PARTICIPANT INFORMATION AND AGREEMENT TO TAKE PART FORM

TITLE: Long-term effects of semaglutide on diabetic retinopathy in subjects with type 2 diabetes (FOCUS)

PROTOCOL NO.: NN9535-4352
WCG Protocol#: 20190391

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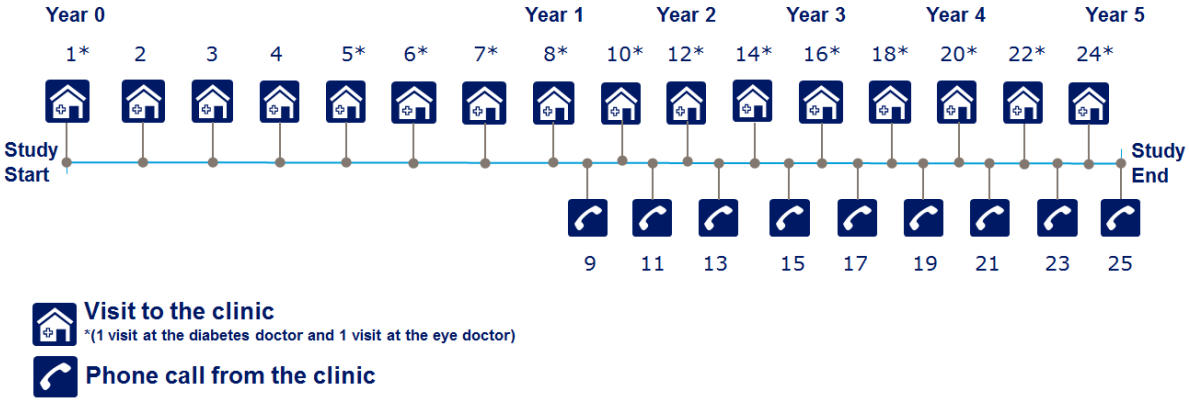
Administrative information:	
Universal trial number: U1111-1201-6256	EudraCT number: 2017-003619-20
Version: 3.0 US Final	
Official name of the study: Long-term effects of semaglutide on diabetic retinopathy in patients with type 2 diabetes (FOCUS)	
Research sponsor contact information: Novo Nordisk 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, www.clinicaltrialsregister.eu and potentially in other regional or local registries	

Visit schedule

The figure below shows the visit schedule



Participant information and Agreement to Take Part Form

A research study to look at how semaglutide compared to placebo affects diabetic eye disease in people with type 2 diabetes

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.

- A new medicine needs to be tested to see if it is safe and if it works as expected.
- This is called a research study. In this document we will call it a study.
- This study will look at the long-term effects of semaglutide (active medicine) on diabetic eye disease when compared to placebo (dummy medicine). The study will be performed in people with type 2 diabetes.
- Semaglutide or placebo will be taken together with your normal diabetes medicines.
- Semaglutide is already approved in some countries and can be prescribed by doctors in addition to diet and exercise to improve glycemic control in adults with type 2 diabetes.
- 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.

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 study, please feel free to talk to your study doctor, eye doctor or contact person 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.

- We are doing this study to look at the long-term effects of semaglutide (active medicine) on diabetic eye disease when compared to placebo (dummy medicine).
- The study will be performed in people with type 2 diabetes.
- You will either get semaglutide or placebo in addition to your diabetes medicine - which treatment you get is decided by chance.
- You will inject the study medicine using a pen-injector. The medicine must be injected in a skin fold in the stomach, thigh or upper arm once a week.
- Like all medicines, the study medicine may have side effects.
- The study will last for 5 years.
- You will have 16 clinic visits and 9 phone calls with the study doctor.
- At 13 of the clinic visits, you will also visit an eye doctor, who will examine your eyes and do different eye tests.
- At each visit to the clinic a blood sample will be taken.
- 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 at the long-term effects of semaglutide (active medicine) on diabetic eye disease when compared to placebo.

The study will be performed in people with type 2 diabetes. Semaglutide is a new type 2 diabetes medicine which already can be prescribed by doctors in some countries. A number of completed studies have shown that semaglutide lowered the blood glucose effectively.

The use of semaglutide to study the effects on diabetic retinopathy over a long term is investigational.

What will this study look at?

Lowering of blood glucose in diabetes can delay or prevent worsening of eye problems caused by diabetes. However, fast lowering of blood glucose levels may worsen the diabetic eye disease to begin with.

This study will look mainly at the long-term effects of semaglutide on diabetic eye disease.

How many people will take part?

1500 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 long-term blood sugar (A1C) is too high.

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 which 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 medical 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 health 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 will inject the study medicine in a skin fold in the stomach, thigh or upper arm. You will use a pen-injector with a needle to inject the medicine under your skin.
- You will be trained in how to inject the medicine by the study staff and they will continue to give support throughout the study.
- You must inject your study medicine once a week on the same day of the week.
- Your dose of study medicine will be changed over time. You start by taking a smaller dose and after 4 weeks the dose will increase. The dose can be further increased at 8 weeks or later in the study, if your doctor thinks it is needed for better control of your blood sugar.

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 must return the study medicine (used, partly used and unused medicine) as requested by site staff.
- You must tell your study doctor about any side effects you might feel.
- You must keep in contact with the site staff during the entire study.

Taking your usual medicines

You must keep taking your normal medicines - including your medicines for type 2 diabetes.

Your study doctor will closely follow your diabetes care and blood sugar. It is important that you are willing to take other medicine for your diabetes if needed.

Tell your study doctor if there are changes to your normal medicines during the study or if you start taking a new medicine. You cannot take DPP-4 inhibitors or other GLP-1 medicine as they are similar to the study medicine you may get.

How long does the study last for?

The total time you will be in this study is about 5 years.

The timeline of the study will be:

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

What will happen at the different visits in the study?

During the study, you will be asked to:

- come to 16 clinic visits, where 13 visits are both at the eye doctor and the diabetes doctor and
- have 9 phone calls with the study doctor or site 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 medicine.

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), previous and current diabetes and eye medications. Your eyes will also be examined by an eye doctor at this visit and different eye tests will be done. You will also be asked about:

- Your type 2 diabetes.
- Your blood sugar.
- Your medical history focusing on any eye disease you may have or have had.
- If you have any planned operations.
- If you have had cancer within the last 5 years.
- If you recently have had a heart disease and/or a stroke
- Permission to get documents from your family doctor, primary eye doctor or other health care professionals, if it is needed and allowed by local regulation.
- If you recently have been or are in another medicine study or if you plan to do so.

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

The study staff will give you a card or a leaflet that contains contact details of people to contact for further information about the study. It will also tell you whom to contact in the event of a study-related medical emergency.

- You may be asked to come for extra visits, for example if you need to have extra eye tests done, if the study doctor thinks it is necessary to make changes to your diabetes medicine or study medicine between planned visits, or 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:

- 13 visits that may take several hours.
- 3 short visits that may take about 1 hour.
- During the first year you will be followed more closely with visits every 1-3 months. Hereafter there will be visits at the site every 6 months.

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:

- Weight and height
- Blood pressure and pulse
- Your body in general

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

- If you are a woman and able to become pregnant, you will have tests to check whether you are pregnant.
- At all of the 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 10 tablespoons (150 mL) of blood will be taken during the study.
- You will also have a small drop of blood taken from your finger at all site visits.
- You will visit the eye doctor 13 times during the trial and have the following tests performed at each visit:

  - general eye examination
  - visual acuity: the ability to read letters on a chart.

  At 8 visits you will also have the following eye tests performed:

  - fundus photography: a special camera will be used to take photographs of the back of your eye (the retina)
  - Optical Coherence Tomography (OCT): a form of ultrasound will be used to measure the thickness of the retina.

If you are wearing contact lenses, it is advised to remove these on the day of the eye examination.

Please see schematic view of the visits noted earlier in this form.

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

There are two study medicines:

- **Semaglutide** (the active medicine being tested)
- **Placebo (or dummy medicine)** (looks like the active medicine but has no effect on the body).

You will only take one of these medicines.

The reason for one group injecting a dummy medicine and the other group injecting the active study medicine is to find out if the active study medicine has any long-term effects on diabetic eye disease compared to the dummy medicine. It is important that you and the study doctor do not know which study medicine you are taking as it might affect the results of the study.

Semaglutide is a medicine doctors can already prescribe in some countries. It is for the treatment of type 2 diabetes. This study will look at whether semaglutide has any long-term effects on development or worsening of diabetic eye 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.

You, your study doctor or eye doctor will not know which of the study medicines 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 (GLP-1) in the body. It acts like the hormone to:

- help the body produce more insulin
- help the liver make less sugar (glucose)
- reduce hunger and lower energy intake

This helps to reduce blood sugar.

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

Your study doctor will watch closely for possible health problems that happen while you are 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 you have while taking part

- Tell the doctor or staff even if you do not think that they 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 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 examination

As part of the eye examination, you will get eye drops to dilate your pupils which will make your eyes more sensitive to light and may cause temporary blurred vision. It is therefore recommended to wear sunglasses after the visit. 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. The risks and discomfort of eye examinations are similar to those of eye examinations you may have had in the past.

Side effects of 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 most often happen at the start of the treatment and are usually mild to moderate in severity.

  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 ('hypoglycemia')

  Early signs may include:

  - feeling hungry, very tired, shaky, worried or irritable, feeling of strong or fast heartbeat, pale skin and sweating or finding it hard to think.

  Signs during the night may also include:

  - damp sheets or bedclothes from sweating, nightmares and feeling tired, irritable or confused when waking up.

  Signs of severe low blood sugar may include:

  - feeling confused, strange behavior such as slurred speech or being clumsy, problems with your vision, fits or passing out.

  Low blood sugar is more likely to happen if you:

  - use the study medicine with other medicines called sulfonylureas 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 straight 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:

- Pain in your stomach area
- Being sick (vomiting),
- Low appetite and losing weight
- Constipation
- Upset stomach or indigestion
- Inflamed stomach
- Feeling dizzy
- Feeling very tired
- Feeling bloated
- Heartburn
- Burping
- Passing wind (or gas)
- Gall-stones (cholelithiasis)
- Increased pancreatic enzymes (shown in blood tests)

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

- Change in how things taste
- Skin problems where the injection is given
- Fast heart beat (pulse)
- Allergic reactions like rash, itching or hives

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

- Serious allergic reactions
  Signs of serious allergic reactions may include: Swelling of your throat and face, breathing problems, fast heart-beat, 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 straight away.**

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

- Inflamed pancreas ('pancreatitis')
  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.

- Tumors in the thyroid gland

This is a type of tumor that has been seen in studies with animals. It is not known if this (including medullar thyroid cancer) will 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 thyroid cancer.

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

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 exams 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 inactive so no side effects are expected.

Pregnancy - information for 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, and if you can become pregnant, you or your male partner must use highly effective birth control. Your study doctor will give you advice about types of birth control that work the best before the study starts.
- At the beginning of the study, and when the treatment with study medicine is done, all women who can become pregnant will have a pregnancy test.
- 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 take part and think you may have become pregnant (for example if you miss your menstrual period), tell the study doctor or staff straight away and 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.

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 and diabetes related eye disease in the future.

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

- Study medicine
- Needles
- Blood testing equipment to test your blood sugar
- All tests and checks required by the study including the eye tests

All other tests and medications including your type 2 diabetes medicines used before entering the study will not be covered by Novo Nordisk.

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.

Will you receive any payments?
You will be reimbursed a $40 travel stipend each time you have to travel into the office. You will not be reimbursed an additional stipend when they travel to the eye 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.

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

- an independent committee called an Institutional Review Board has reviewed the study.
- The Food and Drug Administration (FDA) has reviewed the study.

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 medicine 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. For that reason, you are encouraged to attend all clinic visits until the end of the study. It is up to you if you decide to keep coming or not.

It may be possible to change clinic visits into phone visits, but discuss this with your study doctor. However, the last visit at the eye doctor cannot be changed into a phone visit. You may also decide to start taking 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.

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 at the study doctor and eye doctor. This will be to check your health and any effects of the study medicine on your body up until that point.

What if the company paying for the study or the authorities decide to stop the study?

Novo Nordisk, the 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 trial, you will receive medical care from your trial 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 trial or receiving trial medicine as long as you follow the trial doctor's instruction and the expenses are not covered by insurance. In order to receive payment for injury or illness, the sponsor or the trial 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.

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

What information about you will be collected?

During the study your study doctor and eye 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 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, eye 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 authorised 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 national medicine authorities (such as the FDA) from other countries.

Your study information, blood samples and pictures of your eyes 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 samples and pictures of your eyes will be sent to different places for testing.

- Blood samples will be destroyed after they have been tested.

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 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.

If you are planning to move out of this area within the next five years, please tell the study doctor. The study doctor will see if it can be arranged for you to still be in the study.

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.

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, eye doctor or contact person. Their contact information can be found on the first page of this form. 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.

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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 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 and primary eye 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):

- All subjects are required to assent unless the investigator determines that the capability of the subject is so limited that the subject cannot reasonably be consulted.
- If assent is obtained, document assent by having the subject sign the consent document unless the investigator determines that the subject is not capable of signing

To be completed by participant's legally acceptable/authorised representative, if applicable *I agree with all of the statements on this form:* *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):