent contains information required by federal regulations to help you decide if you want to participate in a research study. It must be approved by an Institutional Review Board (IRB) before it is used in a study.

CONSENT

I have read this Authorization and Informed Consent form (or it has been read to me). I have talked with my doctor about being in the study. All my questions about the study have been answered. I freely consent to be in this study.

_____
Subject Name (printed)

_____ _____
Signature of Subject Date

_____
Printed Name of the Person Conducting the Consent Discussion

_____ _____
Signature of the Person Conducting the Consent Discussion Date

Witness[1] *or Legally Authorized Representative, as applicable:*

_____
Printed Name

_____ _____
Signature Date

_____
Authority of Legally Authorized Representative to act on behalf of Subject

[1] A witness must be used if the subject is illiterate or legally blind. A literate witness must sign, the participant should select this person, and this person should have no connection to the research team.

You will be provided with a signed and dated copy of this form to keep.