# Participant Information Sheet for Medical Research

## ASPIRE: A study on injections for long-lasting Achilles tendon pain

*Full title: "The ASPIRE study: Treatment of chronic Achilles tendinopathy with corticosteroid injections and exercise therapy."*

### Introduction

Dear Sir/Madam,

In this information sheet, we would like to ask you to take part in a medical research study. Participation is voluntary. You are receiving this information because you have Achilles tendon problems.
In this document, you can read what the study is about, what taking part means for you, and what the possible advantages and disadvantages are. It is a lot of information. Please take your time to read it and to decide whether you want to take part.
If you decide to participate, you can fill in the consent form in Appendix D.

### Ask your questions

You can make your decision based on the information in this document, but we also advise you to do the following:

- Ask the researcher any questions you may have.
- Talk to your partner, family, or friends about the study.
- Ask the independent advisor questions (see Appendix A for contact details).
- Read the information on: www.rijksoverheid.nl/mensenonderzoek.

### 1. General information

This study was designed by Erasmus MC, which we will call "the sponsor."
Researchers – these may be doctors or research nurses – will carry out the study in different hospitals and treatment centres in the Netherlands, including Amsterdam UMC, UMC Utrecht, Haaglanden MC, Ziekenhuis Gelderse Vallei, Isala and Bergman Clinics.

For this study, we need 276 participants from the Netherlands. This number has been calculated to make sure the results of the study will be reliable.

The medical ethics review committee of Erasmus MC has approved this study.

## 2. What is the purpose of the study?

We want to find out whether an injection with an anti-inflammatory medicine (a corticosteroid) together with a numbing medicine (lidocaine) is safe and effective for long-lasting Achilles tendon pain.

We will compare a corticosteroid injection with a placebo injection (which contains only lidocaine, a numbing medicine that reduces pain for a short time but does not work in the long term).

Everyone who takes part will also receive:
1) information about Achilles tendon problems,
2) advice about physical activity and sports
3) and an exercise programme with strengthening exercises for the calf muscles and Achilles tendon.

## 3. Background of the study

Exercise therapy is the standard treatment, but about half of all patients continue to have symptoms.

In practice, doctors sometimes use corticosteroid injections. They are careful with these because older studies suggested that the effect may not last long, and there is a small chance of the tendon tearing.

However, newer research in 100 patients showed that an injection around the tendon (not into the tendon itself), combined with strengthening exercises can help in the long term and seems safe. In that study no additional problems, such as tendon tears, were observed.

With the ASPIRE study, we want to confirm whether these findings are correct.

## 4. How does the study work?

*How long does participation last?*

If you take part, the study lasts one year. After that, we will ask you to complete short follow-up questionnaires at 2, 5, and 10 years, to see how you are doing in the long term.

*Step 1: Are you eligible?*

First, we will check whether you are eligible to participate. This is done through an online questionnaire and/or a phone call. If you appear to be eligible, we will schedule an appointment for you at the hospital.

During that hospital visit, the following examinations will be performed:

- Questionnaires: about your symptoms, pain, and daily activities.
- Physical examination: the researcher examines your Achilles tendon and general health.
- Ultrasound scan: to look at the tendon.
- Blood samples (only for participants treated at Erasmus MC). Over the course of the year, a total of 3 tubes of blood (6 ml each) will be taken. This blood will be stored for future scientific research on the recovery from tendon complaints. We will ask for your separate consent for this follow-up research.

*Step 2: The treatment*

You will receive one injection placed next to the Achilles tendon using ultrasound guidance.

If your symptoms do not improve enough, the injection may be repeated once or twice during the first 8 weeks (at least 4 weeks apart).

There are two possible groups:

- Group 1: corticosteroid + lidocaine injection
- Group 2: placebo injection with lidocaine only

Randomisation decides which injection you receive. You, your doctor, and the study team will not know which group you are in. If needed for your safety, this information can be found.

Every participant follows the same exercise program. You will do these exercises for at least 3 months, often longer. You may do the exercises with a physiotherapist, but this is not required. You can also do them at home or in a gym. We will make the exercise program, including videos, available on a website. For the first 3 months after the injection, you should avoid sports that involve running, sprinting, or jumping.

*Step 3: Study visits and measurements*

You will visit the hospital three times in the first year:

- At the start: ± 2 hours;
- At 3 months: ± 45 minutes;
- At 12 months: ± 45 minutes.

During these visits you will:

- complete questionnaires
- have a physical examination
- have an ultrasound scan
- have blood taken (Erasmus MC only; 6 ml each time, total 18 ml)

You will receive questionnaires by email seven times. Each time, it will take you approximately 5 to 30 minutes to complete them. The questionnaires are administered using a digital system. If you give consent, we will use your email address only to send you links to the questionnaires and any reminders. Your email address will be used exclusively for this purpose and will not be linked to your study data. In attachment C you can find which measurements we perform during the visits.

*How is this different from normal care?*
Normally, treatment involves advice and exercises. Corticosteroid injections are used less often because doctors are cautious.

In this study:

- You will receive at least one injection;
- You may receive additional injections if your symptoms persist and you wish to have another injection.
- Your exercises follow a carefully designed programme.
- You will have more check-ups, tests, and ultrasounds than usual.

This means you are monitored more closely than in regular care.

## 5. What agreements do we make with you?

We want the study to run smoothly. Therefore, we make the following agreements with you:

- You will first provide written consent to participate. Only after that will measurements be taken and you will receive an injection.
- You will perform the exercises as explained by the researcher. You will follow the exercise program for at least 3 months, and longer if necessary.
- For the first 3 months, you will avoid running, sprinting, and jumping.
- During the first year after the start of the study, you will not undergo any other treatments for your Achilles tendon complaints. If you do decide to do so, you should discuss this with the study doctor.
- You will not participate in other medical studies for Achilles tendon problems during this study.
- You will attend all hospital appointments.

- You will complete all questionnaires.
- Contact the study doctor if:
  - You want to take new medicines (including supplements or over-the-counter remedies).
  - You are admitted to hospital.
  - You have sudden health problems.
  - You want to stop the study.
  - Your contact details have changed.

*Can you or your partner become pregnant during the study?*
Women who are pregnant or breastfeeding cannot participate in this study. Women may become pregnant during the study, but in that case, any injection scheduled at 4 or 8 weeks cannot be repeated. This is important because the effects of the injection on an unborn child are unknown. If you wish, the researcher can discuss with you the best ways to prevent pregnancy during the study.

*What if you do become pregnant?*
If you become pregnant during the study, you should inform the researcher immediately. In such cases, the pregnancy may be monitored more closely, and information about its course and outcome may be requested from other healthcare providers—but only with your consent. Information about the pregnancy will only be shared with the sponsor of this study (Erasmus MC) and will always be anonymized using a code. Your name will not be disclosed.

*Becoming pregnant after the study?*
After the first 8 weeks of the study, you can become pregnant without it affecting your participation in the study. The injection treatments in this study do not affect any future pregnancy.

## 6. What side effects or discomforts might occur?

Corticosteroid injections can cause side effects. Contact the study team immediately if you notice:

- Sudden severe pain in the Achilles tendon and/or a popping sensation in the Achilles tendon. The Achilles tendon may have ruptured.
- Fever, increasing redness, warmth, or pain at the injection site. This may indicate an infection.
- Severe skin reactions, such as rapid dark discoloration of the skin (dark red, purple, or black) around the injection site, occurring within a few hours after the injection.

Common side effects:

- Pain or bruised feeling at the injection site (this usually goes away on its own within a few days; applying a cold pack may help).
- Temporary worsening of symptoms within the first few days or weeks after the injection.
- Skin discoloration (light brown or light yellow) or thinning of the skin around the injection site; this often develops weeks to months after the injection.
- If you have diabetes mellitus, an injection with an anti-inflammatory medication (corticosteroid) may temporarily increase your blood sugar levels. Therefore, we ask you to monitor your blood sugar more closely for at least the first 3 days after the injection (preferably later in the day, for example before dinner). Please contact your treating physician and the study team if you experience symptoms that may indicate high blood sugar or if you repeatedly have blood sugar levels above 15 mmol/L.

Rare but serious complications (in less than 1 in 100 people)

- Achilles tendon tear
- Infection at the injection site

Some side effects may not yet be known.

More information about corticosteroids can be found in the medicine leaflet. If you participate in the study, you will receive the medicine leaflet.

The placebo injection with a local anesthetic (lidocaine) may cause side effects. This anesthetic can temporarily reduce pain. The effect usually lasts for about one hour. Sometimes, the injection site may also be less sensitive for a short period.

Lidocaine has no long-term effect on Achilles tendon complaints. Therefore, we use this medication in this study as a comparison treatment (placebo).

Possible side effects of lidocaine include:

- Pain or bruised feeling at the injection site.
- Temporary numbness or tingling at the injection site.
- Small risk of infection (as with any injection into the skin).
- Symptoms of an allergic reaction, such as a skin rash, shortness of breath, or fainting. An allergic reaction usually occurs quickly and can be treated immediately in the hospital.

What discomforts might you experience during the study measurements?

- Exercises and functional tests may cause temporary pain or muscle ache.
- Ultrasound is painless, but the gel is cold.
- Blood tests may sting or cause a small bruise (only performed at Erasmus MC study site)
- Questionnaires take time to complete (the first questionnaire takes about 30 minutes, and the follow-up questionnaires take about 5 to 20 minutes each).

## 7. What are the possible advantages and disadvantages?

Participation in the study may have advantages and disadvantages. We have listed them below. Please consider them carefully and discuss them with others.

*Possible advantages*

- Participating in this study does not automatically mean that your complaints will disappear or that you will have less discomfort in your Achilles tendon. However, previous similar studies have shown that a significant reduction in complaints is likely. Even if you are randomly assigned to the placebo group, improvement is still possible.
- It is possible that the injections, combined with the exercise program, may reduce your complaints, but this is not guaranteed. Even if you are in the placebo group, you will still receive good guidance, information, and an exercise program that can help with your recovery. This information and the exercise program are based on all the knowledge currently available.
- Your recovery from the Achilles tendon will be closely monitored during the study. We will conduct more assessments than in usual care.
- Participation in this study will not result in any extra healthcare costs for you.
- By taking part, you will also help researchers gain more insight into the treatment of Achilles tendon complaints. You contribute to the search for better and safer treatments for future patients.

*Possible disadvantages*

- You may experience side effects from the injections (see paragraph 6). The measurements, such as blood draws, may also cause some discomfort.
- Participating in the study requires extra time, for example for hospital visits and completing questionnaires.
- You need to follow the study-related agreements and instructions.
- It is possible that during assessments, such as the ultrasound examination, something may be discovered that is not directly related to the study but could be important for your health or that of your family. See also paragraph 10 on unexpected findings.

*Do you not want to participate?*
Participation in this study is entirely your choice. If you decide not to take part, you will receive the usual care for Achilles tendon complaints from your healthcare provider. If you do not yet have contact with a healthcare provider, you can ask your local general practitioner or physiotherapist for advice. Your healthcare provider can explain the available treatment options and their advantages and disadvantages.

## 8. When does the study stop for you?

The researcher will inform you if new information becomes available about the study that may be important to you. The researcher will then ask whether you wish to continue participating in the study.

The study ends for you when:

- All planned visits and questionnaires are completed
- The study ends completely.
- You choose to stop. You may withdraw from the study at any time. If you decide to do so, please inform the researcher as soon as possible. You do not have to give a reason for your decision. You will then receive the usual treatment for your Achilles tendon complaints. The researcher will still invite you for a follow-up visit.
- The researcher advises you to stop. The researcher will still invite you for a follow-up visit.
- One of the following parties decides that the study must be stopped:
    - Erasmus MC.
    - The government.
    - The medical-ethical committee reviewing this study.

*What happens if you withdraw from the study?*
The researchers will use the data collected up to the time of your withdrawal. If you wish, any blood samples that have not yet been analysed can be destroyed. Please inform the researcher if this is your preference.

The study will be completed once all participants have finished their final study assessment.

## 9. What happens after the study?

*Can you continue receiving the injections?*

The injections you receive as part of this study will not routinely remain available to you after the study has ended. This is because it has not yet been established whether the treatment is sufficiently safe and effective to become part of standard care. The researcher will discuss the treatment options available through usual care according to current guidelines.

*Will you receive the results of the study?*

Approximately one to two years after the study has been completed, the researchers will inform you of the main results. If you wish, you can also find out which study group you were assigned to (the corticosteroid and local anaesthetic injection group or the placebo injection group). If you would prefer not to know, you can let the researcher know."**

## 10. What happens to your data and body material?

If you participate, you agree that your data and blood (if collected) may be collected, stored and used.

*Which data do we store?*

We store the following data:

- Name, sex, address, date of birth.
- Data about your health.
- (Medical) data collected during the study, such as questionnaire results, physical examinations, blood tests, and ultrasound scans.

*Which body material do we store?*

We collect and store blood from participants who are treated at Erasmus MC. This blood is used to investigate which substances in the body may influence the recovery of the Achilles tendon.

*Why do we collect, use, and store your data and body material?*

We do this to answer the research questions of this study and to be able to publish the results. Your data and blood may also be used by the sponsor (Erasmus MC) and organisations that support Erasmus MC in analysing the study data or measuring substances in the blood.

*How do we protect your privacy?*
To protect your privacy, we assign a code to your data and blood samples. Only this code is shown on all data and materials. The key linking the code to your personal details is stored separately and securely at Erasmus MC. In reports and publications about this study, it will never be possible to identify you.

*Who can see your data?*
Some people are allowed to see your name and other personal details without a code. This may include data collected specially for this study, as well as information from your medical record. These are people who check whether the researchers are carrying out the study properly and reliably. They may look at your data:

- members of the committee that monitors the safety of the study
- a monitor who checks the study on behalf of Erasmus MC
- national or international regulatory authorities

These people must keep your information confidential. We ask your permission for these people to review your data. The Health and Youth Care Inspectorate (IGJ) is allowed to view your data without your permission.

*How long do we store your data and body material?*
Your data and blood samples will be stored at Erasmus MC for 25 years. The blood is stored so that additional measurements related to this study can be performed during the course of the study. Once this is no longer necessary, the blood will be destroyed.

*May we use your data and body material for other research?*
Your data and (remaining) blood samples may also be valuable for other scientific research on tendon complaints or other injuries. You can indicate on the consent form whether you agree to this. If you do not give permission, you can still participate in this study and you will receive the same care.

*What happens in case of unexpected findings?*
It is possible that we may find something during, for example, an ultrasound of your Achilles tendon that is not directly related to this study but may be relevant for your health. The researcher will inform you about this. In consultation with you, the researcher may then contact your general practitioner or a medical specialist. Together, you will discuss what needs to be done. Any related costs will be covered by your health insurance. By signing the consent form, you agree that your general practitioner or specialist may be informed if necessary.

*Can you withdraw your consent for the use of your data?*

You may withdraw your consent for the use of your data at any time. Please inform the researcher if you wish to do so. This applies both to the use of your data in this study and in other research. Please note that if you withdraw your consent after data have already been collected, these data may still be used in the study. For your body material, the researchers will destroy them after you withdraw your consent. However, if analyses have already been performed on your samples, the results of those analyses may still be used.

*Will your data be transferred to countries outside the European Union?*

For this study, your data and blood samples are currently not shared with other countries within or outside the European Union. However, it is possible that in the future a request may be made by research organisations or commercial partners with whom we collaborate abroad (both within and outside the European Union) to use the data from this study for new scientific research in the field of your disease or condition.

If your data are shared, this will always be done in coded form (pseudonymised), and measures will be taken to protect your data as well as possible. This means, among other things, that your name and other personal details will be replaced by a code so that the data cannot be directly traced back to you.

On the consent form, you can indicate whether you agree to this. If you do not give permission, you can still participate in this study and receive the same care.

*Would you like to know more about your privacy?*

- Would you like to know more about your rights regarding the processing of personal data? Please visit www.autoriteitpersoonsgegevens.nl.
- Do you have questions or complaints about the processing of your personal data? You can contact the researcher or the Data Protection Officer of Erasmus MC. You may also file a complaint with the Dutch Data Protection Authority. See Appendix A for contact details.

*Where can you find more information about the study?*

You can find more information about the study on the following websites:

- www.onderzoekmetmensen.nl
- www.ClinicalTrials.gov
- https://euclinicaltrials.eu

You can find the study by searching for: ASPIRE trial (EudraCT/CTR number 2025-524057-13-00).

## 11. Will you receive compensation for participating in the study?

The injections, additional tests, and treatments related to this study are free of charge. You will not have to pay any deductible or co-payment from your health insurance for these. You will not receive a fixed payment for participating in the study. However, we will reimburse your (extra) travel expenses to the hospital. The researcher will explain how you can claim these travel costs.

## 12. Are you insured during the study?

Everyone participating in this study is covered by insurance. The insurance will cover damage caused by the study, but not all types of damage. Appendix B contains more information about the insurance and its exceptions. It also explains to whom you can report any damage.

## 13. We will inform your general practitioner

The researcher will send a letter to your general practitioner to inform them that you are participating in this study. This is important for your safety. Your GP will then know that you are receiving an injection with either a corticosteroid or a placebo and that you are undergoing additional tests. If important information arises during the study that may affect your health, the researcher will discuss this with you. You can indicate whether you want this information to also be shared with your GP or specialist.
In addition, information about mortality (death) will also be collected for this study. For this purpose, we will consult the Dutch Personal Records Database (Basisregistratie Personen, BRP, formerly GBA). Consent is not required for this use.

## 14. Do you have questions?

You can ask the researcher any questions about the study. If you would like advice from someone who has no stake in the study, you can contact an independent expert. Contact details can be found in Appendix A. This person is knowledgeable about the study but is not involved in conducting it. Do you have a complaint? You can discuss it with the researcher or the physician treating you. If you prefer not to, you can contact the complaints officer at your hospital. Appendix A contains the contact details.

## 15. How do you give consent for the study?

You can take your time to consider this study. Afterwards, you can inform the researcher whether you understand the information and whether you do or do not wish to participate. If you decide to participate, you should complete the consent form that accompanies this information letter. Both you and the researcher will receive a signed copy of this consent form.

Thank you for your time.

## 16. Appendices to this information

A. Contact details

B. Insurance information

C. Schedule of study procedures

D. Consent form

## Appendix A – Contact details for Erasmus MC

**Study team Erasmus MC:**
Principal investigators:
R.J. de Vos A. Weir (01-06-2026 till 01-08-2026)

Coordinating doctor-researcher:
K.P. van Abswoude

Research nurse:
L.E.M. Bruinaars - Dijks

Email: aspire@erasmusmc.nl
Telephone: 06-49326353
Available during office hours

**Independent doctor/advisor:**
R. van Linschoten
Erasmus MC
Email: r.vanlinschoten.1@erasmusmc.nl
Telephone: 010 704 0136
Available during office hours

Complaints:
If you are not satisfied with the study or your treatment, you can contact the independent complaints officer of Erasmus MC. You can fill in a digital complaint form on the Erasmus MC website: https://www.erasmusmc.nl/nl-nl/patientenzorg/klachtenopvang-en-klachtenbemiddeling. After completing the form, it will be automatically sent to the complaints officer.
If this is not possible, you can also send your complaint by post to Erasmus MC: Erasmus MC, Complaints Office Secretariat (GK-745), Reply number 55, 3000 WB Rotterdam. Please include your name, the name of the study, and your contact details. After receiving your complaint, the complaints officer will contact you.

Data Protection Officer (Erasmus MC):
You can contact the Data Protection Officer of Erasmus MC via the Legal Affairs department.
Email: functionaris.gegevensbescherming@erasmusmc.nl
Telephone: +31 10 703 4986

For more information about your rights:
For more information or if you have questions about your rights, you can contact the Data Protection Officer or the Dutch Data Protection Authority.

For medical emergencies:
For medical emergencies during or outside office hours, you can contact your general practitioner. In life-threatening situations, call 112.
If it becomes medically necessary to know which medication you received in the ASPIRE study, your treating physician can contact the on-call orthopedic physician at Erasmus Medical Center via 010-7040704. The on-call orthopedic physician can then contact the on-call pharmacist to find out which medication was administered. This will only be done if it is medically necessary.

Once the emergency has passed, we ask you to contact the study team to inform us about what happened.

## Appendix B – insurance information

Erasmus MC has taken out insurance for everyone who takes part in this study. This insurance covers damage or injury caused directly by participation in the study. This applies to damage that occurs during the study or within four years after your participation ends. You must report any damage within four years.

If you experience damage caused by the study, please contact the insurer:

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|---|
| Insurer: Centramed B.A.<br>Address: PO Box 7374, 2701 AJ Zoetermeer, The Netherlands.<br>Telephone: +31 70 301 70 70.<br>Email: schade@centramed.nl. |

The insurance covers up to €650,000 per participant, with a maximum of €5,000,000 for the entire study and €7,500,000 per year for all studies from the same sponsor.

The insurance does **not** cover:

- Damage caused by risks that were explained to you in this information sheet, unless the risk turned out to be greater than expected or very unlikely.
- Health problems that would also have occurred without participation.
- Damage caused by not following instructions.
- Damage to the health of your children or grandchildren.
- Damage caused by an existing treatment or research into an existing treatment.

These provisions are included in the ‘Besluit verplichte verzekering bij medisch-wetenschappelijk onderzoek met mensen 2015’. This regulation is published in the government’s legal database (Wettenbank, https://wetten.overheid.nl).

## Bijlage C – Schedule of study procedures

| Moment | Actions |
|---|---|
| **Before the study (screening)** | - Contact with the researcher by email or phone<br>- Check if you are suitable to take part<br>- Information about the study<br>- Appointment at the hospital |
| **Start (week 0)** | - Sign consent form<br>- Discussion of medical history and medication<br>- Questionnaires<br>- Physical examination<br>- Ultrasound of the Achilles tendon<br>- Blood sample (only at Erasmus MC)<br>- Randomisation (which treatment group)<br>- First injection<br>- Start exercise programme (via website) |
| **Between 4–8 weeks** | - Short online questionnaires<br>- Possible second or third injection (only if needed, at least 4 weeks after the previous injection) |
| **After 3 months** | - Questionnaires<br>- Physical examination<br>- Ultrasound<br>- Blood sample (only at Erasmus MC) |
| **After 6 months** | - Online questionnaires |
| **After 9 months** | - Online questionnaires |
| **After 12 months** | - Questionnaires<br>- Physical examination<br>- Ultrasound<br>- Blood sample (only at Erasmus MC) |
| **Long-term follow-up (after 2, 5 and 10 years)** | - Online questionnaires |

## Bijlage D – Consent form

Related to:

ASPIRE: Study on injections for long-lasting Achilles tendon pain

- I have read the information sheet and had the opportunity to ask questions.
- My questions were answered clearly.
- I had enough time to decide whether to take part.
- I understand that participation is voluntary. I know that I can stop taking part at any time, without giving a reason.

I give permission:

- to inform my GP that I am taking part in this study
- to collect and use my data for this study
- for authorised persons to review my data to check the study

Below you can indicate what you do or do not give consent for.
This includes, for example, the storage and use of your data and body material, the sharing of coded data with researchers within and outside the European Economic Area (EEA), being contacted for possible follow-up research, and the recording of additional information such as a potential pregnancy.
Please indicate yes or no for each item in the table below.

| | | |
|---|---|---|
| I agree that my data may be stored and used for other research, as described in the information letter. | Yes ☐ | No☐ |
| I give permission to use my email address to send me (links to) questionnaires for this study and, if necessary, reminders to complete them. My email address will only be used for this purpose. My questionnaire responses will be processed in coded form and used for this study as described in the information letter. | Yes ☐ | No☐ |
| I give permission for information about a possible pregnancy during the study to be recorded. | Yes ☐ | No☐ |
| I agree that my remaining blood samples may be stored and used for other research, as described in the information letter. The body material will then be stored for 25 years. | Yes ☐ | No☐ |
| I agree that I may be contacted for future research. | Yes ☐ | No☐ |
| I agree to be informed after the study which treatment group I was in. | Yes ☐ | No☐ |
| I agree that my coded data and/or body material (blood) may be shared with organisations or commercial partners within the | Yes ☐ | No☐ |

| | | |
|---|---|---|
| European Economic Area (EEA) for scientific research related to my disease or condition that is conducted in collaboration with Erasmus MC. | | |
| I agree that my coded data and/or body material (blood) may be shared with organisations or commercial partners outside the European Economic Area (EEA) for scientific research related to my disease or condition that is conducted in collaboration with Erasmus MC. In these countries, the level of personal data protection may be lower than within the EEA. In such cases, Erasmus MC will ensure, together with the receiving party, that technical and organisational measures are taken to protect your personal data as effectively as possible. | Yes ☐ | No☐ |

I agree to take part in this study.

My name is (participant): ……..

Signature: …… Date : __ / __ /

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I declare that I have fully informed this participant about the above-mentioned study. If new information becomes available during the study that may affect the participant's decision to take part, I will inform the participant in a timely manner.

Name of researcher (or authorised representative):…….

Signature:…… Date: __ / __ / __

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