PARTICIPANT INFORMATION SHEET

STUDY TITLE	Prospective, randomised, double-blind, placebo-controlled, multicenter clinical trial of efficacy and safety with *Dermatophagoides pteronyssinus* and *Dermatophagoides farinae* mannan-conjugated allergoids in patients with rhinitis/ rhinoconjunctivitis, allergic to *Dermatophagoides pteronyssinus* and/or *Dermatophagoides farinae*
STUDY CODE	MM09-SIT-069
SPONSOR	INMUNOTEK S.L.
STUDY DOCTOR	
CENTRE	
CONTACT Email/telephone Opening hours	
24-hour contact Telephone	

INTRODUCTION

We are writing to inform you about a research study in which you are invited to take part. The study has been approved by a Medicines Research Ethics Committee (CEIm) and by the relevant Health Authority, in accordance with current legislation, namely European Regulation 536/2014 of 16 April, which governs clinical trials involving medicinal products.

Our aim is to ensure that you receive accurate and sufficient information so that you can decide whether or not to take part in this study. To this end, please read this information sheet carefully and we will clarify any queries you may have.

You are also welcome to consult with anyone you feel is appropriate.

VOLUNTARY PARTICIPATION

We are inviting you to take part in the study because, for at least one year, you have required medication to treat moderate to severe allergic rhinitis/rhinoconjunctivitis, with or without controlled mild to moderate asthma.

Please be aware that your participation in this study is voluntary and that you may choose NOT to take part. If you decide to participate, you may change your mind and withdraw your consent at any time, without this affecting your relationship with your doctor or causing any detriment to your healthcare.

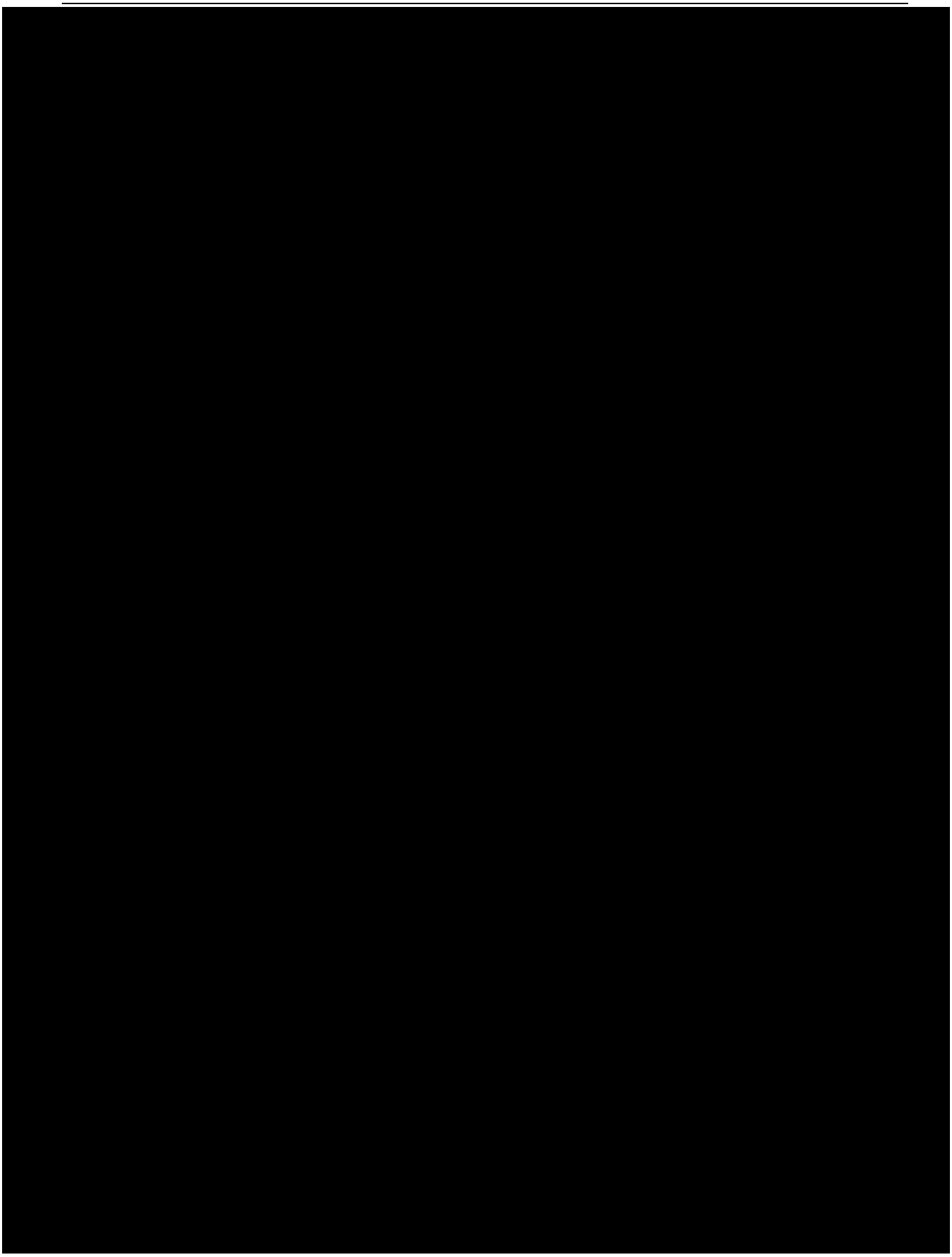
AIM OF THE STUDY

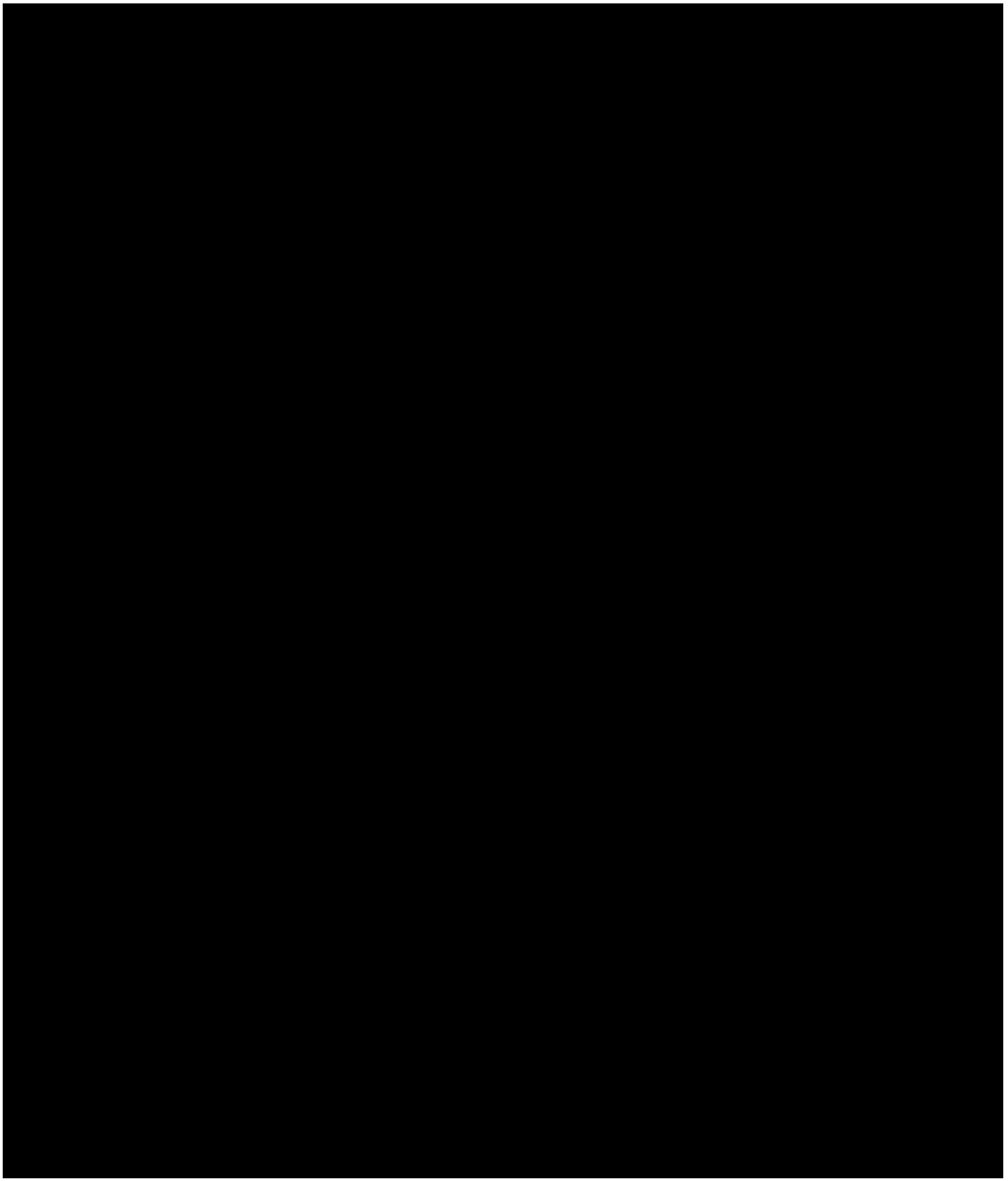
Currently, immunotherapy (allergy vaccines) is the only treatment available that addresses the root cause of the condition and involves the administration of vaccines over a period of time.

The other medicines you have probably already taken provide symptomatic relief; in other words, they do not treat the cause of the allergy, but rather the troublesome symptoms when they occur. It is precisely for this reason that this study is being conducted using a vaccine designed to treat house dust mite allergy.

Both the safety and clinical efficacy of the vaccine will be assessed by comparing it with a placebo treatment. The ultimate aim of the study is to determine whether the vaccine is safe and effective for treating your allergy.







[redacted]

RISKS AND DISCOMFORT ASSOCIATED WITH YOUR PARTICIPATION IN THE STUDY

Please note that the vaccine under investigation is not yet available on the market. However, there is a wealth of information readily available to the public regarding the side effects of immunotherapy (allergy vaccines).

The potential drawbacks for you of taking part in the study include possible adverse reactions to the treatment and to the diagnostic skin test, the need to attend appointments, as well as the risks associated with any blood sample collection, such as pain, bleeding, bruising and, in very rare cases, infection at the injection site.

Adverse reactions that may occur during the course of allergy treatment can be classified into two groups:

- Local reactions:

  Redness, swelling, itching or hardening at the injection site are common.
- General/systemic reactions:

  These range from feeling unwell, dizziness, gastrointestinal discomfort, nasal symptoms (runny nose, congestion or itching), eye symptoms (itching, redness), difficulty breathing, coughing and wheezing, to rarer manifestations such as vaginal bleeding, and even more serious reactions such as a generalised allergic reaction known as anaphylaxis, although this is very rare.

Anaphylaxis may include symptoms such as itching and redness on the palms of the hands and soles of the feet, a feeling of warmth, a faster heart rate, difficulty breathing and a drop in blood pressure, amongst others. In between these extremes, symptoms such as sneezing, hives, and irritation of the eyes and nose may occur.

These reactions occur relatively infrequently, and their likelihood depends largely on the symptoms you usually experience before receiving the vaccine. If these symptoms occur, contact the study investigator immediately.

Due to these possible adverse reactions, you will need to remain in the Allergy Unit for at least 30 minutes after the subcutaneous vaccine has been administered. This is standard practice both for participation in a study and for routine treatments, and your doctor is prepared should any such reaction occur. For the following three hours, you must not engage in strenuous physical exercise or take hot baths, although you may have a shower.

We would also like to inform you of your responsibilities upon agreeing to take part in the study, such as attending all study visits and activities, as well as reporting any adverse events that occur or changes to your medication. Please note that, except in an emergency, you must not alter the medication you are taking or take any other medicines or ‘herbal remedies’ without first consulting the study doctor.

POSSIBLE BENEFITS

[redacted]

[redacted]

CONTACT IN CASE OF QUESTIONS

If, whilst taking part, you have any queries or require further information, please contact the principal investigator at your hospital, whose details are set out on the first page of this document.

WARNING REGARDING PREGNANCY

[redacted]

ALTERNATIVE TREATMENTS

[redacted]

[redacted]

EXPENSES AND FINANCIAL COMPENSATION

Conducting the study involves specific research work; therefore, both the hospital and the professionals taking part in it, including the research team, will receive financial compensation. The study sponsor is responsible for managing the study's funding. To carry out the study, the sponsor has signed a contract with the centre where it is to be conducted and with the study doctor.

You will not receive financial compensation, but you will not have to pay for the medicines or for any specific tests carried out as part of the study. Your participation in the study will not involve any additional costs beyond those associated with your usual clinical care.

WHAT TREATMENT WILL I RECEIVE ON COMPLETION OF THE CLINICAL TRIAL?

[redacted]

INSURANCE

The study sponsor has an insurance policy that complies with current legislation (Royal Decree 1090/2015) and which will provide you with compensation and indemnity in the event of any harm to your health or injuries that may arise in connection with your participation in the study, provided that these are not a consequence of the disease under investigation itself or of the natural progression of your disease as a result of the treatment's ineffectiveness. If you would like further information regarding this section, please consult the principal investigator at your centre.

Please be aware that your participation in this clinical trial may alter the general and specific terms and conditions (cover) of your insurance policies (life, health, accident). We therefore recommend that you contact your insurer to determine whether participation in this trial will affect your current insurance policy.

PROTECTION OF PERSONAL DATA

The sponsor and the healthcare centre where the study is being conducted are jointly responsible for the processing of your personal data, in accordance with the provisions of Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April on the protection of personal data and on the free movement of such data. The legal basis for the processing of your data is the performance of a

task carried out in the scientific interest within the field of health research, as well as compliance with legal obligations applicable to the sponsor and the centre. You may exercise your rights of access, rectification, objection and erasure of data, and you may restrict the processing of data that is inaccurate, request a copy or request that it be transferred to a third party; to do so, you should contact your doctor involved in the study.

We would like to remind you that the data cannot be deleted, even if you cease to participate in the study, in order to ensure the validity of the research and to comply with legal obligations and the requirements for the authorisation of medicinal products. You also have the right to contact the Data Protection Agency if you are not satisfied.

The data collected for the study will be identified by a code, and only your study doctor and/or collaborators and authorised staff of the sponsor will be able to link this data to you and your medical records. Appropriate safeguards will be put in place to protect your coded data during and after the clinical trial. Therefore, your identity will not be disclosed to anyone, except in exceptional circumstances, such as a medical emergency or where required by law. Only representatives of the Health Authorities, the Ethics Committee for Clinical Trials (CEIm) and authorised staff of the sponsor will be able to access the data to verify personal details, study procedures and compliance with good clinical practice.

The investigator and the sponsor are obliged to retain the data collected for the study for at least 25 years after its completion. Thereafter, your personal information will be retained by the centre for the purposes of your healthcare.

Should we transfer your anonymised data outside the EU, the participant's data will be protected by safeguards such as contracts or other mechanisms put in place by data protection authorities.

If the participant would like to know more about this, they may contact the **centre's Data Protection Officer: [.....]** or the **sponsor's Data Protection Officer** [redacted]

OTHER RELEVANT INFORMATION

[redacted]

[redacted]

CLINICAL TRIALS INVOLVING MINORS

Please note that, as this concerns your child's participation – who must be at least 12 years old – they will be given an information sheet and informed consent form adapted to their level of understanding, which they must sign if they wish to take part in the study.

COLLECTION AND USE OF BIOLOGICAL SAMPLES

[redacted]

[redacted]

ACKNOWLEDGEMENT

Whatever your decision, the sponsor and the research team would like to thank you for your time and attention.

INFORMED CONSENT

STUDY TITLE: Prospective, randomised, double-blind, placebo-controlled, multicenter clinical trial of efficacy and safety with *Dermatophagoides pteronyssinus* and *Dermatophagoides farinae* mannan-conjugated allergoids in patients with rhinitis/rhinoconjunctivitis, allergic to *Dermatophagoides pteronyssinus* and/or *Dermatophagoides farinae*

I (participant's full name):.....

- I have read the information sheet provided to me about the study.
- I have been able to ask questions about the study.
- I have received sufficient information about the study.

I have spoken to: .....(first name and surname of the researcher)

I understand that my participation is voluntary and that I may withdraw from the

study: 1. At any time.
2. Without having to give any reasons.
3. Without this affecting my medical care.

I will receive a signed and dated copy of this information sheet and informed consent form. I freely give my consent to take part in the study.

PARTICIPANT'S SIGNATURE	**INVESTIGATOR'S** SIGNATURE
Date: ____/___/_____	Date: ____/___/_____

(Handwritten signature and date)

I would like to be informed of any information arising from the research that may be relevant to my health: YES☐ NO☐

PARTICIPANT'S SIGNATURE	**RESEARCHER'S** SIGNATURE
Date: ____/___/_____	Date: ____/___/_____

(Handwritten signature and date)

INFORMED CONSENT before witnesses

STUDY TITLE: Prospective, randomised, double-blind, placebo-controlled, multicenter clinical trial of efficacy and safety with *Dermatophagoides pteronyssinus* and *Dermatophagoides farinae* mannan-conjugated allergoids in patients with rhinitis/rhinoconjunctivitis, allergic to *Dermatophagoides pteronyssinus* and/or *Dermatophagoides farinae*

I,.....(first name and surname of the witness)

As a witness, I hereby confirm that in my presence Mr/Ms .....

(participant's full name)

- has read (or had read to them, in the event that the participant is unable to read) the information sheet provided to them regarding the study.
- They have been able to ask questions about the study.
- They have received sufficient information about the study.

They have spoken to: .....(researcher's full name)

You understand that your participation is voluntary and that you may withdraw from the study: 1.

At any time.

2. Without having to give any reasons.

3. Without this affecting your medical care.

You will receive a signed and dated copy of this information sheet and informed consent form.

You freely give your consent to take part in the study.

Signature of **the WITNESS**	Signature of the **RESEARCHER**
Date: ____/___/_____	Date: ____/___/_____

(Handwritten signature and date)

Do you wish to be informed of any information arising from the research that may be relevant to your health: YES☐ NO ☐

Signature of **the WITNESS**	Signature of the **RESEARCHER**
Date: ____/___/_____	Date: ____/___/_____

(Handwritten signature and date)

parents/guardians INFORMED CONSENT

STUDY TITLE: Prospective, randomised, double-blind, placebo-controlled, multicenter clinical trial of efficacy and safety with *Dermatophagoides pteronyssinus* and *Dermatophagoides farinae* mannan-conjugated allergoids in patients with rhinitis/rhinoconjunctivitis, allergic to *Dermatophagoides pteronyssinus* and/or *Dermatophagoides farinae*

I .....(first name and surname of the mother/legal guardian)
in my capacity as mother/legal guardian of.....
(participant's full name)

- I have read the information sheet provided to me.
- I have been able to ask questions about the study.
- I have received sufficient information about the study.

I have spoken to .....(researcher's first name and surname)

I understand that participation is voluntary and that I may withdraw from the study: 1. At any time.
2. Without having to give any reasons.
3. Without this affecting my medical care.

I freely give my consent to take part in the study and agree to the access and use of my data under the conditions set out in the information sheet.

I, ...(name and surname of the parent/legal guardian)

as the parent/legal guardian of .....
(participant's first name and surname)

- I have read the information sheet provided to me.
- I have been able to ask questions about the study.
- I have received sufficient information about the study.

I have spoken to ..... (name and surname of the researcher)

I understand that participation is voluntary and that I may withdraw from the study: 1. At any time.
2. Without having to give any reasons.
3. Without this affecting my medical care.

I freely agree to take part in the study and give my consent for my data to be accessed and used under the conditions set out in the information sheet.

I/we will receive a signed and dated copy of this information sheet and informed consent form.

Tick the appropriate box to authorise the minor's participation in the study:

□ Both parents

MOTHER'S SIGNATURE Date: _____/___/_____	**FATHER'S** signature Date: _____/___/_____
RESEARCHER'S SIGNATURE Date: _____/___/_____	

(Handwritten signature and date)

□ I hereby confirm that the other parent has no objection to our child's participation in the study.

Signature of the **MOTHER/FATHER** Date: _____/___/_____	Signature of the **RESEARCHER** Date: _____/___/_____

(Handwritten signature and date)

□ The undersigned is the sole legal guardian.

Signature of **the LEGAL GUARDIAN** Date: _____/___/_____	Signature of the **RESEARCHER** Date: _____/___/_____

(Handwritten signature and date)

I would like to be informed of any information arising from the research that may be relevant to my child's health: YES☐ NO ☐

□ Both parents

MOTHER'S signature Date: _____/___/_____	**FATHER'S** signature Date: _____/___/_____
RESEARCHER'S SIGNATURE Date: _____/___/_____	

(Handwritten signature and date)

□ I hereby confirm that the other parent has no objection to our child's participation in the study.

Signature of the **MOTHER/FATHER** Date: _____/___/_____	Signature of the **RESEARCHER** Date: _____/___/_____

(Handwritten signature and date)

□ The undersigned is the sole legal guardian.

Signature of **the LEGAL GUARDIAN** Date: _____/___/_____	Signature of the **RESEARCHER** Date: _____/___/_____

(Handwritten signature and date)

[redacted]

Minor of age participant INFORMED ASSENT

I, ...

(participant's first name and surname)

Aged.....years old.

- ✓ I understand everything I have read or that has been read to me from the information sheet.
- ✓ My doctor has answered all the questions I had.
- ✓ I know that I can say I do not want to take part and that is fine.
- ✓ I know that I can ask my doctor any questions I have, either now or later.
- ✓ I know that later on, if I no longer wish to take part in this, I can say so and nobody will tell me off for it.

And I wish to take part in the clinical trial.

PARTICIPANT'S SIGNATURE	**INVESTIGATOR'S** SIGNATURE
Date: _____/___/_____	Date: _____/___/_____

(Handwritten signature and date)

The researcher shall tick the appropriate box:

The child has understood everything I have explained to them	YES □	NO □

Have the parents/guardians signed the informed consent form?	YES □	NO □