PARTICIPANT INFORMATION AND AGREEMENT TO TAKE PART FORM

TITLE: A 78-week trial comparing the effect and safety of once weekly insulin icodec and once daily insulin glargine 100 units/mL, both in combination with non-insulin anti-diabetic treatment, in insulin naïve subjects with type 2 diabetes.

PROTOCOL NO.: NN1436-4477
IRB Protocol # 20202252

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:	U1111-1247-3878	EudraCT number/IND number:	2020-000442-34 /137406
Version:Final 2.0			
Official name of the study:	A 78-week trial comparing the effect and safety of once weekly insulin icodec and once daily insulin glargine 100 units/mL, both in combination with non-insulin anti-diabetic treatment, in insulin naïve subjects with type 2 diabetes. ONWARDS 1.		
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 and potentially in other regional or local registries.			

Participant Information and Agreement to Take Part Form

A research study to compare two types of insulin, a new insulin, insulin icodec and an available insulin, insulin glargine, in people with type 2 diabetes who have not used insulin before (ONWARDS 1)

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.
- In this study a new investigational insulin, called insulin icodec, will be compared to a known insulin called insulin glargine. Insulin glargine is injected once a day. Insulin icodec is injected once a week. "Investigational" means that the drug (insulin icodec) is currently being tested and has not been approved by the U.S. Food and Drug Administration (FDA).
- 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 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.

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 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 insulin icodec (a new investigational insulin taken once a week) to insulin glargine (an insulin taken once daily which is already available on the market) in people with type 2 diabetes.
- The study will look at how well insulin icodec taken weekly controls blood sugar compared to insulin glargine taken daily.
- You will either get insulin icodec that you will have to inject once a week on the same day of the week or insulin glargine that you will have to inject once a day at the same time every day. Which treatment you get is decided by chance (like flipping a coin).
- The insulin is injected with a needle in a skin fold in the thigh, upper arm or stomach.
- Like all medicines, the study medicines may have side effects.
- The study will last for about 1 ½ years.
- You will have 37 clinic visits and 26 phone calls with the study doctor.
- At 11 clinic visits you will have blood samples taken.
- At 6 clinic visits you cannot eat or drink (except for water) for 8 hours before the visit.
- You will be asked to wear a sensor that measures your blood sugar all the time in 5 periods of about one month during the study (about 5 months in total).
- 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:

- find out how well insulin icodec (a new investigational insulin taken once-weekly) controls blood sugar compared to insulin glargine (an insulin taken once-daily that is already on the market).

Type 2 diabetes is an illness where the body does not make enough insulin. Insulin is a hormone that helps the body control blood sugar.

When you have type 2 diabetes your blood sugar is not well controlled. Many people with diabetes need treatment with insulin after some time.

What will this study look at?

This study will look mainly at:

- how well insulin icodec lowers the blood sugar to a normal level
- how long the blood sugar stays within a normal and safe level when getting insulin icodec.

How many people will take part?

Around 1000 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 is too high
- You need to start insulin treatment.

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 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 inject the insulin with a pen, which has a small needle, into a skin fold in your stomach, thigh or upper arm. Your study doctor/staff will train you in the use of the pen-injector, provide written instructions and help you the first time that you inject yourself.
- Every week or every other week your study doctor will adjust your dose of insulin to find the amount of insulin that works best for you.
- You will either get insulin icodec or insulin glargine.
- Insulin icodec should be injected once a week, on the same day of the week.
- Insulin glargine should be injected once a day at the same time every 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 will be asked to measure your blood sugar before breakfast every day during the study using a blood sugar meter. You do this by pricking your finger. The study staff will train you in how to do this and use of the meter.
- You will be instructed to transfer blood sugar values from the blood sugar meter to your electronic diary (eDiary), which is an APP on a study phone.
- The study staff will show you how to use the eDiary.
- If you think you have a low blood sugar value (this is called hypoglycaemia or 'hypo') during the day or night, you should measure your blood sugar with the blood sugar meter. You will also need to fill in some information in the eDiary. This is so the study doctor knows when it happened and how you felt.
- You must inject yourself either every day or once a week and adjust your dose as told by the study doctor. After the injection, you need to type your insulin dose and date in the eDiary.
- If you have any irritations on your skin where you have injected the study medicine, you must tell your study doctor as soon as possible.
- You need to have a tiny and flexible sensor inserted under your stomach skin. The sensor measures your blood sugar all the time.
- During the study you will have to wear the sensor during 5 periods of around 1 month. You must carry a receiver (the size of a small

phone) with you all the time and make sure to keep it charged.
- The sensor must be changed every week. In the first 4 periods of wearing the sensor, this will be done at the clinic visit every week, where the study staff can help you. During the last period, where you are no longer taking the study medicine, you have to change the sensor yourself every week at home. The study staff will train you, so you can change the sensor yourself.
- You and the study staff will not get any information about your blood sugar from the receiver. At the clinic visit the staff will collect and store the information from the receiver. The information is used to learn more about how the medicines work.

Taking your usual medicines

If you are taking sulfonylureas or glinides you must stop taking these 2 medicines before you start on the study medicine, the study doctor will tell you how. You need to keep taking your usual medicines - including any medicines for your disease.

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?

The total time you will be in this study is about 1½ years.

- 2 weeks at the start - to check that you can take part in the study
- almost 1½ years where you will be taking the study medicine
- 5 weeks at the end of the study - to check on your general health after you have stopped taking the study medicine.

What will happen at the different visits in the study?

During the study, you will be asked to:

- come to 37 visits at the clinic and
- have 26 phone calls with the study doctor or staff.

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

At 6 study visits you cannot eat or drink (except water) for 8 hours before the visit. If you have eaten within the last 8 hours, you will be asked to come back again.

- You may be asked to come for extra visits, for example
  - if the study doctor considers changing the dose of your study medicines 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:

- 14 visits that may take several hours
- 23 short visits that may take about 1 hour
- 26 phone contacts that may take 10-30 minutes.

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:

- Standard health checks.
- If you are a woman and able to become pregnant, you will have tests to check if you are pregnant.
- At 6 clinic visits you will have body measurements taken, including body weight. This should be done in light clothing.
- At 4 of the clinic visits you will have an electrocardiogram (ECG) - a test to check the electrical activity of your heart.
- At 11 of the clinic visits you will have blood samples taken. These samples are like those you have when you normally go to the clinic. About 85 mL (around 5.5 tablespoons) of blood will be taken during the study.
- At 2 of the clinic visits the doctor or a specialised eye doctor will check your eyes. You may have to go to another clinic. If at your first eye check, your eye doctor diagnoses you with a serious eye condition, such as:
  - Build-up of fluid in a part of your eye known as the macula (macular edema)
  - Many of the blood vessels in your retina are blocked (severe non-proliferative diabetic retinopathy)

- Small blood vessels start to grow from the surface of the retina (proliferative diabetic retinopathy)

- You will be referred to an eye doctor who specialises in treating people with eye conditions caused by diabetes.
- If you have signs of a hypersensitivity reaction that affects the whole body or a part of the body that is not the injection site of the study medicine (called systemic hypersensitivity):
  - you will be asked to take photos and send them to your doctor and
  - come to the clinic to have a photo and extra blood samples taken.

  The photos may be sent to independent doctors to evaluate your safety.

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

There are two study medicines:
- **Insulin icodec** (the new investigational insulin being tested)
- **Insulin glargine** (an already available insulin).

You will only take one of these insulins as told by your study doctor.

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

- A computer chooses which study medicine you will get.
- The chance of receiving insulin icodec and insulin glargine is the same.
- The study is open-label, so you and the study doctor will know which drug you are taking.

About insulin icodec
Insulin icodec is a type of insulin like the insulin the body makes. Insulin icodec lowers the blood sugar. Insulin icodec stays in the body longer than current available insulins, so you only have to inject it once a week.

About insulin glargine
Similarly, insulin glargine is a type of insulin like the insulin the body makes that lowers the blood sugar in the body. You have to inject insulin glargine once a day.

5 What are the possible side effects or harms 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.

Sensor inserted under the skin
During this study you will have a small sensor placed under your skin that measures your blood sugar.

- When you insert the sensor there is a small risk of getting an infection, bleeding, pain or skin irritations (redness, swelling, bruising, itching, scarring or skin discoloration).

Side effects of insulin icodec

These are side effects we know about from other studies with insulin icodec. We do not know how often these may happen.

- 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, irritable or confused when waking up.

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

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.

Low blood sugar is more likely to happen if you:
- exercise more than usual
- eat too little or miss a meal
- drink alcohol.

Severe low blood sugar may lead to death if not treated.

- Hypersensitivity reactions (a reaction of the immune system) may occur upon injection of a medicine. It may occur also with insulin icodec. Hypersensitivity reactions may show as local skin problems at the injection site or allergic reactions.

Signs of mild allergic reactions may include:
- rash, redness, hives and itching.

Signs of a serious allergic reaction may include:
- swelling of your throat, tongue and/or face, trouble breathing, wheezing, fast heartbeat, pale and cold skin, feeling dizzy or weak.

Allergic reactions may become severe and can 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.

- Skin problem where the injection is given

Skin problem where the injection is given have been observed with the insulin icodec you will receive in this study.

Signs at the injection site may include:
- bruising
- bleeding
- pain or discomfort
- redness
- swelling
- itching.

These problems usually go away after a few days.

The chance of skin problems may be less if you change where you inject each time.

- Antibodies formed in your blood

Formation of antibodies was seen in people with diabetes who were treated with insulin icodec.

Your immune system may make antibodies against your medicine. In rare cases, your insulin dose may need to be changed if the blood sugar is too low or too high. If certain

antibodies are formed in your body, it may result in an allergic reaction.

Side effects of insulin glargine

Very common side effects (may affect more than 1 in 10 people)
- Low blood sugar

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.

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

Signs of severe low blood sugar may include:
- feeling confused
- strange behaviour such as slurred speech or being clumsy
- problems with your sight
- fits or passing out.

Severe low blood sugar is a serious problem that can lead to death.

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.
Low blood sugar is more likely to happen if you:
- exercise more than usual
- eat too little or miss a meal
- drink alcohol.

Common side effects (may affect up to 1 in 10 people)
- Skin site problem where the injection is given

Signs at the injection site may include:
- bruising
- bleeding
- pain or discomfort
- redness
- swelling
- itching.

These problems usually go away after a few days.

The chance of skin problems may be less if you change where you inject each time.

- Skin changes where you inject your medicine ('lipo-hypertrophy').

The fatty layer under the skin may get thicker ('lipo-hypertrophy').

Uncommon side effects (may affect up to 1 in 100 people)
- Skin changes where you inject your medicine

The fatty layer under the skin may shrink ('lipo-atrophy').

If you inject in the area of the skin changes, this could lower the amount of medicine getting into your body.

The chance of skin changes may be less if you change where you inject each time.

Rare side effects (may affect up to 1 in 1,000 people)
- Allergic reactions

Signs of mild allergic reactions may include:
- rash, redness, hives and itching, wheezing.

Signs of serious allergic reactions may include:
- swelling of your throat and face, breathing problems, fast heartbeat, pale and cold skin, feeling dizzy or weak.

This may become severe and could lead to 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.

- Worsening of an eye problem caused by diabetes ('diabetic retinopathy') and problems in how you can see ('visual impairment')
- It is due to damaged blood vessels at the back of your eye.
- It can potentially lead to blindness.

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

- Swelling ('edema')

When you first start using your medicine, your body may keep more water than it should. This causes swelling around your ankles and other joints. This usually lasts a short period of time.

Very rare side effects (may affect up to 1 in 10,000 people)
- Change in how things taste ('dysgeusia')
- Muscle pain ('myalgia')

Other side effects (we do not know how often these may happen)
If you inject insulin too often at the same place, lumps under the skin caused by build-up of a protein called amyloid might occur (cutaneous amyloidosis). The insulin may not work very well. Changing where you inject each time may help to prevent these skin changes.

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

This is because having high or low blood sugar can affect your ability to drive or use any tools or machines.

Also, if your blood sugar is high or low, your ability to concentrate or react might be affected. This could be dangerous to yourself or others. Ask your doctor whether you can drive if you:

- often get low blood sugar
- find it hard to recognise low blood sugar.

Pregnancy – information for women and men

- 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.
- At the beginning and at the end of the study, all women who can become pregnant will have pregnancy tests done.
- If you take part in the study and if you can become pregnant, you and your male partner must use birth control. Your study doctor will give you advice about this before the study starts.
- If you take part and think you may have become pregnant, tell the study doctor or staff right away.
  - If you become pregnant, tell the study doctor or staff right away and your study doctor will tell you how to stop taking the study medicine
  - 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 a form (like this one) to collect his health information.

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 the study medicine is effective for you, your blood sugar levels may lower and stay within a normal and safe level.

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

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.

You will not have to pay for the following things - as long as you stay in the study:
- Study medicine including pen and needles
- Blood sugar meter – a small device to measure your blood sugar level
- Continuous glucose monitoring system - a small sensor inserted under the skin to measure your blood sugar all the time
- eDiary on a study phone
- Training and introduction to the use of pens and blood sugar meters
- Close contact with your study doctor and all the tests and checks
- Better understanding of your diabetes.

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 they have to travel to the office. Patients will be paid following each visit, they 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 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
- 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?
After your last dose of the study medicine 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 a few 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. It is up to you if you decide to keep coming or not. The clinic visits include:

- A clinic visit as soon as you have stopped taking the study medicine
- Follow-up visits

  - If you take insulin icodec, clinic visits 3 weeks and 6 weeks after you have stopped taking the medicine.
  - If you take insulin glargine, clinic visits 2 weeks and 5 weeks after you have stopped taking the medicine.
- Final clinic visits 1 and 1 ½ years after you started. During the period before the final clinic visits, you will be contacted by your study doctor.

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.

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/year, contact information, social security number, 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.

Photos taken by you or your study doctor during the study (if any), will only be used for documenting the signs of hypersensitivity/allergy you had (if you have any). 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 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, people working on behalf of Novo Nordisk, the IRB 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)
- national medicine authorities from other countries
- the FDA

Your study information and blood samples may be sent securely to other countries in the world for testing and analysing. The laws on personal information in these countries may be less strict than in the US.

- 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.
- If the test result is not normal, then a part of the sample may be kept for up to two years or according to local regulations.
- Antibody samples may be taken to help with the diagnosis of a suspected hypersensitivity reaction. These samples will be stored until the drug has been approved for use or for up to 15 years after the end of the study. This is due to requirements from the health authorities.

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

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 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 any questions, concerns or complaints about this research study, please feel free to talk to your study doctor or contact person. Their contact information can be found on the first page of 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.

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:

- 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.
  - 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.

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 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):