PARENT

Clinical Study Code and Title ReGI/21/Rcr-Dpe/001 - YOUNG study "Multicenter, double-blind, randomized, vehicle-controlled clinical trial to evaluate the efficacy and safety of RelizemaTM cream, in the management of atopic dermatitis in pediatric patients." ICF Version *1.0 - 04 October 2021* Site Number/Subject Code

Dear Parent/Guardian,
in light of the atopic dermatitis from which the child suffers, we invite the child to participate in this clinical investigation (or clinical study), regarding the medical device RelizemaTM cream for the symptomatic treatment of atopic dermatitis.
National regulations and international law require clinical investigations to be carried out on medical devices even when already authorized but used according to an indication for use other than the authorized one, because the data collected during clinical investigations are necessary to gather and expand knowledge about the effectiveness and tolerability of the device.
The clinical investigation outlined in this paper has been reviewed and approved by the independent Ethics Committee, which will ascertain that the research, conducted on human beings, is appropriate and that the rights and welfare of the subjects are guaranteed.
The child's participation in this clinical study is completely voluntary.
The following section provides detailed information about the clinical investigation. It explains the purposes, procedures, benefits, risks, restrictions, and inconveniences related to the investigation. It also describes alternative treatments and procedures that may be available as well as the right to withdraw from the investigation at any time.
Please read this policy carefully. The Physician Responsible for the Practice or his/her delegate is available to answer your questions and provide further explanation.
Written consent from both parents or guardian is required before participating in this clinical investigation. Please sign the Consent Statement only after you understand the clinical investigation and the activities involved, the rights and duties of the child as a participant, and only if you consent to the child's participation in this clinical investigation.

1. Title of the clinical investigation

"Multicenter, double-blind, randomized, vehicle-controlled clinical trial to evaluate the efficacy and safety of RelizemaTM cream, in the management of atopic dermatitis in pediatric patients."
The survey is also referred to by an abbreviated designation "YOUNG."

2. Why is this investigation being carried out?

RelizemaTM cream is a licensed and marketed medical device manufactured by Relife Srl.
The Clinical Study, which was proposed to her for the minor, aims to specify the indication for use of RelizemaTM cream on a pediatric population.

Atopic dermatitis is a long-term (chronic) inflammatory skin disease. It causes redness and itching of the skin. It is a very common condition in infants, children and adolescents.
Symptoms may come and go, or always remain present. Any area of the body can be affected by atopic dermatitis: in infants, symptoms usually affect the face, neck, scalp, elbows, and knees; in children and adolescents, however, the inside of the elbows, back of the knees, sides of the neck, contour of the mouth, wrists, ankles, and hands.
The disease often causes sleep problems due to itchy skin, and this can have a negative impact on the quality of life of patients and families.
To date, there is no curative therapy for atopic dermatitis but only products that allow control and relief of symptoms and prevention of infections that are most likely to occur with altered and sensitive skin.
Topical treatments (to be applied directly to the areas affected by atopic dermatitis) include products to be applied to the skin containing corticosteroids or immunosuppressants, drugs that act to reduce the underlying inflammation and hypersensitivity of the epidermis. They are effective but are also associated with a high incidence of transient skin reactions, making them not well accepted by the patient and generally not recommended for young children.
Instead, the application of topical moisturizing products not containing steroids or immunosuppressants, with an emollient and protective function on the skin, is useful and usually free of side effects. In addition to improving the symptomatology of atopic dermatitis, the use of such products can also reduce the need for pharmacological intervention to treat the flare-ups of the disease.
RelizemaTM cream is a topical dermatological cream indicated for the treatment of itching and redness associated with dermatitis, including atopic dermatitis.
The product creates a real physical barrier that separates the skin from the surrounding environment, and this is helpful in generating favorable conditions for maintaining and/or recovering the integrity of the physiological skin layer in cases of dermatitis. It improves dry skin by keeping it moisturized.
As part of this clinical investigation RelizemaTM cream will be compared with what is called a "vehicle," that is, the same product but stripped of some components, to better understand its effectiveness in treating the symptoms of atopic dermatitis.
This clinical investigation is carried out for research purposes. The investigation is carried out in compliance with national and international regulations and in accordance with the principles of the *World Medical Association* outlined in the Declaration of Helsinki.

3. What do I need to know about the device under investigation?

As mentioned above, RelizemaTM cream is an already licensed and already marketed medical device. It is a dermatological cream indicated for the treatment of itching and redness associated with dermatitis, including atopic dermatitis. Applied twice daily, it helps keep the skin protected and moisturized.

4. What are the alternatives/the medical device comparator?

There are several emollient and protective skin products on the market as well as medicated creams with steroids or immunosuppressants. The doctor in charge of the practice will be able to describe to you the benefits and potential risks of other treatments for atopic dermatitis.

The comparator that will be used in this study is a cream, which is called a "vehicle" (or placebo), equivalent to RelizemaTM cream but deprived of some functional components. The "vehicle" will still have a moisturizing effect on the skin, although not as complete as RelizemaTM cream.

5. What are the rules for participation in the clinical investigation?

Sixty children and young people aged 6 months to 16 years will be enrolled in this clinical investigation who have mild-to-moderate atopic dermatitis.

If you agree to have the minor participate in this investigation, you must sign the Consent Statement at the bottom of this form and comply with the provisions of Section 7 below. Otherwise, you may decide not to have the minor participate in this investigation, without having to provide any explanation and without any consequences for his or her further medical care.

After the Consent Statement is signed, the child's eligibility to participate in this clinical investigation will be ascertained by the physician in charge of the Study during the initial visit. When she has made all the assessments, the physician in charge of the Study will inform her of the final decision regarding the child's participation in the investigation before receiving the device under examination.

Although there is no scientific evidence that the use of the Study product can cause embryo damage (fetal harm), fertile women will only be allowed to participate in this clinical investigation if they are not breastfeeding and if pregnancy is ruled out before and throughout the duration of the clinical investigation. Therefore, the Study doctor will ask/ask you/the minor if an ongoing pregnancy can be reasonably ruled out.

6. How is this clinical investigation carried out?

This clinical investigation will take place in Italy, at three hospital centers of excellence in the management of atopic dermatitis. As mentioned above, a total of 60 children and young people, aged between 6 months and 16 years old, of both sexes and suffering from mild-to-moderate severity atopic dermatitis, will be involved.

Participation in the clinical investigation will last about 42 days for each patient.

Patients participating in this clinical investigation will receive either RelizemaTM cream or the product defined as "vehicle." The assignment of the type of treatment to each patient participating in this clinical investigation will be completely random, so the minor will have an equal chance of receiving either treatment in the study. No one, neither the patient nor the physician in charge of the study, will know which treatment is assigned to each patient and used by them, except in cases of necessity related to serious health reasons. This modality, called double-blind, will allow both the minor and the physician in charge of the study, to evaluate as objectively as possible, the efficacy and safety of RelizemaTM cream.

The assigned study product, should be applied to the body areas affected by atopic dermatitis twice a day (morning and evening) for the duration of the study, starting the morning after the first visit. The product should never be applied on days when follow-up visits are made to the clinical center.

During the 42 days of the study, the child will be required to visit the clinical center for 3 follow-up visits, in addition to the initial visit. The timing of the visits and the procedures that will be performed at each visit are outlined in the table below.

Description of Procedures	Basal Screening	Treatment	Termination of the Study
Procedures	**Visit 1** **Day 0**	**Visit 2** **Day 14 (±2)**	**Visit 3** **Day 28 (±2)**	**Visit 4** **Day 42 (±2)**
Informed Consent		The physician in charge of the Study will explain the investigation to you and the minor in detail. At the end of the information procedure, she will be asked to sign and date the Consent Statement and the minor to sign the Consent Statement.	□	
Collection of Data and Demographic Information		You will be asked to provide the child's demographic data (e.g., his/her date of birth)	□	
Medical History Assessment		You will be asked to report previous and current illnesses and/or surgeries and/or any recent medical interventions related to the child	□	
Control of Suitability for Investigation		The physician in charge of the Study will ascertain the suitability of the minor to participate in the Clinical Study	□	
Physical Examination	The doctor in charge of the study will assess the general health of the child by performing a physical examination geared toward assessing the health of the skin.	□	□	□	□
IGA and EASI	The physician in charge of the Study will assess the severity of the child's atopic dermatitis and the severity and extent of the	□	□	□	□

	(redness state) of the areas affected by atopic dermatitis				
NRS scale and quality of life questionnaire	You will be asked/will be asked to define the severity of itchy skin in areas with atopic dermatitis and to assess your own quality of life relative to the atopic dermatitis from which you suffer. For children under 4 years of age, the quality of life assessment will not be done.	□	□	□	□
Concomitant treatments	The doctor in charge of the practice will ask her if the child is taking/using other therapies or other products either for atopic dermatitis or for other diseases or conditions	□	□	□	□
Receipt of the device under investigation	The physician in charge of the Study will provide the minor (or her) with the Study product assigned to him/her and the specific cleaner, with instructions for use	□	□	□	
Return of the Device Subject of the Study	You will be asked to return all devices covered by the Study that remain unused as well as all empty packages	□	□	□	
Receipt of daily diary	The doctor in charge of the study will provide the child (or her) with a diary to fill out each day at the end of the day, indicating applications of the product in the study	□	□	□	
Daily diary return	You will be asked to return the completed diary, which will be verified by the physician in charge of the practice	□	□	□	
Satisfaction questionnaire	Both the doctor in charge of the study and the child (or her) will express their degree of satisfaction regarding the effectiveness of the treatment received.	□			
Assessment of Adverse Events and Contextual Therapy	You will be asked to report to the physician in charge of the study any adverse events suffered by the participant as well as any changes to his or her contextual therapy	□	□	□	□

7. What are you required to do during the clinical investigation?

Notify the primary care physician or pediatrician of the minor's participation in this clinical investigation. The minor's primary care physician/pediatrician should not change his/her treatment of the Study unless an emergency situation exists.

In order to obtain meaningful data of high quality from the present clinical trial and to be able to draw the right conclusions, it is necessary to limit or exclude certain confounding factors, and for this reason the minor is required to comply with the following provisions throughout the duration of the investigation study.

You will therefore need to avoid using:

- any other product for atopic dermatitis
- oral antihistamines and antidepressants
- corticosteroids (any route of administration)
- antibiotics
- immunosuppressive drugs and immunotherapies
- Any systemic treatment or any procedure that might affect atopic dermatitis
- Exposure to sun or tanning lamps or UV sources.

Should there be a need to use any of the above treatments, please inform the doctor in charge of the Practice first.

.

The minor will also be given a daily cleansing product, Dermorelizema liporestitutive, which is particularly gentle on sensitive skin. We recommend using only this product for daily cleansing of body, during the study.

In addition, during the course of the clinical investigation the child must visit the investigation center for all 3 visits following the first one, on the agreed days and times. If the minor cannot make it to the scheduled appointment for a visit, please contact the doctor in charge of the Practice immediately.

He or she should inform the physician in charge of the Study about the treatment the minor is undergoing at the screening and 30 days prior to the start of the investigation, as well as about related changes during the minor's participation in the Study.

If an illness occurs or a prescribed medical treatment is required for the minor, the study doctor will decide whether or not the minor can continue to participate in the study. Should participation in this study be terminated, the study doctor will indicate the most appropriate treatment for the minor's condition.

The minor should not participate in any other clinical investigations for the entire duration of the Study.

8. Any risks arising from participation in the study

RelizemaTM cream medical device and "vehicle" are safe and well-tolerated products. RelizemaTM cream is a product already authorized and on the market in several countries.
Participation in this clinical investigation does not involve instrumental examinations or procedures that may in any way cause pain, generate fear, or endanger the health of the child.

9. Benefits of participating in the study

We hope that the minor will benefit from the study's proposed treatment. However, the study involves treatment with RelizemaTM cream or the "vehicle" product, which, although it has a moisturizing effect, lacks some components that are effective on atopic dermatitis. The minor may not derive the desired benefit from participating in this clinical investigation.
By participating in the present clinical investigation, the minor will contribute to the development of RelizemaTM cream through the possible integration of current data for the treatment of atopic dermatitis. We hope that in light of the information gained from the present Study, patients with atopic dermatitis may have better treatment options in the future than they currently have.

10. Will I be informed of new knowledge about the device under study during the clinical investigation?

The physician in charge of the Study will report to you any new knowledge about the device being investigated that may be important to you as it becomes available. You may reconsider whether the minor can continue to participate in this clinical trial in light of this new information. In some cases, you may be asked to provide consent again after being informed about the new knowledge available. Should you decide to withdraw the minor from the study during the clinical investigation, the physician in charge of the Study will make arrangements for the minor's continued treatment.
There is also the possibility that, based on new information about the Study, the Physician decides that the minor should no longer participate in the investigation. In that case, the Physician will explain how to continue treatment for the minor's atopic dermatitis.

11. Is insurance provided for the clinical investigation?

Although it is not anticipated that the child's participation in the investigation may adversely affect his or her health, the child is covered by insurance, as required by applicable regulations, against any unforeseeable risks that are proven to be caused by his or her participation in the clinical investigation itself.
The Promoter has taken out an insurance policy in order to cover any damage related to the Study: insurance company Chubb European Group SE policy number ITLSCQ58482
The maximum coverage under the insurance certificate is € 7,500,000.00 per claim, with a sublimit per subject of € 1,000,000.00. The insurance policy covers damage that occurred within 120 months after the end of the trial and for which a

claim within 132 months after the end of the trial. The claim must be submitted within 132 (indicate the period stipulated in the policy).
In the unlikely event that the child suffers harm as a result of his or her participation in this clinical investigation, please contact the physician in charge of the Practice.
Insurance coverage is guaranteed only if the minor has followed the instructions of the doctor in charge of the Study and complied with the conditions stipulated in the participation notice.
The agreement to provide medical treatment free of charge does not cover expenses incurred for the treatment of damages or illnesses that occurred during the course of the trial but are not a direct result of the trial itself. Relife Srl, the Promoter of this clinical investigation, will not compensate for damages caused by procedures performed in a manner inconsistent with the Clinical Investigation Plan.

12. Can I withdraw the child/may the child be excluded from the clinical investigation?

You may revoke the minor's participation at any time, without having to provide any justification, without any inconvenience to the minor, and without any loss of the minor's right to receive medical treatment appropriate to his or her condition.
In certain cases, it is possible that the physician in charge of the Study or the Promoter may decide to terminate the child's participation in the clinical investigation prematurely, without seeking the child's consent. This may occur, for example, for the following reasons:

- - the child no longer meets the criteria necessary to participate in the investigation;

- - the physician in charge of the Study believes that further participation of the child in this investigation is not in the child's best interest;

- - the Study Promoter decides to terminate the clinical investigation as a whole or the participation of the child in particular.

If you decide to withdraw the child from the survey or the child's participation in the survey is ended before the end, it is important for the child's safety that the child undergoes a final follow-up visit according to the procedure outlined for Visit 4; after this visit, no further data will be collected.
In any case, the data collected until you decide to withdraw the child from the clinical investigation, including the final follow-up visit, will be retained and used for the purpose of the investigation.

13. Will I receive compensation for the child's participation in this clinical investigation?

There is no monetary compensation for the minor's participation in this Study. On the other hand, you will incur no additional costs because of the child's participation in this clinical investigation
The center visits and procedures followed specifically for this investigation, as well as the device that is the subject of the Study, will be provided to you at no cost to you.

14. How is the child's data processed?

Your son/daughter's participation in the survey will involve the processing of the child's personal data; if your son/daughter agrees to participate in the study, the child's personal data will be processed in accordance with applicable data protection laws and regulations, including Regulation (EU) 2016/679, as well as local laws and regulations, applicable to data protection (Legislative Decree 101/2018 as amended and supplemented) and the following conditions.

The child's data will be used to fulfill the investigation and/or for supervisory purposes.

The processing of the child's personal data is necessary to carry out the investigation; if you deny your consent (which is the legal basis for the processing of personal data), the child will not be able to participate in the clinical investigation.

The legal basis for processing is the consent of the person exercising parental authority.

Processing for medical device surveillance purposes is necessary to comply with legal obligations to which the Promoter is subject (legal basis).

In addition, with her optional and further consent, the Promoter and/or the Center may use the child's data collected during the survey for further medical and scientific research purposes in the same field as the present Study. This may include, for example: retrospective clinical studies; clinical studies relevant to the child's pathology/clinical conditions or similar conditions; studies comparing data from the present investigation with data from other sources to identify factors involved in a disease.

As part of the present research activities, the child's data will be processed, pseudonymized and transferred abroad as specified below, and may be shared with future research partners.

In any case, you should be aware that it is not possible to completely rule out the possibility of identifying the child's identity by combining other available data, although neither the Promoter nor its suppliers/business partners will attempt to re-identify the child's identity.

All documents and files subject to the investigation involving the child and containing the child's data will not bear the child's name but will be identified by a numeric identification code for the Study (e.g., 02-001) issued by the physician in charge of the Study. Only the physician in charge of the Study, the clinical staff involved in the Study, and individuals/legal persons authorized by law will be able to match the survey code with the identity of the minor and the results of the survey. The process of replacing the child's real name with the numeric survey identification code is referred to as "pseudonymization."

The child's personal data includes (a) the child's personal data (first name, last name, etc.); (b) the child's contact information; (c) the child's health data, such as clinical data pertaining to the child's health status; and (d) other sensitive data, such as the child's medical records, lifestyle, ethnic origin.

The minor's data will be processed electronically and/or manually by the Center and Promoter Relife Srl ("Data Controller") and other authorized individuals and legal entities, such as the company Latis Srl and the doctor in charge of the Practice ("Data Processors").

Only coded data will be sent to:
- Relife Srl ("Promoter"),
- other companies in the Promoter's group other companies in the Promoter's group, grantors-licensees of the Promoter (or any grantors/licensees/business partners),
- third parties acting on behalf of the Promoter, including the company Latis Srl of Genoa experts/suppliers who assist the Promoter's analyses and maintain the Firm's data,
- Health Control Authority (e.g., the Ministry of Health which is the local competent authority), if applicable, the child's pediatrician or family doctor, the Insurance Company.

The latter entities and the Promoter may check the Study documentation to verify that the results of the Study have been adequately recorded, as well as for purposes of scientific research, supervision, security, and insurance: to this end, it may be essential to match the minor's personal code with his or her data and identity. In addition, the minor's data may be disclosed in aggregated or pseudonymized form in scientific publications.
Please keep in mind that data from the child may be transferred to countries that do not offer personal data protection standards equivalent to those that exist in the European Union, due to the lack of adequate legislation at the local level.
When this happens, the Promoter will ensure that the transferred data has an adequate level of protection, in line with European Union legislation, by selecting recipients in third countries that commit to comply with European Union data protection standards in one of the following ways: (i) the receiving party and the Promoter have entered into European Commission-approved standard contractual clauses designed to protect its data, drafted in compliance with European legislation; or (ii) measures required by such legislation have been taken for a lawful transfer of personal data to third countries. However, please keep in mind that if the Promoter registers and markets RelizemaTM cream in countries outside the European Union, the minor's data may have to be submitted to the authorities in charge of monitoring the safety and reliability of medicines in those countries. In such cases, it may not be possible to ensure that the child's data is processed in line with European Union law, so you may not be able, for example, to exercise your right to access or modify the child's data processed by those non-European authorities-the data transferred will, however, be "encrypted." By signing this form, you consent to the transfer of the child's data to non-EU countries as described above. The updated list of foreign countries is available upon request.
The permanent trial file and the data in it will be kept under the care of the Trial Site for at least 10 years after the completion of the Study, according to the regulations applicable to the clinical investigation.
The Sponsor may retain personal data collected in the course of this study for longer periods of time if this is necessary for:
(i) comply with legal obligations (e.g., adverse event reporting requirements, whereby its coded data must be retained for 10 years after the termination of the study product's marketing authorization in all countries); (ii) conduct scientific research; (iii) obtain a new marketing authorization for the study product, including outside the European Union; and (iv) institute court actions and defend against legal claims.
You have the right to contact the Center to exercise the rights attributed by law to you/the child in relation to the child's data, including those provided for in Art. 15-22 of Regulation (EU) 2016/679," namely: to know whether data relating to the child are processed by the Data Controller; to access the child's data; to verify the content, origin, accuracy, location (including, if applicable, the Third Countries where the data may be located); to obtain a copy of the data, including its transmission to another person indicated by you; to request that the data be supplemented, updated or modified; in cases provided by law, to request that the data processing be restricted, that the Data be anonymized or blocked; to object to the processing of the child's data for legitimate reasons. You have the right to file a complaint with the Data Protection Authority and/or notify the DPO of any use of the child's personal data that you consider inappropriate.
You are free to withdraw the child at any time from this survey. In that case, you may ask us to destroy/delete the child's personal data so as to prevent any further processing or analysis of his/her data. However, data and test results that may be used to establish the results of the Study will not be deleted, so as not to change or completely invalidate the results of the survey.
For the same reason, we will note requests for correction/supplementation/update of the child's data alongside the data originally collected, to ensure that we keep track of all changes, in line with data quality standards applicable to scientific research and to avoid altering the results.
Contact references are given below in this document.
Promoter: Relife S.r.l., Via dei Sette Santi 3 - Florence
Centro clinico: _____
You may contact the Promoter's DPO by writing to dpo@menarini.com.

15. Who can I turn to if I have further questions?

If you need further information or have medical questions related to the investigation, you may contact the Clinical Practice office at any time.
The doctor in charge of the study will be happy to answer any questions you may have, including about the rights and obligations of the child as a patient and participant in this survey study.

Name of the physician in charge of the study: _____
Phone number(s): _____
Email: _____
Thank you very much for your consideration of this survey study.
Please take your time to discuss the information regarding the minor's participation with his or her family and friends, if you wish. If you agree to the minor's participation in this Study, you will be asked to sign the parent/guardian consent statement form below. A copy signed by you and the doctor in charge of the Study will be given to you for your reference.

Consent Statement
"Multicenter, double-blind, randomized, vehicle-controlled clinical trial to evaluate the efficacy and safety of RelizemaTM cream, in the management of atopic dermatitis in pediatric patients."
I/we consent/agree that the child will participate in this clinical investigation of my/our own free will and to follow the instructions given and the limitations resulting from the child's participation in this clinical investigation.
I/We declare that I/We are willing to inform the physician in charge of the Study or his/her designee of any kind of adverse event that may occur. The child will not participate in any other clinical investigation while enrolled in this clinical investigation.
I/We have received, read and understood the Subject Disclosure Statement in relation to the clinical investigation ReGI/21/Rcr-Dpe/001 (YOUNG) version 1.0 dated 04 October 2021. The type, scope, and risks of this clinical investigation have been explained in a manner that I consider entirely adequate. I/we had the opportunity to ask questions, which were answered satisfactorily.
I/we understand that I/we may withdraw my/our consent at any time, without having to provide any justification, and that I/we may terminate the child's participation in this clinical investigation without any detrimental effect. It is sufficient that I/we inform the physician in charge of the Study or the site at which the investigation is conducted of this decision.
I/we have been told that the trial in which I/we want/desire the child to participate is covered by an insurance policy, the terms and conditions of which have been communicated to me/us.
I do not depend/we do not depend in any way on the physician in charge of the Study or the Clinical Investigation Promoter.
To be completed by both parents or guardian of the minor.

_____
Subject's full name
(in capital letters)
Parent Guardian

_____ _____ _____
First parent's full name Parent's signature o Date
or the guardian of the guardian
(in capital letters) (first and last name)

_____ _____ _____
First and last name of the second Parent's signature o Date
parent or guardian of the guardian
(in capital letters) (first and last name)

By signing this form, you consent to the processing of the child's personal data as stated above; you also consent to the transfer abroad of the child's personal data. **I/we consent/agree to the processing of the minor's personal data,** including data relating to his/her health, as well as the transfer of such data outside the European Union,] for the purposes of the Study, in accordance with the conditions and methods specified in the notice provided herein.
I am aware/we understand that my/our consent is essential for the conduct of the trial; **if I/we do not consent/we agree to disclose such data, the child will not be able to participate in the clinical investigation.**
Signature of first parent or guardian_____
Signature of second parent or guardian_____
I personally explained the purpose, duration, and foreseeable risks of this clinical investigation to the above participant and his parents/guardian and answered all their questions fully.
I guarantee that the said participant is in no way dependent on me.
To be completed by the physician in charge of the Practice who informed the parents/guardian and collected the relevant Consent

_____ _____ _____
Name of the investigating physician Signature of the physician in charge of the study Date
(in capital letters) (first and last name)

CHILDREN 6-11 YEARS OLD

Clinical Investigation Code and Title ReGI/21/Rcr-Dpe/001 - YOUNG study "Multicenter, double-blind, randomized, vehicle-controlled clinical trial to evaluate the efficacy and safety of RelizemaTM cream, in the management of atopic dermatitis in pediatric patients." ICF Version *1.0 - October 04, 2021* Site Number/Subject Code

Dear .....,
doctors have asked your parents for permission for you to participate in a clinical study. With this document we would like to briefly explain to you what a clinical study is and specifically what the one proposed to your parents consists of. They will decide, but it is appropriate for you to be informed. We have provided your parents with a document similar to this one, only much more complex.
We have thought about the questions you would probably ask, and we have given answers that we hope will clear up your doubts. Of course, you can ask the doctor who is going to talk to you about it any other questions you can think of, so that you are clear on the subject.
If, after reviewing the document given to them and getting all the clarification from the doctor, your parents decide that it is good for you to take part in the study, they will be asked to sign a document called an "informed consent statement."
What is the purpose of this clinical study?
We would like to consider whether it might be useful to include, in treatments for skin disorders such as yours, the product called Relizema Cream. The information available to date indicates that this product works safely, and we would like to make sure that it works and is safe in children as well. However, more studies are needed to better confirm its effectiveness.

From the study we expect that:
the investigational product increases your chances of alleviating the symptoms of your disease, especially itchy skin, without side effects, which many other products have.
What will happen to me during the study?
Participation in the study is not too different from the care you are already receiving.
First they will give you an examination to make sure that you can really take part in the study. In particular, your skin will be checked to see if it has the symptoms of dermatitis (for example, if it is red or dry or if there are bubbles)
There will be no examinations or other activities that may cause pain or fear, only the doctor's visit. Thereafter you will have to repeat the same visit 3 more times.
If so, you will be prescribed a cream that will be given to your parents should be put on the skin and massaged twice a day, in the morning and evening, for more than 1 month.
At regular intervals (every 2 weeks) you will undergo examinations and checkups during which the doctor will ask you to give him or her directions on how you are feeling.
How long will the study last?
The study we propose will last just over 1 month, during which you will be kept in constant contact with the center where the clinical study is being developed.

Will I have any benefit from participating in the study?

Doctors speculate that this experimental treatment will be more helpful against your disease than the treatments known so far, but at the moment there is no evidence of this yet. But we do know that the information gathered in this study will help doctors learn more about this new treatment, and this information could help children in the future with the same disease as you.

I take risks in participating in the study

All medical practices carry risks, even those you are already doing.

Participation in this study does not involve examinations or other painful or risk-taking activities. The product that will be applied to your skin is safe, however, and we do not expect you to take any risks in using it.

You will always be under control, however, as you already are now. For your part, immediately report to your parents any discomfort you should experience, such as skin burning, headache, stomach ache, nausea, and the doctors will help you get better.

How do we use your data?

To complete the study, we will collect and use some information about you, called "personal information," which we will keep safe.

In order to use your information we need to know that you and your parents are happy for us to collect and use it, otherwise you will not be able to participate in the study.

You and your parents can always change your mind and decide that you no longer want us to use your data, in which case you will have to leave the study and we will not collect any new information about you, but we will have to keep the information we have collected up to that point.

We use only the information necessary for the study, such as your first name, last name, and other health information.

Your information will be processed only by the people in charge of the study and will be disclosed only to those who really need to know it.

We will keep your data only as long as it is necessary for the study.

You and your parents have many rights over your information, for example, you can always ask us to tell you what data we have about you, where we keep it, and whether the information is accurate.

Can you elaborate on that?

You can ask the doctor any questions you find interesting, and he will do his best to give you clear and simple answers.

Hopefully, what you have read and heard has been enough to give you a fairly clear idea of what a clinical trial is. All that's left at this point is to talk to your parents about it.

MINORS 11-17 YEARS OLD

Dear Patient,
given your current atopic dermatitis, we invite you to participate in this clinical investigation (or clinical study), regarding the medical device RelizemaTM cream for the treatment of symptoms of atopic dermatitis.
Your participation in this clinical study is completely voluntary.
The following section includes detailed information on clinical investigation. It explains the purposes, procedures, benefits, risks, restrictions, and inconveniences related to the investigation. It also describes the alternative treatments and procedures that are available to you and your right to withdraw from the investigation at any time.
Please read this information carefully. The Physician Responsible for the Practice or his/her delegate is available to answer your questions and provide further explanation.
Your consent in writing is required before participating in this clinical investigation. We encourage you to sign the Declaration of Assent only after you understand the clinical investigation and the activities that will be carried out as part of it as well as your rights and obligations as a participant-and, in any case, only if you agree to participate in this clinical investigation.

1. Title of the clinical investigation

"Multicenter, double-blind, randomized, vehicle-controlled clinical trial to evaluate the efficacy and safety of RelizemaTM cream, in the management of atopic dermatitis in pediatric patients."
The survey is also referred to by an abbreviated designation "YOUNG."

2. Why is this survey conducted?

RelizemaTM cream is an already licensed and marketed medical device manufactured by Relife Srl.
The Clinical Study, which has been proposed to you, aims to specify the indication for use of RelizemaTM cream on a pediatric population
Atopic dermatitis is a long-term (chronic) inflammatory skin disease. It causes redness and itching of the skin. It is a very common condition in infants, children and teens.
Symptoms may come and go, or remain ever-present. Any area of the body can be affected by atopic dermatitis: in adolescents it generally affects the inside of the elbows, back of the knees, sides of the neck, contour of the mouth, wrists, ankles, and hands.
The disease often causes sleep problems, due to itchy skin, and this can impact the quality of life of patients, who like her, and families.
To date, there is no curative therapy for atopic dermatitis but only products that allow control and relief of symptoms and prevention of infections that are most likely to occur with altered and sensitive skin.

Topical treatments (i.e., to be applied directly to the areas affected by atopic dermatitis) include products to be applied to the skin containing corticosteroids or immunosuppressants, i.e., drugs that work in reducing the underlying inflammation and hypersensitivity of the epidermis. They are effective but are also frequently associated with transient skin reactions that make them not well accepted by the patient.
Instead, the application of topical moisturizing products that do not contain corticosteroid or immunosuppressive drugs, with an emollient and protective function for the skin, is useful and usually free of side effects. The use of such products, in addition to improving the symptomatology of atopic dermatitis, can also reduce the need for drug intervention to treat the flare-ups of the disease, that is, those times or periods when symptoms worsen.
RelizemaTM cream is a topical dermatological cream indicated for the treatment of itching and redness associated with dermatitis, including atopic dermatitis.
The product creates a real physical barrier that separates the skin from its environment, and this is helpful in generating favorable conditions for the maintenance and/or recovery of the physiological (normal) skin layer in cases of dermatitis. It improves dry skin by keeping it moisturized.
As part of this clinical investigation RelizemaTM cream will be compared with what is called a "vehicle," that is, the same product but stripped of some active component, to better understand its effectiveness in treating the symptoms of atopic dermatitis.
This clinical investigation is done for research purposes to improve knowledge about your disease and about a product that may help you reduce your symptoms of the disease.

3. What do I need to know about the device under investigation?

As mentioned above, RelizemaTM cream is an already authorized medical device. It is a dermatological cream indicated for the treatment of itching and redness associated with dermatitis, including atopic dermatitis. Applied twice daily, it helps keep the skin protected and moisturized.

4. What are the rules for participation in the clinical investigation?

Sixty children and young people between the ages of 6 months and 16 years will be enrolled in this clinical investigation who have mild-to-moderate atopic dermatitis.
If she intends to participate in this survey, she must sign the Declaration of Consent at the bottom of this form, and her parents or guardian must in turn issue a Declaration of Consent. Otherwise, he/she may decide not to participate in this survey, without having to provide any explanation and without any consequences for the continuation of his/her treatment.
After she and her parents/guardian sign the Declaration of Assent and Consent Statement, respectively, her eligibility to participate in this clinical investigation will be ascertained by the physician in charge of the Study during the screening visit, following the medical and laboratory examinations scheduled for the investigation.

When all the results of these examinations are available, the physician in charge of the Study will notify you of the final decision regarding your further participation in the investigation, before you receive the device under investigation.
Although there is no scientific evidence that the use of the Study product may cause harm to the fetus, fertile women will be allowed to participate in this clinical investigation only if they are not breastfeeding and if pregnancy is ruled out before and throughout the clinical investigation. Therefore, you will be asked by the Study doctor whether you are pregnant or not during the screening visit.

5. How is this clinical investigation conducted?

This clinical investigation will take place in Italy, at three hospital centers of excellence in the management of atopic dermatitis. A total of 60 children and young people, aged between 6 months and 16 years, of both sexes and with mild-to-moderate atopic dermatitis severity, will be involved. Participation in the clinical investigation will last about 42 days for each patient.
Patients participating in this clinical investigation will either receive RelizemaTM cream or the product called "vehicle," which is a cream equivalent to RelizemaTM cream but deprived of some functional components. The "vehicle" will still have a moisturizing effect on the skin, although not as complete as RelizemaTM cream. The assignment of the type of treatment to each patient participating in this clinical investigation will be completely random, so she will have an equal chance of receiving one or the other treatment in the study. Neither you nor the physician in charge of the study will know which treatment you have been assigned, except in cases of necessity related to serious health reasons. This modality, called double-blind, will allow both you and the physician in charge of the Study, to evaluate in the most objective manner possible, the efficacy and safety of RelizemaTM cream.
The assigned study product, should be applied to the body areas affected by atopic dermatitis twice a day (morning and evening) for the duration of the study, starting the morning after the first visit. The product should never be applied on days when follow-up visits are made to the clinical center.

During the 42 days of the study you will need to visit the clinical center for 3 follow-up visits, in addition to the initial visit. The timing of the visits and the procedures that will be performed at each visit are outlined in the table below. In each of the activities shown in the table, you may be helped by your parents or guardian if you need them.

Description of Procedures	Beginning of the Study	Treatment	Termination of the Study

Procedures	Visit 1 Day 0	Visit 2 Day 14 (±2)	Visit 3 Day 28 (±2)	Visit 4 Day 42 (±2)
Informed Consent	The doctor in charge of the practice will explain the clinical investigation to you and your parents/guardians in detail.		□	
	At the end of the information process, you will be asked to sign and date the Declaration of Consent and your parent/guardian to sign the Declaration of Consent.			
Collection of Data and Demographic Information	You will be asked to provide your demographic information (e.g., your date of birth)		□	
Medical History Assessment	You will be asked to report your previous and current illnesses and/or surgeries and/or any recent medical interventions		□	
Control of Suitability for Investigation	The physician in charge of the Study will ascertain your eligibility to participate in the Clinical Study		□	
Physical Examination	The doctor in charge of the practice will assess your general health by performing a physical examination geared toward evaluating the health of your skin.	□	□	□	□
IGA and EASI	The physician in charge of the study will assess the severity of his or her atopic dermatitis and the severity and extent of the erythema (redness state) of the areas affected by the atopic dermatitis	□	□	□	□
NRS scale and quality of life questionnaire	It will enable her to define the severity of itchy skin in areas with atopic dermatitis and to assess her quality of life relative to the atopic dermatitis she suffers from	□	□	□	□
Concomitant treatments	The doctor in charge of the practice will ask you if you are taking/using other therapies or other products either for atopic dermatitis or for other diseases or conditions	□	□	□	□
Receipt of the device under investigation	The physician in charge of the Study will provide you with the Study product assigned to you and the specific cleaner,	□	□		□

	along with instructions for use				
Return of the Device Subject of the Study	You will be asked to return all devices covered by the Study that remain unused as well as all empty packages	□		□	□
Receipt of daily diary	The doctor in charge of the study will provide you with a diary to fill out each day at the end of the day indicating the applications of the product in the study	□		□	□
Daily diary return	You will be asked to return the completed diary, which will be verified by the physician in charge of the practice	□		□	□
Satisfaction questionnaire	Both the doctor in charge of the study and you will express your degree of satisfaction regarding the effectiveness of the treatment you received.		□		
Assessment of Adverse Events and Contextual Therapy	You will be asked to report to the physician in charge of the study any adverse events that have occurred since the start of treatment, as well as any changes to your concurrent therapy	□		□	□

6. What am I required to do during the clinical investigation?

You should inform your primary care physician or any other trusted physician of your participation in this clinical investigation. Your primary care physician should not change your treatment for the Study except in an emergency.

In order to obtain meaningful high-quality data from this clinical trial and to be able to draw the right conclusions, it will be necessary to limit or exclude certain confounding factors. Therefore, we ask you to comply with provisions below throughout the duration of the Study.

We ask you to avoid the use of:

- any other product for atopic dermatitis
- oral antihistamine and antidepressant drugs
- Corticosteroids (by any route of administration)
- antibiotics
- immunosuppressive drugs and immunotherapies
- Any systemic treatment (taken by mouth, injection, etc.) or any procedure that

Could influence atopic dermatitis

- Exposure to sun or tanning lamps or UV sources.

Should there be a need to use any of the above treatments, please inform the doctor in charge of the Practice first.

You will also be given a daily cleansing product, Dermorelizema liporestitutive, which is particularly gentle on sensitive skin. We recommend using only this product for daily cleansing during the study.

In addition, during the course of the investigation, he/she will be required to visit the investigation center for all 3 visits, beyond the first one, on the agreed days and times. If you cannot show up for a scheduled appointment for a visit, you must make alternative arrangements with the physician in charge of the Study as soon as possible.

At screening and prior to starting the investigation, he or she should inform the physician in charge of the Study about the therapies he or she is currently taking and has taken in the 30 days prior to the start of the investigation, as well as about any related changes during his or her participation in the Study.

If an illness occurs or a prescribed medical treatment is required, the study doctor will decide whether or not the child can continue to participate in the study. Should participation in this study be terminated, the study doctor will indicate the most appropriate treatment for the minor's condition.

You are not to participate in any other clinical investigations for the duration of the Study.

7. What are the potential risks related to this clinical investigation?

RelizemaTM cream medical device and "vehicle" are safe and well-tolerated products. RelizemaTM cream is a product already authorized and on the market in several countries.

Participation in this clinical investigation does not involve instrumental examinations or procedures that may in any way cause you pain, generate fear, or endanger your health.

8. Will I benefit from participating in this clinical investigation?

We hope that you will benefit from the study's proposed treatment. However, the study involves treatment with RelizemaTM cream or the "vehicle" product, which, although it has a moisturizing effect, lacks some components that are effective on atopic dermatitis. You may therefore not derive the expected benefit from participating in this clinical investigation.

By participating in the present clinical investigation, you will contribute to the development of RelizemaTM cream by the possible integration of current data for the treatment of atopic dermatitis. We hope that in light of the information gained from the present Study, patients with atopic dermatitis may have better treatment options in the future than they currently have.

9. Will I be informed about new knowledge related to the device under study during the clinical investigation?

The physician in charge of the study will report to you any new knowledge related to the present study that may be important to you as it becomes available. You may reconsider whether to continue participating in the present study in light of such new information. In some cases, you may be asked to provide your consent again after being informed about the new knowledge available. Should you decide to withdraw from the study, the physician in charge of the Study will make arrangements for your continued treatment.

There is also the possibility that, based on new information about the Study, the Physician decides that you should no longer participate in the survey. In that case, the Physician will explain the relevant information to you.

10. Is insurance provided for the clinical investigation?

Although it is not anticipated that your participation in the survey will adversely affect your health, you are covered by insurance, as required by applicable regulations, against any unforeseeable risks proven to be caused by your participation.

The Promoter has taken out an insurance policy in order to cover any damage related to the Study (Insurance company: Chubb European Group SE, policy number: ITLSCQ58482) The maximum coverage under the insurance certificate is € 7,500,000.00 per claim, with a sublimit per subject of € 1,000,000.00. € In the unlikely event that you suffer an injury as a result of your participation in this clinical investigation, contact the physician in charge of the Practice.

11. Can I withdraw/be excluded from the clinical investigation?

You may withdraw your participation at any time, without having to provide any justification, without suffering any inconvenience, and without losing your right to receive medical treatment appropriate to your condition.

If you decide to withdraw early from the clinical investigation, your doctor will let you know your future treatment and visit.

In certain cases, it is possible that the physician in charge of the Study or the Promoter, Relife Srl, may decide to terminate your participation in this clinical investigation study prematurely, without seeking your consent. This may occur, for example, for the following reasons:

- - you no longer meet the criteria necessary to participate in the survey;

- - the physician in charge of the Study believes that his further participation in this investigation is not in his best interest;

- - the Investigation Study Promoter decides to terminate the clinical investigation as a whole or its participation in particular.

If you decide to withdraw from the survey or your participation in the survey is ended before the end, it is important for your safety that you undergo a final follow-up visit according to the procedure outlined for Visit 4; after this visit, no further data will be collected.

In any case, the data collected until you decide to withdraw from the survey, including the final follow-up visit, will be retained and used for the purposes of the survey.

12. Will I receive compensation for my participation in this clinical investigation?

There is no monetary compensation for his participation in this Study.

You will not incur any costs for your participation in this clinical investigation, as the visits made to the center, the device under study, and other products used for the study will be provided by the Promoter.

13. How is my data processed?

If you agree to participate in this survey, we (the Center and the Promoter) will collect, use, and share with companies and bodies of the Public Administration certain information about you, defined by law as "personal data"; we absolutely want to protect your privacy and keep your information safe, and therefore we will always handle your data with the utmost care, complying with all laws and regulations regarding the processing of personal data, including Regulation (EU) 2016/679, as well as local laws and regulations, applicable to data protection (D.Legislative Decree 101/2018 as amended and supplemented). We will now briefly explain how we will use your information collected by us during the survey.

The reasons why we need your data are:

- accomplish the investigation (e.g., collect documentation on how the medical device works, based on the results of all the tests we conducted during the investigation);
- Monitor the safety of the medical device;
- support the registration of the medical device (for this purpose, we must provide the authorities with evidence that the device is functioning properly, including information on all investigations we have made in this regard, such as the one in which you are about to participate).

We cannot do the survey without using your personal data, and therefore we cannot allow you to participate if you/your parent(s)/guardian(s) are not happy that we collect and use your personal data. In order to process your personal data, we also need the consent of your parent(s)/guardian(s): without such consent, you will not be able to participate in the study.

You/your parent(s)/guardian(s) may change your mind at any time and decide that you no longer want us to use your data (without the need for you to explain to us the reasons for such a choice); however, in that case (i) you will have to leave the survey and (ii) we will not collect any new information about you, but we will have to keep the data we have collected until you have left the survey -

if we eliminated them we would lose valuable information for the investigation, which we could not gather otherwise.

In addition, if you participate in the survey, even for a short time, we are obligated by law to collect and retain certain information about you, particularly information about the safety of the medical device and information required to support the registration of the device: this means that we will not be able to delete this information, even if you/your parents/guardian ask us to.

If you/your parent(s)/guardian(s) allow it, we would also like to use the information collected during the survey for future investigations and scientific research: for example, to reanalyze the documentation of the Survey and combine the data we collected with data from other surveys to better understand how the device works.

As part of these further research activities, we will use your data as specified below, and share them with other companies, scientists, or study centers with which we collaborate; we will not use your first and last name, but rather a code, which only the Center will be able to link to your name.

In any case, even when we use a code, it could happen that those who read your data could find out who you are by combining your health information with other information they have, although this is really unlikely and in any case they will not actively try to re-identify you.

All documents and files under investigation concerning you and containing your data will not contain an indication of your name, but will be identified by a numeric identification code for the Study (e.g., 02-001) issued by the physician in charge of the Study. Only the physician in charge of the Study, the hospital, the authorities, and a few other persons authorized by law will be able to know your name.

Your personal data include (a) your personal data (first name, last name, etc.); (b) your contact references; (c) your health data, such as clinical data pertaining to your health status; and (d) other sensitive data, such as your medical records, lifestyle, ethnic origin.

Your data will be processed by the Center, the Promoter Relife Srl and other authorized individuals and legal entities, such as the company Latis Srl and the doctor in charge of the Practice ("Data Processors").

Only coded data will be shared with Relife Srl ("Promoter"), other companies in the Promoter's group (details of which are posted at www.menarini.it, section "Menarini in the World") or companies that are in business with the Promoter or are its suppliers, including the company Latis Srl. However, the Health Control Authorities (e.g., the Italian Ministry of Health), if applicable, your primary care physician, the Insurance Company, and the Promoter may check the Study records to verify that the results of the Study have been adequately recorded, as well as for purposes of scientific research, surveillance, security, and insurance: for this purpose, it may be essential to match your personal code with your first and last name. In addition, your data may be disclosed in articles or presentations at conferences by us

published along with the results of the investigation, but still in such a way that his name is not disclosed.
Your data may be sent outside the EU, to countries that do not have privacy laws like the European ones; the updated list of foreign countries is available upon request. In these cases we will make sure that the recipient still complies with European law, although in some cases (i.e., when government agencies of non-European states receive the data) this may not be possible, even though the data sent to them are data without first and last names.
Your data will be kept for at least 10 years after the completion of the Study, according to the regulations applicable to the clinical investigation.
By law, you/your parent(s)/guardian(s) have the right to contact the Center to ask us to let you know whether we have your data; to let you know what data we have, where we collected it, whether all the information we have is correct, where we keep it; you also have the right to have a copy of the data or to ask that we send it to a company/hospital of your choice; you can ask us to supplement that data with missing, updated, changed information. In certain cases, you will be able to ask that the processing be restricted or that the data be anonymized or blocked, or object to the processing-as we said before, these possibilities may be restricted due to the fact that we have to keep personal data for legal reasons and to avoid compromising the results of the investigation.
For the same reasons, should you/your parent(s)/guardian(s) revoke consent, we will keep the data collected until that time, as we said before. If you/your parent(s)/guardian(s) are unhappy with the way we process your data, you may file a complaint with the Data Protection Authority, or notify the Data Protection Officer (the person in charge of ensuring privacy at the Promoter).
Contact references are given below in this document.
Promoter: Relife S.r.l., Via dei Sette Santi 3 - Florence
Centro clinico: _____
You may contact the Promoter's DPO at dpo@menarini.com.

14. Who can I turn to if I have further questions?

If you need further information or have medical questions related to the investigation, you may contact the Clinical Practice office at any time.
The physician in charge of the study will be happy to answer any questions you may have, including about your rights and obligations as a patient and participant in this survey study.

Name of the physician in charge of the study: _____
Phone number(s): _____
Email: _____
Thank you very much for your consideration of this survey study.
Please take the time to discuss the information about your participation with your family and friends, if you wish. If you agree to participate in this Study, you will be asked to complete the Declaration of Consent form below. A copy signed by you and the physician in charge of the Study will be given to you for your reference convenience.

Declaration of Assent

"Multicenter, double-blind, randomized, vehicle-controlled clinical trial to evaluate the efficacy and safety of RelizemaTM cream, in the management of atopic dermatitis in pediatric patients."

The form containing the disclosure was delivered to me on (date) _____ at _____
I understood everything the doctor explained.
The Doctor listened to all my questions and was able to answer them.
Should I need anything else in the future, the doctors in the practice will be at my disposal.
I agree to participate in this clinical investigation of my own volition and to follow the instructions given and the limitations resulting from my participation in this clinical investigation.
I declare that I am willing to inform the physician in charge of the Study or his/her designee of any kind of adverse event that may occur. I will not participate in any other clinical investigation while enrolled in this clinical investigation.
I have received, read and understood the Subject Disclosure Statement in relation to the clinical investigation ReGI/21/Rcr-Dpe/001 (YOUNG) version 1.1 dated October 27, 2021. The type, scope, and risks of this clinical investigation have been explained in a manner that I consider entirely adequate. I had the opportunity to ask questions, which were answered satisfactorily.
I understand that I may withdraw my consent at any time, without having to provide any justification, and that I may terminate my participation in this clinical investigation without any detrimental effect. It is sufficient that I inform the physician in charge of the Study or the site at which the investigation is conducted of this decision.
I have been told that the trial in which I plan to participate is covered by an insurance policy, the terms and conditions of which have been communicated to me.
I am in no way dependent on the physician in charge of the Study or the Clinical Investigation Promoter.

To be completed by Subject

_____ _____ _____ Subject's full name
Subject's signature Date
(in capital letters)

To be completed by a responsible, independent witness, if the patient can only give oral consent, or by a legally authorized representative, if the patient cannot give consent.

Legal representative Witness
Witness' full name Witness' signature or Date
or the Legal Representative of the Legal Representative.
(in capital letters) (first and last name)

By signing this form, you give your **consent** to the processing of your personal data as indicated above; you also give your **consent** to the transfer abroad of your personal data. **I give my consent to the processing of my personal data**, including my health data, as well as to the transfer of such data outside the European Union, for the purposes of the Study, in accordance with the conditions and methods specified in the notice provided herein.
I understand that my consent is essential for the conduct of the trial; **if I do not give my consent to the disclosure of these data, I will not be able to participate in the clinical investigation.**
Firma_____

USE OF YOUR DATA FOR FUTURE RESEARCH

We inform you that, with your further consent (and the consent of your parents/guardian), the Promoter and/or the Center may use your data for further medical and scientific research purposes such as studies for registration of new treatments, studies comparing data from this Study with data from other sources, etc.
As part of these further research activities, your data will be processed, pseudonymized, and may be shared with future research partners and/or transferred abroad.
Your decision whether or not to grant your consent for this purpose and/or to revoke it at any time in the future is optional and will in no way affect your participation in this Study. You may exercise all the rights outlined in this document at any time.
Having read the foregoing, I hereby:
I consent (optional) I do not consent
To the processing of my personal data for further medical and scientific research purposes.
Firma_____

I personally explained the purpose, duration, and foreseeable risks of the present the clinical investigation to the participant named above and answered all his questions in full.
I guarantee that the said participant is in no way dependent on me.

To be completed by the physician in charge of the Study who informed the Subject and collected the Subject's Consent, in addition to the Consent from the parents/guardian

_____ _____ _____
Name of the study physician Signature of the study physician Date
(in capital letters) (first and last name)