PARTICIPANT INFORMATION AND AGREEMENT TO TAKE PART FORM

TITLE: Efficacy and safety of once-daily oral semaglutide 25 mg and 50 mg compared with 14 mg in subjects with type 2 diabetes

PROTOCOL NO.: NN9924-4635
IRB Protocol # 20203479

SPONSOR: Novo Nordisk A/S, Novo Allé, 2880 Bagsvaerd, Denmark

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STUDY RELATED PHONE NUMBER(S): 515-329-6800 (24 hours)

Administrative information:

Universal trial number: U1111-1247-0210	EudraCT number: 2020-000299-39
Version: Final 3.0_US	
Official name of the study:	Efficacy and safety of once-daily oral semaglutide 25 mg and 50 mg compared with 14 mg in subjects with type 2 diabetes
Research sponsor contact information: Novo Nordisk Inc, 800 Scudders Mill Road, Plainsboro, NJ 08536	
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. Information about the study and the results will also be made available at www.novonordisk-trials.com, www.clinicaltrialsregister.eu and potentially in other regional or local registries.	

The table below shows the visit schedule and the research study-related activities. Please see Section 3 for more information.

V1	V2	V3	V4	V5	P6	V7	P8	V9	V10	V11	V12	V13	V14	V15	V16	V17
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V = Visit; P = Phone contact

Visit to the clinic.

Study staff will contact you by phone.

Attend the visit fasting. This means you cannot eat or drink 6 hours before, and you cannot have water 2 hours before.

On the day of these visits do not take your study medicine or any other medicine that you would take with a meal. You should wait to take the medicine until after the study doctor has taken blood samples.

At these visits you will be given study medicine.

At these visits you will have blood taken.

At these visits you are asked to give a sample of your morning urine.

At these visits you will bring a diary where you record if you have episodes of low blood sugar.

Participant Information and Agreement to Take Part Form

Research study to compare three doses of semaglutide tablets taken once daily in people with type 2 diabetes (PIONEER PLUS)

You are invited to take part in a research study

You are free to decide if you want to take part in this study or not.

- Before a new medicine can be prescribed by doctors, it must be tested. This is to see if it is safe and if it works as we expect it to.
- This is called a research study. In this document we will call it a study.
- This study compares three doses of semaglutide tablets in people with type 2 diabetes who were previously treated with other diabetes medicines taken by mouth. The company testing this investigational medicine is called Novo Nordisk. “Investigational” means that the drug (Semaglutide C 25 mg and 50 mg) is currently being tested and has not been approved by the U.S. Food and Drug Administration (FDA).
- Before you decide if you want to take part in the study, it is important that you understand:
  - why the study is being done
  - the possible risks and benefits
  - what you will have to do if you take part.
- Deciding if you want to take part is called giving your ‘informed consent’. This participant information will help you decide. Please take your time to read the information carefully. You may wish to talk to your doctor, study staff, family or friends before deciding.
- Please ask the study staff if there is anything that is not clear or if you would like more information.
- If you decide to take part in the study, you need to sign the ‘Agreement to take part form’ at the end of the document.
- If you decide not to take part, your current and future medical care will not be affected.
- You may benefit from having tests, checks and general talks with your study doctor.
- The results may also show that you have other illnesses that may not have been found if you did not take part in this study. In this case you will be informed.

Please read the rest of this participant information. It gives you more information about the study.

What is in this document?

Who to contact

If you have any questions, concerns or complaints about this research study, please feel free to talk to your study doctor or contact person at the telephone number(s) listed on the first page of this form.

Important things that you need to know

This is a summary of the important things that you need to know about the research study.

- This study compares three doses of semaglutide tablets in people with type 2 diabetes who were previously treated with other diabetes medicines taken by mouth.
- You will start the treatment with a lower dose of semaglutide tablet. The dose will be increased gradually before reaching a final dose of 14 mg, 25 mg or 50 mg semaglutide – which final dose you get is decided by chance.
- Semaglutide tablets are a medicine that lowers blood sugar.
- Currently, lower doses (3 mg, 7 mg and 14 mg) of semaglutide tablets (Rybelsus®) can be prescribed in some countries. The 25 mg and 50 mg semaglutide tablets are a new version.
- You will get one tablet per day for 68 weeks.
- Like all medicines, the study medicines may have side effects.
- The study will last for about 75 weeks.
- You will have 15 clinic visits and 2 phone calls with the study doctor.
- Blood samples will be taken at all visits.
- You will give a urine sample at 5 visits.
- You will have an eye test done at 3 visits.
- You will have a test to check your heart done at 3 visits.
- Women cannot take part if they are pregnant, breast-feeding or plan to become pregnant during the study period. If you are a woman and can get pregnant, you will be checked for pregnancy via urine pregnancy tests.

Please read the rest of this participant information. It gives you more information about the study.

1 Why are we doing this study?

We are doing this study to compare how three different doses of semaglutide tablets work. Semaglutide is taken once a day for the treatment of type 2 diabetes.

What will this study look at?

This study will look mainly at how well your blood sugar is controlled when you are taking one of the three semaglutide doses. The study will also look at how the semaglutide doses affect weight and how safe the doses are.

How many people will take part?

More than 1600 men and women across the world will take part in this study.

2 Deciding if you want to take part

Why are you being asked to take part in the study?

You are being asked to take part because:

- you have type 2 diabetes.
- your blood sugar level may be too high with your current treatment for type 2 diabetes.
- you are already being treated with diabetes medicines taken by mouth, but your doctor thinks you will benefit from semaglutide tablets.

What happens if you say ‘yes’?

First you need to sign this form saying you agree to take part. We call this an ‘agreement to take part form’ - also called an ‘informed consent form’.

- You will be given a copy of this participant information and the signed form to take home and keep.

What happens if you say ‘no’?

You are free to say no - the choice is yours. Your decision will **not** affect your current and future medical care to which you are otherwise entitled and there will be no penalty.

What are my alternatives?

You do not have to take part in this study. There may be other medicines available for you which

your study doctor can tell you about. The study doctor will discuss these options, and their risks and benefits, with you.

What happens if you change your mind and no longer want to take part?

You can decide not to take part in the study at any time - you do not have to give a reason.

- Your current and future care to which you are otherwise entitled will not be affected if you decide to stop taking part and there will be no penalty.
- You will continue to be treated as you were before you started this study.
- After the end of the study and if you decide to stop taking part during the study, information about you that has already been collected cannot be deleted. This is required by the national medicine authorities (such as the FDA) to make sure that the results for the entire study can still be used.

Taking part in other studies

You cannot take part in this study if you are already taking part in another study that is testing a medicine or treatment. You must also not join any other studies that are testing a medicine or treatment*. You decide to take part in this study. This is to protect your safety and the conclusions of this study.

*Because the development of safe and effective COVID-19 interventions is critical to containing the current outbreak and helping to prevent future outbreaks of COVID-19 pandemic, you are allowed to take part in a study about:

COVID-19 treatment, prevention and vaccines at the same time as taking part in this study. Before you start this study, PIONEER PLUS, you must not have had a COVID-19 medicine or treatment given to you in the last 30 days. If you choose to take part in a COVID-19 study at the same time as taking part in this study, we ask that you tell your study doctor about your participation in a COVID-19 study.

3 What will you need to do if you take part?

How do you take the study medicines?

- You will be asked to swallow one tablet whole every morning with half a glass of water (about 120 mL or 4 fluid ounces).
- Do not split, crush or chew the tablet before swallowing.
- You need to take the tablet in the morning before you eat or drink anything.
- After taking the tablet, you must **not** eat, drink or take any other medicines by mouth for at least 30 minutes.
- After the 30 minutes:
  - take any other medicines you need, and if you like
  - have your first meal of the day

It is important that you store and take the study medicines as directed by your study doctor during the study.

What are your responsibilities?

- You must give correct and complete information about your medical history and your present health.
- You must follow the instructions given by your study doctor including coming to the clinic for all the scheduled visits and be available for the planned phone calls.
- You must inform your study doctor in advance, if you have problems keeping an appointment.
- You must take the semaglutide tablets as instructed.
- You must remember to fill in the diary and bring it at every visit.
- You must bring all your study medicine (used and unused) to every visit.
- You must remember to bring samples of your morning urine – see visit schedule at page 2.
- You must remember to tell your doctor about any side effects that you felt and any changes in or worsening of existing conditions.

Taking your usual medicines

Talk to your study doctor about what changes are needed to your usual medicine.

Tell your study doctor if there are changes to your usual medicines during the study or if you start taking a new medicine.

How long does the study last for?

The total time you will be in this study is about 75 weeks.

- 2 weeks at the start - to check that you can take part in the study,
- 68 weeks where you will be taking the study medicine, and
- 5 weeks after your last dose of study medicine - to check on your general health after you stop taking the study medicine.

What will happen at the different visits in the study?

During the study, you will be asked to:

- come to 15 visits at the clinic and
- have 2 phone calls with the study doctor or staff.

It is important that you take part in all the visits during the study to evaluate your health and how the study medicines work.

- At 7 of the visits you cannot eat or drink for 6 hours before the visit. Water is fine to drink up to 2 hours before the visit.
  - On the day of these visits you should not take your study medicine until after the study doctor has taken blood samples.
  - On the day of these visits you should not take any other medicine to be taken before a meal or with a meal. You should wait until after the study doctor has taken blood samples.
  - If you **did** eat or drink anything (except water) within the last 6 hours, you will be asked to come back to the clinic again.
- You may be asked to come for extra visit. For example, if:
  - the study doctor considers changing the dose of your study medicine between planned visits.
  - if you have any side effects that the study doctor needs to look at.

The amount of time you will spend at the clinic at each visit may vary. This is because the tests and checks will differ at each visit. There will be:

- 4 visits that may take several hours
- 11 short visits that may take about 1 hour.

Talk to your study doctor if you want to know more about this.

Tests and checks

During the study you will have the following tests and checks:

- At the first visit you will be asked about your diabetes and if you have any other illness.
- At all 15 clinic visits you will have blood samples taken. These samples are like those you have when you normally go to the clinic. A total of about 136 mL (approximately 9 tablespoons or 4.6 fluid ounces) of blood will be taken during the study.
- At 3 visits a physical exam will be performed
- At 5 visits you are asked to give a urine sample.
- An eye test will be done at 3 visits.
- At 3 visits you will have an ECG – a test to check the electrical activity of your heart.
- At all clinic visits and phone calls you will be asked about:
  - your health and how you are doing.
  - if you have had any episodes of low blood sugar since the last clinic visit or phone call.
  - how much study medicine you have taken and should take.
  - if you are taking any new medicine.
- If you are a woman and able to become pregnant, you will have tests to check whether you are pregnant.

On page 2 you will find the visit schedule and the study activities.

Diary

At all visits you will receive a diary with visit specific information, which you will need to record and bring back to the clinic at your next visit. This includes the following:

- Information about the dose of study medicine taken.
- Information about any episodes where you feel unwell or have low blood sugar (‘hypo’). This is so the study doctor knows when it happened and how you felt.
- Information about any health issues.

4 What do you need to know about the study medicine?

You will get semaglutide tablets in addition to other diabetes medicines you are already taking by mouth. If you take a diabetes medicine of the kind called DPP-4 inhibitor you must stop taking the medication when starting semaglutide tablets. Your study doctor can help you find out if your diabetes medicine is a DPP-4 inhibitor.

There are 5 different types of semaglutide tablets in the study:

Rybelsus® tablets:
- semaglutide 3 mg
- semaglutide 7 mg
- semaglutide 14 mg

New investigational tablets:
- semaglutide C 25 mg
- semaglutide C 50 mg

Semaglutide can already be prescribed at 3 mg, 7 mg and 14 mg doses. Semaglutide C 25 mg and 50 mg are new doses of semaglutide investigated in this study.

Which study dose will you get?
The study medicine you get is decided by chance - like flipping a coin. This is called randomization.

- The study medicine for each person is chosen by a computer.
- You are just as likely to get the final treatment dose of 14 mg semaglutide as 25 mg semaglutide or 50 mg semaglutide.

You or your study doctor will not know which final treatment dose you will get. However, if your safety is at risk, your study doctor will be told in order to decide your future treatment.

About semaglutide

Semaglutide is similar to a hormone in the body. It acts like the hormone to:

- help the body produce more insulin
- help the liver make less sugar (glucose).

Both of these help to reduce blood sugar levels.

At visit 2 you will be assigned to one of three treatment groups. The dose of semaglutide tablets will be increased in 4-week intervals until you reach the final treatment dose:

- 3 mg to 7 mg to **14** mg
- 3 mg to 7 mg to 14 mg to **25** mg
- 3 mg to 7 mg to 14 mg to 25 mg to **50** mg

5 What are the possible side effects or risks of taking part?

Your study doctor will watch closely for possible health problems that happen in relation to you taking part in the study.

- As with all medicines, side effects may happen.
- If side effects happen, they will be treated if needed.
- You may be asked for an extra blood sample or clinical test if you have any side effects that the study doctor needs to look at.

Tell your study doctor or the study staff about any side effects or health problems you have while taking part.

Tell the doctor or staff even if you do not think that the side effects were caused by the study medicine.

If there is an outbreak of COVID-19, then the clinic will take actions to minimize any risk of transmission and inform you about these changes.

In addition to the risks or discomforts listed here, there may be other risks that are currently not known.

Side effects of study tests and checks

Blood sampling

During this study, small amounts of your blood will be taken. This allows the study doctor to see how you are doing and if the study medicine works.

- You may feel a little discomfort, bruising, bleeding or swelling where the needle goes in.
- There is also a very small risk of infection where the needle goes in.

Eye test

As part of the eye test, you will get eye drops to make your pupils larger. This will make you more sensitive to light and your vision may be blurred temporarily. It can take some hours before the effects of the eye drops are gone. Occasionally, the eye drops may cause local irritation or an allergic reaction or higher eye pressure. If these happen, medication can be given.

Electrocardiogram

An electrocardiogram (ECG) is a recording of the activity of your heart. Your skin may react to the sticky electrode patches used. Any skin irritation usually disappears when the patches are removed.

Side effects of oral semaglutide

Very common side effects (may affect more than 1 in 10 people):

- Feeling sick (nausea)
- Diarrhea (loose, watery and more frequent stools)

These side effects are usually mild to moderate and do not last longer than a few days or weeks. They also happen more often at the start of treatment.

If you have sickness (vomiting) or diarrhea which is bad or does not go away:
- **This may lead to not enough water in the body ('dehydration'). Severe dehydration may lead to kidney problems.**
- **Drink plenty of fluids and talk to a doctor or the study staff.**

- Low blood sugar ('Hypo')

Early signs may include:
- feeling hungry, very tired, shaky, worried or irritable, rapid or irregular heartbeats, pale skin and sweating, finding it hard to think and focus.

Signs during the night may also include:
- Damp sheets or bedclothes from sweating, nightmares, feeling tired or irritable or confused when waking up.

Signs of severe low blood glucose may include:
- feeling confused, strange behavior such as slurred speech or being clumsy, problems with your sight or fits (seizures) or passing out.

Low blood glucose is more likely to happen if you:
- use the study medicine with other anti-diabetic medicines or insulin
- exercise more than usual
- eat too little or miss a meal
- drink alcohol

If you have any signs of low blood sugar, eat or drink something sweet (juice, soft drinks with real sugar, sweets, glucose tablets).

If this does not work, talk to a doctor or the study staff right away.

Common side effects (may affect up to 1 in 10 people):
- Worsening of an eye problem caused by diabetes (diabetic retinopathy).

Contact your study doctor if you experience eye problems.
Other common side effects include:

- Being sick (vomiting)
- Pain in your stomach area
- Feeling bloated
- Constipation
- Upset stomach or indigestion
  - Pain or discomfort in your stomach – you may also feel sick (nausea) or be sick (vomiting), have heartburn or feel bloated
- Inflamed stomach
  - Signs may include: Gnawing or burning ache or pain ('indigestion') in your stomach that may become either worse or better with eating. Feeling sick (nausea) and being sick (vomiting).
- Heartburn
  - Heartburn is a burning pain in the chest – usually after eating and often at night. The pain may be worse when lying down or bending over.
- Passing wind (or gas)
- Feeling very tired
- Low appetite
- Increased pancreatic enzymes (shown in blood tests)

Uncommon side effects (may affect up to 1 in 100 people):

- Fast heartbeat (pulse)
- Burping
- Weight decreased
- Gallstones
  - Gallstones may not cause any signs. If they do, they may include pain in your upper right stomach area, yellowing of your skin or whites of your eyes ('jaundice') or pale stools.

If you have any signs of gallstones, talk to a doctor or the study staff as soon as possible.

Rare side effects (may affect up to 1 in 1,000 people):

- Serious allergic reactions
  - Signs of serious allergic reactions may include: breathing problems, swelling of your face, lips, tongue and/or throat with difficulty swallowing and a fast heartbeat.

Allergic reactions may become severe and could lead to shock (very low blood pressure) and/or death if not treated (this is called 'anaphylaxis').

If you have any signs of a serious allergic reaction stop taking the study medicine and get emergency help right away.

- Inflamed pancreas
  - Signs may include severe and long-lasting pain in your stomach (the pain may move to your back), feeling sick (nausea) or being sick (vomiting)

This is a serious problem that can lead to death.

If you have any signs of an inflamed pancreas, talk to a doctor or the study staff right away.

Other side effects (we do not know how often these may happen)

- Tumors in the thyroid gland
  - A type of tumor (including medullar thyroid cancer) that has been seen in studies with animals. It is not known if this can also happen in humans.

Tell your health care provider if you get a lump or swelling in your neck, hoarseness, trouble swallowing, or shortness of breath. These may be symptoms of medullary thyroid cancer.

Driving and using machines

If you have signs of low blood sugar, such as feeling tired or confused, do not drive or use tools or machines.

Following the use of eye drops for the eye exam you may experience temporary blurred vision for some hours. You should not drive as long as your vision is affected.

Talk to a doctor or study staff if you are in doubt.

Pregnancy – information for women and men

Women

- Do not take part in this study if you are pregnant, breast-feeding or planning to become pregnant.
  - This is because we do not know how the study medicine may affect you or your baby.
- If you take part in the study, you and your male partner must use contraception. Your study doctor will give you advice about this before the study starts.
- At the beginning of the study, during the trial and when the treatment with study medicine is done, all women who can become pregnant will have a pregnancy test done.
- Semaglutide can stay in your body for some weeks after you stop taking your study medicine. Therefore, you should not get pregnant and you should continue to use birth control for at least 5 weeks after you stop taking the study medicine.
- If you miss your menstrual period or if you think you may be pregnant during the study, you must take a pregnancy test as soon as possible
- If you take part and think you may have become pregnant, tell the study doctor or staff right away.
  - If you become pregnant, your study doctor will tell you how to stop taking the study medicine.
  - However, information about you, your pregnancy and your baby will still need to be collected. This is so that we can watch for anything unusual.
  - In case of anything unusual, your partner will be asked to sign an 'agreement to take part form' (like this one) to collect paternal information.

Men

No birth control measures are required for men.

6 What might the benefits be to you?

You may or may not benefit from taking part in this study or taking the study medicine.

- The information collected from you during the study may help you or other people with type 2 diabetes in the future.

7 Who is involved and more information about taking part

Who is paying for this study?

Novo Nordisk, a company that makes medicines, is paying for this study.

- Novo Nordisk will pay for the cost of the study medicine, the tests and checks, the time spent by the study doctor and staff and use of the clinics.
- The study medicines will not be provided for free to you after the study has ended.

You will not have to pay for the following things - as long as you stay in the study:

- Study medicine
- Blood glucose meter and test strips to test your blood sugar
- Urine pregnancy tests, if you are a woman and able to become pregnant

You or your insurance company may have to pay for routine care you would receive whether or not you

are in the study. You may talk to the study staff and your insurance company about what is covered.

Will you receive any payments?
You will be paid $40.00 for each visit where you must travel to the office. You will be paid following each visit. You will not be paid for telephone visits.

You will not receive any money for the actual time you spend at the clinic.

Are clinical research study payments considered taxable income?
- In a calendar year, if you are paid for participation in a clinical research study $600 or more, (excluding travel related costs), it must be reported to the Internal Revenue Service (IRS).
- In a calendar year, if you have participated in more than one clinical research study, the total payments you received from all studies must be considered when confirming if you exceeded the $600 payments.
- If you are paid $600 or more, you must provide an Internal Revenue Service (IRS) W-9 tax form to your study doctor.
- The study doctor will generate a Form 1099-MISC and use Box 3 to report what was paid to you. A copy of the Form 1099-MISC will be sent to Internal Revenue Service (IRS) and you.

Who has reviewed this study?
The study has been reviewed by:

- an independent committee called an Institutional Review Board (IRB)
  and
- The US Food and Drug Administration (FDA).

The IRB is a group of scientists and non-scientists who review the ethics of research. The goal of the IRB is to protect the rights and welfare of study subjects.

What treatment will you get when you stop taking part?
At the final visit your study doctor will discuss the available choices for your future care with you. After the end of the study, Novo Nordisk will not supply the study medicines or offer any free medicines or extra care.

What if new information becomes available during the study?
During the study, your study doctor will let you know if there is new information that might be important for you. This might be information about:

- the study medicine
- the study visits
- the possible risks and benefits.

You can then decide if you want to stay in the study.
- If you choose to stay in the study, you may be asked to sign a new 'agreement to take part form' (like this one).
- If you choose to stop, the study doctor will discuss your options for future care and treatment.

What if you decide to stop taking the study medicine?
You can stop the study medicine early and still remain in the study. This means you would stop taking the study medicine - but still come to the clinic visits and have the tests performed. This is because it will help us to understand the study results better and you may benefit from the clinic visits. You can change clinic visits to phone contacts. However, certain visits are more important to have as a clinic visit face to face, such as visits V10, V14, V16 and V17. Please discuss with your study doctor which clinic visits you should prioritize. It is up to you if you decide to keep coming or not. You may also decide to start to take the study medicine again after having stopped.

If you decide to stop taking your study medicine, please talk to your study doctor before making any changes. This is to make sure the study medicine is stopped in a safe way.

What if the study doctor decides to stop the study medicine?
The study doctor may stop you from taking the study medicine at any time - even if you want to carry on. Some reasons may include:

- for your safety - for example if your body has a bad reaction to the study medicine
- if the study medicine is not the best choice for you
- if your illness becomes worse
- if you are a woman and you become pregnant or would like to become pregnant
- if you take part in another research study

What if you decide to stop taking part in the study?
If you decide to stop taking part, please talk to your study doctor before making any changes to your medication. This is to make sure the study medicine is stopped in a safe way.

- You will be asked to come for a final visit. This will be to check your health and any effects of the study medicine on your body up until that point.

What happens to your blood samples if you decide to stop taking part in the study?
If you wish, you can ask the study staff to arrange for any stored samples to be destroyed.

What if the company paying for the study or the authorities decide to stop the study?
Novo Nordisk, the national medicine authority (FDA) or the Institutional Review Board may end the study early at any time - for safety or if there is another good reason to do so. If this happens, you will be told by your study doctor. The study doctor will discuss your options for future care and treatment.

What if something goes wrong?
If you are injured or become ill as a result of taking part in this study, you will receive medical care from your study doctor or they will refer you for treatment. Payment for medical care will be limited to reasonable and customary medical expenses for any illness or injury you experience as a direct result of being in this study or receiving study medicine as long as you follow the study doctor's instructions and the expenses are not covered by insurance. In order to receive payment for injury or illness, the sponsor or the study doctor may need to ask you to provide additional details, such as bills for medical services.

Tell your study doctor right away if you feel that you may have been harmed as a direct result of taking part in this study.

8 How will information collected about you be used and who can see it?

What information about you will be collected?
During the study your study doctor will collect information about your health and certain types of personal information. This may include your name, birth date, contact information, gender and ethnic origin. The information will be written down in your personal medical file. Any information about you or samples that leave the clinic will **not** have your name on it. It will also **not** include your picture, address, telephone number or anything else that links it to you. Instead it will have a participant number on it.

It is your study doctor's job to keep a code list. This links you to your participant number. The code list will be used to identify you, if needed. The code list may be looked at by Novo Nordisk, the IRB, people working on behalf of Novo Nordisk or people from the FDA. The code list must be kept at the clinic for at least 15 years after the end of the study.

Who will be able to see the information about you?
Your study doctor and Novo Nordisk will take all steps needed to make sure that your study information is kept confidential, as required by the law in the United States.

- Your study doctor and Novo Nordisk will make sure that the study information we have collected about you cannot be looked at by people who are not authorized to do so.
- Novo Nordisk will protect your identity in all presentations and publications.

To make sure that the study is done correctly and to check the results, the following people will be able to see your study information:
- Novo Nordisk staff and consultants, auditors, research organizations or laboratories working for Novo Nordisk
- the Institutional Review Board (IRB),
- the Food and Drug Administration (FDA) and national medicine authorities from other countries.

Your study information and blood urine samples may be sent securely to other countries in the world for testing and analyzing. The laws on personal information in these countries may be less strict than in the United States of America.

- Your information will only have your participant number on it.

This information may be shared with other researchers who are not working on this study.
It would only be shared to help other research about the study medicine(s) or your illness and to help improve medical care and science.

How long will your information be stored?
After the end of the study your information will be stored in a database. This is a way of storing information electronically.

All information from this study will be stored for at least 15 years at the clinic after the end of the study. Novo Nordisk will store the information even longer - at least 20 years after the medicine is no longer available to patients.
Blood and other samples will be sent to different laboratories for testing.

- Samples will be destroyed either after they have been tested or when the 'Clinical Study Report' -

this contains the full results of the study - is finished.
- Antibody samples (an antibody is something that your body may produce which can stop the medicine from working) will be stored for further testing - for up to 15 years after the end of the study.

What will happen with the study results?
Some results from the study will be made publicly available sometime after the study finishes.
This may include the Clinical Study Report and a summary of the results - this will be available on the internet at:

- www.clinicaltrials.gov
- www.novonordisk-trials.com
- www.clinicaltrialsregister.eu

The results will not include any information that will identify you.

You can ask your study doctor after the end of the study to receive information about the study dose you received, and the overall results of the study.

If the study staff lose contact with you
It is really important that you keep in contact with the study doctor or staff. If the study staff loses contact with you during the study, your study doctor may ask for information from someone else. This might include:

- family members or other people that you have given the names of to the study staff
- your family doctor
- other health care professionals, medical records and publicly available records.

9 Who can you talk to for more information?

Information about the study
If you have questions, concerns, or complaints, or think this research has hurt you or made you sick, talk to the research team at the phone number(s) listed above on the first page.

This research is being overseen by an Institutional Review Board ("IRB"). An IRB is a group of people who perform independent review of research studies. You may talk to them at 1-855-818-2289 or Researchquestions@wcgirb.com if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research subject.

Thank you for taking the time to read this participant information.

If you have decided to take part, please fill in the 'Agreement to take part form' on the next pages.

10 Agreement to take part form (Informed Consent Form)

By signing this form, I agree with all the following statements:

Taking part

- I have been given spoken and written information about this study.
- I have read and understood the information given to me.
- I have had enough time to think about taking part.
- I have had the chance to ask questions - and all my questions have been answered.
- I understand that I do not have to take part and that I am free at any time to stop taking part. Also, that I do not have to give a reason and that this will not affect my future treatment.

Information about me

I understand the following points:

- Several people can see my personal medical file. This is to make sure that the study is done correctly and that all information is recorded correctly. All personal details will be treated as strictly confidential by all of these people. The people who can see my records are:
  - Novo Nordisk staff and consultants, auditors, research organizations or laboratories working for Novo Nordisk.
  - Institutional Review Board and national medicine authorities (such as the FDA).
- All information collected during the study is stored electronically in a database and may be shared with other researchers who are not working on this study. The information can also be sent to other countries in the world.
  The information will never have my name on it.
- If I decide to stop taking part during the study, information already collected cannot be deleted. This is required by the national medicine authorities to make sure that the results for the entire study can still be used.
- The results of this study may be made publicly available.
- I accept that the study staff may get information related to the study from people like my family doctor. They may also look at publicly available information.

About this form

- I will get a copy of this information and this signed and dated form.
- I agree to take part in this research study.

Now please turn over to sign the form.

To be completed by you

I agree with all of the statements on this form and would like to take part in the study:

Signed: Date:

Name (print):

To be completed by the study staff seeking the informed consent

(to be signed by the study doctor or appropriately medically qualified designee)
By signing this form, I confirm that the entire informed consent process has been conducted before any study procedures have taken place:

Signed: Date:

Name (print):