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-063
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 you have been diagnosed with 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

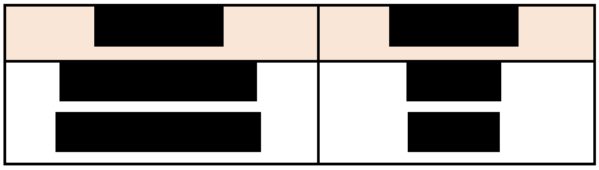
Currently, immunotherapy (allergy vaccines) is the only treatment available that addresses the root cause of the condition and involves the administration of vaccines over a period of time.

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.

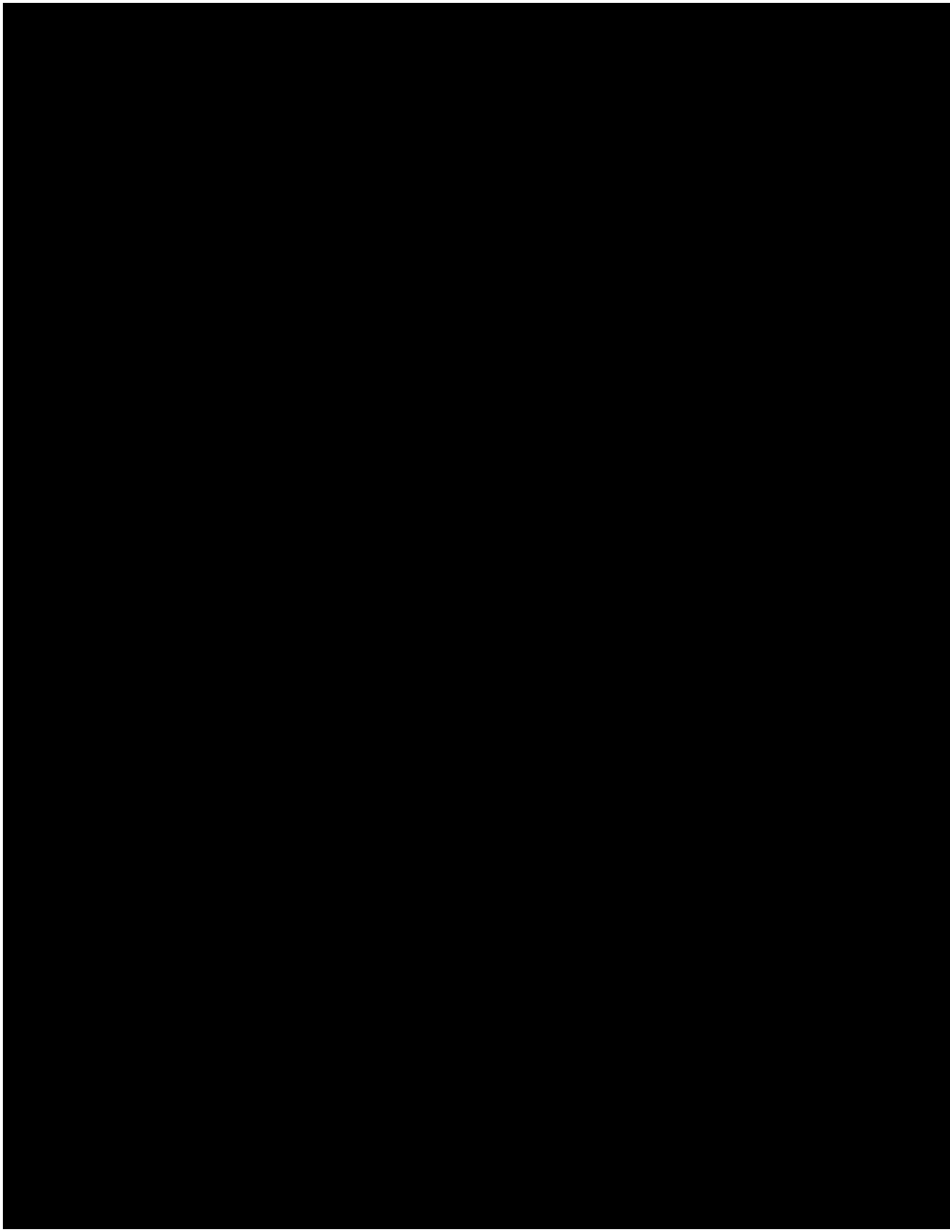
STUDY DESCRIPTION

[redacted]



[redacted]

STUDY ACTIVITIES









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, please contact the study investigator immediately.

Due to these potential adverse reactions, you will need to remain in the Allergy Unit for at least 30 minutes after receiving the subcutaneous vaccine. This is standard practice both for participation in a trial 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]

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]

[redacted]

ALTERNATIVE TREATMENTS

[redacted]

COSTS AND FINANCIAL COMPENSATION

[redacted]

WHAT TREATMENT WILL I RECEIVE ONCE THE CLINICAL TRIAL HAS ENDED?

[redacted].

INSURANCE

The study sponsor has an insurance policy that complies with current legislation (European Regulation 536/2014) and which will provide you with compensation and indemnity in the event of any harm to your health or injury that may occur 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.

The insurance policy will only cover study participants.

In the event of pregnancy, neither the participant nor the baby will be covered by the insurance policy taken out by the sponsor, as, as indicated in the section 'Warning regarding pregnancy', she will be withdrawn from the study.

If a participant's partner becomes pregnant whilst he is taking part in the clinical trial, neither the woman nor the baby will be covered by the insurance.

PROTECTION OF PERSONAL DATA

The processing, disclosure and transfer of the personal data of all participants will comply with the provisions of current legislation (Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April on the protection of personal data) and you may exercise your rights of access, rectification, objection and erasure of data; you may also restrict the processing of incorrect data, request a copy or request that your data be transferred to a third party, for which you should contact your study doctor.

We would like to remind you that your 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 Research Involving Medicinal Products (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 wishes to know more about this, they may contact the **sponsor's Data Protection Officer** [redacted]

OTHER RELEVANT INFORMATION

Any new information regarding the treatments used in the study that may affect your willingness to participate, and which comes to light during your participation, will be communicated to you by your doctor as soon as possible.

You should be aware that you may be excluded from the study if the sponsor or the study investigators deem it appropriate, whether for safety reasons, due to any adverse event arising from the study medication, or because they consider that you are not complying with the established procedures . In any such case, you will receive a proper explanation of the reason for your withdrawal from the study.

By signing the attached consent form, you agree to comply with the study procedures that have been explained to you. You should be aware that your GP may be informed of your participation in this study.

CLINICAL TRIALS INVOLVING MINORS

We would like to inform you 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:……(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	**INVESTIGATOR'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, ... (witness's full name)

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.
- Has been able to ask questions about the study.
- Has received sufficient information about the study.

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

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 **WITNESS** Date: ___/___/____	Signature of the **RESEARCHER** 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** Date: ___/___/____	Signature of the **RESEARCHER** 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, …… (mother's/legal guardian's full name)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 …… (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 give my consent for them to take part in the study and I consent to the access and use of their 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 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 …… (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 the access and use of my data 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 participation of the minor 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 signatory is the sole legal guardian.

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

(Handwritten signature and date)

I would like to be informed of any findings 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)

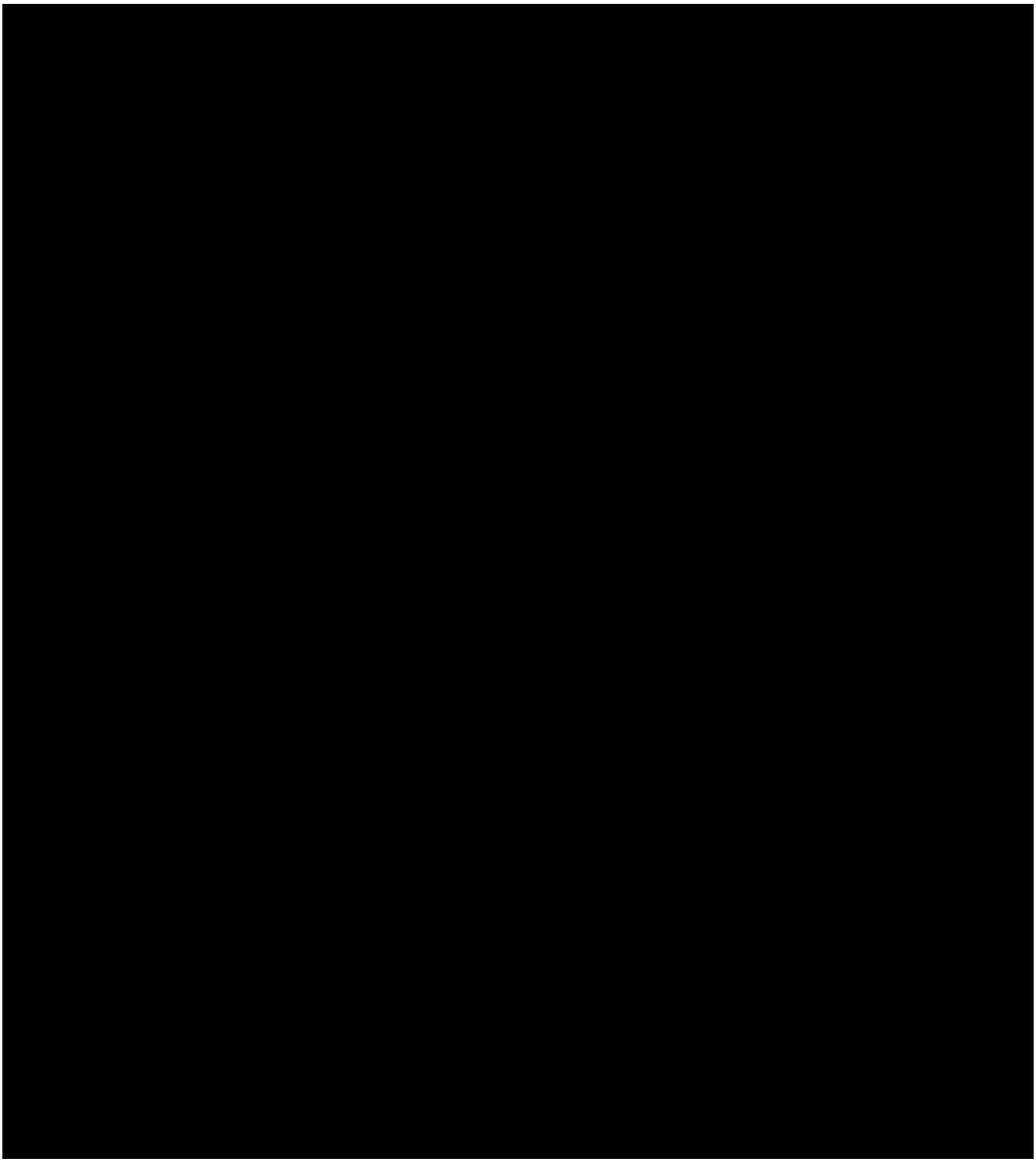
□ The signatory is the sole legal guardian.

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

(Handwritten signature and date)

Minor of age 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*



Minor of age participant INFORMED ASSENT

I, ...

(participant's full name)

aged …… years.

- ✓ 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	YES □ NO □

Do the parents/guardians sign the informed consent form?	YES □ NO □