PARTICIPANT INFORMATION AND AGREEMENT TO TAKE PART FORM

TITLE: Semaglutide cardiovascular outcomes trial in patients with type 2 diabetes (SOUL)

PROTOCOL NO.: EX9924-4473
WCG Protocol# 20190784

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

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IRB APPROVED
AS MODIFIED
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Administrative information:	
Universal trial number: U1111-1218-5368	EudraCT number/IND number: 2018-003141-42
Version: US_6.0	
Official name of the study: Semaglutide cardiovascular outcomes trial in patients with type 2 diabetes (SOUL)	
Research sponsor contact information: Novo Nordisk A/S, Novo Allé, 2880 Bagsvaerd, Denmark	
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 and www.clinicaltrialsregister.eu.	

Visit schedule

The table shows visit schedule and the study related activities

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26
⌂	⌂	⌂	⌂	⌂	⌂	⌂	⌂	⌂	⌂	⌂	⌂	⌂	⌂	⌂	⌂	⌂	⌂	⌂	⌂	⌂	⌂	⌂	⌂	⌂	☎
	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M		
	B			B			B				B				B				B				B	B	

⌂ *Visit to the site*
☎ *Study staff will contact you by phone*
M *At these visits you will be provided with study medicine*
B *Bloodsamples*

Participant information and Agreement to Take Part Form

A heart disease study of semaglutide in patients with type 2 diabetes (SOUL)

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.

This is called a research study. In this document we will call it a study.

- 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.
- In this study, researchers want to learn more about a possible new medicine called 'semaglutide'. They want to find out if it can be used to treat people with type 2 diabetes who have a high risk of heart disease.
- To take part, you will take semaglutide or placebo (a dummy medicine).
- The company testing this medicine is called Novo Nordisk.
- 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 harms and benefits
  - what you will have to do if you take part.
- Deciding 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.

What is in this document?

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

Who to contact

If you have any questions, concerns or complaints about this study, please feel free to talk to your study doctor 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 study.

We are doing this study to look whether the type 2 diabetes medicine, semaglutide, has a positive effect on heart disease. You will either get semaglutide or placebo (a "dummy" medicine) - which treatment you get, is decided by chance.

- You will take 1 tablet a day with up to half a glass of water. You must take the tablet first thing in the morning on an empty stomach.
- After taking the tablet, you must not eat or drink anything for at least 30 minutes. After 30 minutes, you can have your first meal of the day and
- take any other medicines you may need.

  Like all medicines, the study medicines may have side effects.
- The study will last for about 3.5-5 years.
- You will have up to 25 clinic visits and 1 phone call with the study doctor.
- Blood samples will be taken at some site visits.
- Women: Women cannot take part if pregnant, breast-feeding or plan to become pregnant during the study period.

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 look whether the type 2 diabetes medicine, semaglutide, has a positive effect on heart disease. This will be done by comparing semaglutide against placebo on the effect on heart disease.

What will this study look at?

This study will look mainly at the effect of semaglutide on heart disease.

The use of semaglutide in this study is investigational. This means it has not been approved by the US Food and Drug Administration (FDA) for affecting heart disease in persons with Type II Diabetes.

To find out if semaglutide has an effect on heart disease this study will collect information about your health, diabetes and heart disease and or other related diseases such as, for example, diabetic kidney disease.

It is very important that your health is carefully monitored, so different blood samples and measurements will be taken during the study.

How many people will take part?

About 9,600 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.
- You have had or have heart disease, certain diseases of the arteries and/or kidney disease.
- You are at least 50 years old.

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. There may be other medicines available for you that your study doctor can tell you about.

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 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 if you decide to take part in this study. This is to protect your safety and the conclusions of this 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 1 tablet every day with up to half a glass of water (approximately 4 fluid ounces or 120 mL).
- 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 or drink anything for at least 30 minutes.
- **After 30 minutes:**
  - have your first meal of the day, if you like and
  - take any other medicines you need.

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

What are your responsibilities?

- You should measure your blood sugar (glucose). Discuss with your study doctor how to do this at home.
- You must remember to return the study medicines at certain visits as told by the study staff.
- You must keep in contact with the study staff during the entire study.
- You must follow study doctor's instructions
- Talk to your study doctor or the study staff if you feel unwell.

How you should take your usual medicines

You need to keep taking your usual medicines - including any medicines for your type 2 diabetes and related disease.

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

You cannot take GLP-1 medicines during the study as these are medicines like semaglutide. If in doubt talk to your doctor about this.

How long does the study last for?

The study will end when there is enough information collected to show clear results. The total time you will be in this study is estimated to be about 3.5 to 5 years, but it could be shorter. This includes:

- 0-3 weeks at the start - to check that you can take part in the study.
- up to 5 years where you will be taking the study medicine.
- 5 weeks after your last dose of study medicine an appointment will be made to check on your general health.

When the study ends, you can ask your study doctor to get information about the study medicine you received, and the overall results of the study.

What will happen at the different visits in the study?

During the first visit in the study, you will be asked some general questions about your personal data (date of birth, gender, ethnicity and race), and previous and current medicine(s). You will also be asked about:

- your type 2 diabetes
- your blood sugar levels
- your medical history of the disease(s) you may have had
- if you have any surgery planned
- if you had cancer within the last 5 years
- permission to get medical records from your family doctor, or other health care professionals, if it is needed
- if you have recently been or are in another research study or if you plan to enroll in one.

The study staff may ask your family doctor or other health care professionals, about health records with information about you. This information is relevant for you to be able to take part in the study. It could be records from both before and after you started taking part in this study. The records will be part of your personal medical file.

Your study doctor will go through your information and let you know if you can take part in the study.

During the study, you will be asked to:

- come to up to 25 visits at the clinic and
- have 1 phone call with the study doctor or staff.

It is important that you come to all of the visits during the study to evaluate your health and the effect of the study medicines.

- You may be asked to come for more visits, for example if the study doctor considers changing the dose of your study medicine between planned visits, or if you have any side effects that the study doctor needs to look at. Talk to your study doctor if you want to know more about this.

How much time will I spend on the different visits in the study?

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.

After the first 3 months there will be visits every 3 months.

There will be:

- Up to 8 visits that may take around 2 hours
- Up to 16 short visits that may take less than 1 hour. Talk to your study doctor if you want to know more about this.

For some English and/or Spanish speaking patients in Argentina, Canada, Columbia, Mexico, Spain, United Kingdom and United States:

You may spend approximately 60 minutes extra at 6 of the above 8 clinic visits. The study doctor or research staff will let you know if this pertains to you or not.

The study staff will give you a card or a leaflet on who to contact for more information about the study. It will also tell you who to contact in case of a medical emergency related to the study.

Discuss with the doctor if you keep taking your current diabetes medicines, or if changes will be made.

Tests and checks

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

- Weight
- Waist circumference
- Height
- Blood pressure
- Pulse
- Eyes
- Your body in general

For this you may need to take off some of your clothes to help the doctor check you.

- At up to 8 of the 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 up to 4 tablespoons of blood will be taken during the study.
- You may also be asked to have a finger prick test or similar taken at all site visits to test a drop of your blood.
- At about 5 of the visits you will be asked to write down the answers to some questions or interviewed about your memory. The questions will be related to your short-term memory, your ability to recognize illustrations as well as about your attention and concentration.
- Some English and/or Spanish speaking patients in Argentina, Canada, Columbia, Mexico, Spain, United Kingdom and United States will participate in online brain memory testing. This will not apply to patients that have already been enrolled in the trial. The study doctor or research staff will let you know if this additional testing pertains to you or not. If so at 6 of the visits you will be asked to complete online tests of your short-term memory, mental reasoning and aspects of attention mental processes that will take an additional 60 minutes.
- Additionally, at up to 3 visits you may be asked about your expectations and experience in the study and, twice a year, at visits you may be asked about how you feel about your participation in the study. Completing these extra surveys is not required to participate in this trial.

If you are a woman and able to become pregnant, you will have tests to check whether you are pregnant.

Please see visit schedule at the beginning of this document.

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

There are 2 study medicines:

- **Semaglutide** (the active medicine being tested)
- **Placebo** (a dummy medicine)

You will only take 1 of these medicines.

Semaglutide is already available in the injection form. This study will test semaglutide as a tablet. In this study, the study doctors will check to see if semaglutide has a positive effect on heart disease.

Which study medicine 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.
- The chance of you getting the active medicine or the placebo medicine is the same.
- The dummy medicine placebo looks like the study medicine but has no active ingredients. The dummy medicine placebo needs to be used in the study to find out if the study medicine works as expected.

You or your study doctor will not know which of the study medicines you will get. 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 make more insulin
- help the liver make less sugar (glucose).
- reduce hunger and lower energy intake. All of these help to lower blood sugar levels.

About placebo

Placebo does not do anything to your body.

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

Your study doctor will watch closely for possible health problems that may happen in relation to you while 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 study doctor or study staff even if you do not think that the side effects were caused by the study medicine.

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 watch for possible health problems and to see 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 examination

Your eye examinations may need to be done by a specialist. As part of the eye exam, you may get eye drops to dilate your pupils which will make your eyes more sensitive to light and may cause temporary blurred vision. It can take hours before the effects of the eye drops are gone.

Occasionally, the eye drops may cause local irritation, an allergic reaction or higher eye pressure. If these happen, medication can be given.

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:

- These side effects can cause dehydration (loss of fluids). Severe dehydration may lead to kidney problems.
- Drink enough fluids and talk to a doctor or the study staff.
- Low blood sugar (‘Hypoglycaemia’)

Early signs may include:

- feeling hungry, very tired, shaky, worried or irritable, feeling of strong or fast heartbeat, 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 behaviour 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 glucose, 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 straight away.

Common side effects (may affect up to 1 in 10 people):

- 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 heart rate
- 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 reaction
  - Signs of serious allergic reactions may include: Swelling of your throat, tongue inflamed and / or face, trouble breathing, wheezing, fast heartbeat, pale and cold skin, feeling dizzy or weak.
  - Allergic reactions may become severe and could lead to shock (very low blood pressure) and /or to death if not treated (this is called 'anaphylaxis').

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

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

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

- 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 straight away.

Eye problem caused by diabetes (diabetic retinopathy).

- It is due to damaged blood vessels at the back of your eye.
- The condition usually affects both eyes. At first, there may be no signs of diabetic retinopathy or only mild vision problems.
- It can potentially lead to blindness.

Your study medicine may improve your blood glucose very fast. If you have diabetic retinopathy this may then get worse.

Contact your study doctor if you experience impaired vision.

Tumors in the thyroid gland
A type of tumour (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.

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.

Side effects of placebo

Placebo is a dummy medicine, which does not do anything to your body. Therefore, doctors do not expect that it will give any side effects.

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 highly effective birth control, unless you are post –menopausal. 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. Information about you, your pregnancy and your baby will 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 male participants in the study.

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.

If you receive semaglutide and it has a positive effect on your heart disease, you may benefit.

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

7 What are my alternatives?

You do not have to take part in this study to receive medicine that may reduce the risk of cardiovascular disease events in adult patients with type 2 diabetes mellitus and known cardiovascular disease. You should speak with your doctor to discuss other available alternatives.

8 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.

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

- Study medicine
- Blood testing equipment to test your blood sugar levels
- All study related tests and checks

Will you receive any payments?

Subjects will be paid $40 for each visit where they have to travel to the office. Subjects will be paid following each visit. Subjects will not be paid for telephone visits.

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 send 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 and reviewed by
- The FDA (Food and Drug Administration).

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 harms 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 done. This is because it will help us to understand the study results better and you may benefit from the clinic visits. It is possible to change clinic visits into phone visits, but discuss this with your study doctor. It is up to you if you decide to keep coming or not. You may also decide to start taking the study medicine again after having stopped. If you decide to stop completely to take part in the study, the study doctor may ask you to allow one final phone call at the end of the study.

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 start taking part in other studies.

You should stay in the study even if the study doctor decides to stop your study medicine early. The same conditions as when you decide to stop taking the study medicine yourself will then apply.

Why should I continue with the clinic visits and phone contacts, even though I have stopped taking the study medicine?
It is important that you attend all study visits from start to finish so we can follow the progress of all people taking part. Even if you or your study doctor decides to stop taking the study medicine early, your information is still important and will help us understand the study results better.

For that reason, you are encouraged to attend the visits until the end of the study. This means that you will be asked to keep coming to the visits as planned until the end of the study. The support and guidance you get at the visits may also benefit you. If you wish to come for fewer visits or change the visits to phone contacts, this can be done. Please discuss with your study doctor.

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 medicine. This is to make sure the study medicine is stopped in a safe way.

- The study doctor or staff may also find out more information about your vital status in publicly available sources at the end of the study. This is important for the overall study results. You will, however, not be contacted.

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 Food and Drug Administration 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. 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 straight away if you feel that you may have been harmed as a direct result of taking part in this study.

9 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/year, 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. If, however, the study staff loses contact with you during the study some of your personal information may be shared with a patient search agency. You can find more information about this at the end of this section.

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, people working on behalf of Novo Nordisk or people from national medicine authorities (such as 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 your country.

- 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 Copernicus Group Independent Review Board (CGIRB) and Western Institutional Review Board® (WIRB®) and the Food and Drug Administration (FDA)
- national medicine authorities from other countries.

Your study information and blood and other 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.

- 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.

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 medicine 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 will 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.

If the study clinic is closed, your contact information will be shared with another doctor from a study clinic close to the one you are visiting. This is to ensure someone stays in contact with you.

A ‘patient search agency’ may also help the clinic get back in contact with you or look up your vital status in publicly available sources. To do this, we will need to share some of your personal information with the patient search agency. This may include your name, address, telephone number and birth date.

10 Who can you talk to for more information?

Information about the study

If you have any questions, concerns or complaints about this study, please feel free to talk to your study doctor or contact person. Their contact information can be found in this document.

This includes if you feel you have been harmed as a direct result of taking part in the study.

Information about your rights and ethics

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 (888)-303-2224 or (800)-562-4789, irb@cgirb.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.

11 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:

- A number of 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
  - IRB and national medicine authorities in the US (such as the Food and Drug Administration) and from other countries.
- 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, family members or other people that I have given the names of to the study staff. In addition they may also contact other healthcare professionals and look at medical records and 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 study.

Please now 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 Signed	Date
Name	

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	