

**SUBJECT INFORMATION SHEET AND INFORMED CONSENT TO TAKE PART IN A
CLINICAL RESEARCH STUDY AND AUTHORIZATION TO DISCLOSE HEALTH
INFORMATIONN**

Sponsor / Study Title: Center for Clinical Studies, LTD, LLP / “Picato for the Treatment of Molluscum Contagiosum in Immunocompromised Patients”

Protocol Number: IIS-PICATO-1386

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You are being invited to take part in a research trial.

Before you decide if you want to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends and relatives if you wish. Ask the trial doctor or trial staff if there is anything that is not clear, or if you would like more information. Take time to decide whether or not you wish to take part.

Participating in a trial is not the same as getting regular medical care. The purpose of regular medical care is to improve your health. The purpose of a trial is to gather information.

What is this trial about?

You have been diagnosed with a condition known as molluscum contagiosum. Molluscum contagiosum is a common skin condition in children and adults with weakened immune systems and is caused by a poxvirus. The virus is extremely contagious and is transmitted through direct skin-to-skin contact, contact with an infected surface, or autoinoculation (self-infection) by scratching or picking molluscum lesions and then touching other parts of the skin not previously affected by the virus. Molluscum contagiosum is usually a benign condition, but in rare cases, lesions may grow larger and may even cause scarring. People with molluscum contagiosum in the face and/or trunk (including buttock and genital regions) may be eligible to participate in this trial. This trial is testing a drug product called Picato for the treatment of molluscum contagiosum in people with weakened immune systems.

What is the purpose of the trial?

The purpose of the trial is to test if Picato gel is effective and safe in the treatment of molluscum contagiosum in patients with immunocompromised conditions when applied to a maximum area of 100 cm².

Picato gel will be applied once nightly for three consecutive nights at home.

It is planned that approximately 10 people with molluscum contagiosum on the face and/or trunk will be included in this trial.

What is the drug that is being tested?

Picato is a drug product that has been developed by LEO Pharma A/S and has been approved by the FDA for the treatment of a condition known as actinic keratosis. Picato is being studied in this trial for a different indication, molluscum contagiosum, and has not been approved by the FDA for this indication for use outside of trials like this one.

Picato is a drug that works by causing cell death in the lesion and also causes the immune system to act on the lesional cells.

Why have I been chosen?

You have been chosen because you have molluscum contagiosum on your face and/or trunk, which is suitable for trial treatment with the Picato gel.

Do I have to take part?

It is up to you to decide whether or not to take part. Your decision to participate is voluntary.

If you do decide to take part, you will be asked to sign and date a consent form. You will be given a copy of this signed and dated consent form to keep. If you decide to take part in the trial, you are still free to withdraw at any time and without giving a reason.

If you decide not to take part or withdraw from the trial, this will not affect the standard of care you receive, and there will be no penalty or loss of any benefits you would otherwise receive, except for potential benefits having to do with the trial. If you want to stop your participation in the trial, tell the trial doctor or trial staff and return all trial drug. They will review specific procedures that are required for you to safely exit the trial.

What will happen to me if I take part?

Before you can start the screening part of the trial, the trial doctor or trial staff will talk to you about the trial. If you agree to participate in the trial, you will have to sign and date this form. Your participation will last 24 weeks, and there will be 8, 12 or 16 visits depending on the clearance of molluscum contagiosum.

You will then be screened to see if you can take part in the trial. If you are eligible to participate in the trial and would still like to participate, you will be enrolled in the trial and receive trial medication on Day 0.

During Visit 1, the trial staff will show you how to apply the Picato gel on your trial treatment area.

You will take the Picato gel home, and you will apply the gel to your trial treatment area for three consecutive nights. You will be asked to return for seven (7) more trial visits. If the trial doctor determined that an additional course(s) of treatment is/are necessary, you may receive an additional one or two treatment course(s) and will be asked to return for an additional four or eight trial visits. You should ask the trial staff how long your visits will last. You must attend all visits. If this is not possible, you should not be part of this trial.

You are the only one who should use the trial gel that is given to you. You must make sure that no one else uses it.

The table below shows the visit schedule in the trial:

Visit schedule: first course of treatment and follow-up period

	Screening/ Baseline	First course of treatment				Follow-up period			
Visit Number	1	2	3	4	5	14	15	16	Unscheduled/ Early Term
Week	0	1	2	3	4	16	20	24	N/A
Day	0	7	14	21	28	112	140	168	N/A
Visit Window	N/A	±3 days	±3 days	±3 days	±3 days	±3 days	±3 days	±3 days	N/A

Visit schedule: second and third course of treatment

	Second course of treatment				Third course of treatment			
Visit Number	6	7	8	9	10	11	12	13
Week	5	6	7	8	9	10	11	12
Day	35	42	49	56	63	70	77	84
Visit Window	±3 days	±3 days	±3 days	±3 days	±3 days	±3 days	±3 days	±3 days

What happens when I come to the trial visits?

After you sign and date this form, have decided to participate and have qualified for the trial, your trial doctor or trial staff will assess and document the following at trial visits. You will visit the trial site at least 8 times and up to 16 times during the trial, at the screening/baseline visit (Day 0), Week 1, Week 2, Week 3, Week 4, Week 16, Week 20 and Week 24. If you receive a second course of treatment, you will also visit the trial site at Week 5, Week 6, Week 7 and Week 8. If you receive a third course of treatment, you will also visit the trial site at Week 9, Week 10, Week 11 and Week 12. Not all procedures will be done at all visits. If you would like more information about which procedures that will be done at each trial visit, please ask the trial doctor or trial staff.

Demographic Questions: You will be asked to give personal information, such as your date of birth, gender, race, ethnicity, etc. Your height and weight will also be recorded.

Health and Medication Questions: Questions about your general health; your medical history (including injuries, illnesses, surgeries, and any treatment for molluscum contagiosum you may have had), and any medications, vitamins, and dietary supplements you take.

Physical Examination, including the skin: The trial doctor will perform a physical examination that includes looking at the skin and any skin lesions, on all areas on your body.

Vital Signs: Check your blood pressure by putting a band around your arm. This will squeeze your arm for about a minute. Check your pulse. Check your temperature.

Pregnancy Test: If you are a female capable of becoming pregnant, urine will be collected for a pregnancy test at every visit. The trial doctor or trial staff will tell you if the pregnancy test result is positive. The result of the pregnancy test must be negative in order for you to be in the trial.

Questionnaires: At each trial visits you will be asked to fill in some questionnaires about your symptoms, your well-being, and how satisfied you are with the trial treatment. It will take approximately 10 minutes to complete the questionnaires.

Transparency: The trial staff will use a transparency (a clear plastic sheet) to outline the area where the Picato gel must be applied. The corners of the selected trial treatment area will be marked on your skin with a marker. At subsequent visits your trial doctor will count the molluscum contagiosum. The trial doctor/staff will re-identify the selected trial treatment area before your trial doctor starts counting.

Your trial doctor will also assess the condition of the skin in the treated area.

Molluscum Contagiosum Examination: At every visit, your trial doctor will identify and count the molluscum contagiosum in your trial treatment area. You must have at least 10 molluscum contagiosum within your trial treatment area at screening and baseline to be considered for trial participation.

Trial Drug: If the trial doctor finds that you can participate in the trial and you would like to participate, you will be given two kits of trial drug at Day 0. Each kit contains two tubes of Picato gel. The trial staff will also give you the corresponding “Patient safety and study instruction sheet” and thoroughly explain it to you. You will be instructed how to use the trial gel. You will start your trial treatment with the trial gel at home and apply it as instructed on the selected skin area once nightly for three nights in a row (on Day 0, Day 1, and Day 2). If you require a second course of treatment with the trial gel, you will apply it as instructed on the selected skin area once nightly for three nights in a row (on Day 28, Day 29, and Day 30). If you require a third course of treatment with the trial gel, you will apply it as instructed on the selected skin area once nightly for three nights in a row (on Day 56, Day 57, and Day 58).

Review of side-effects: Your trial doctor will ask you about your health at each visit to check for any possible side effects and to ensure your safety. Your trial doctor will also record if you start any new medications while you are in this trial. It is important you tell your trial doctor if you are prescribed anything between trial visits.

Your regular medical care might already include some of the trial tests and procedures listed above. Your trial doctor or a member of the trial staff can answer any questions you may have about the procedures that are not part of your regular medical care.

After the trial is over, you should talk to the trial doctor and your regular doctor about the future treatment of your molluscum contagiosum.

What do I have to do?

Your responsibilities as a trial subject include the following:

- Come to all of your trial visits as scheduled.
- Provide accurate information about your medical history and current conditions.
- Provide accurate information about any health problems you are having, even if you do not think they are important.
- Follow the instructions as given by your trial doctor, and as explained on the “Patient Safety and Study Instruction Sheet” that you will be given to take home with you. If you can’t reach an area to be treated, the person helping you must be instructed by the trial staff before he/she helps you apply the trial gel and he/she must follow the instructions for the application of the trial gel as stated in this form. Persons under 18 years may not help you apply the trial gel.
- For the entire duration of the study you will not be permitted to use other treatments for molluscum contagiosum without permission from your trial doctor.
- Store the trial gel in the fridge until you apply it. Do not place the trial gel in the freezer.
- Tell the trial staff if you want to stop taking part in the trial.
- Tell the trial doctor about all other medications you are taking, regardless of the reason or condition for which they are for. This includes prescription or over-the-counter medications, including herbal or “natural” remedies.
- Do not change any of your medicines without checking with your trial doctor.
- Women of child bearing potential must use an adequate method of contraception during the trial until Week 24. Please review the list of adequate methods of contraception in the **FEMALE ONLY** risks section below.

What are the possible side-effects of taking part?

Below are some of the side effects that you may experience during the trial. If you do not understand what any of these side effects mean, please ask the trial doctor or trial staff to explain these terms to you.

Although Picato gel is an approved and marketed product, there could be side effects that are, as yet, unknown. There may be rare and unknown side effects. Side effects will be continuously monitored during the trial, and the trial doctor will be informed in case new safety information emerges.

You must tell the trial doctor about all side effects that you get during the trial. If you are not honest about your side effects, it may not be safe for you to stay in the trial.

What can happen when I use the trial gel?

Some people who have used Picato have had skin irritation at the area where Picato gel was applied. The following are some of the reported skin irritations from other trials with Picato:

- Redness
- Flaking/scaling
- Itching
- Scabbing/crusting
- Swelling
- Vesicle, pustule, blister
- Skin erosion, skin peeling

- Pain or burning at the treatment area.

Some people who have used Picato have experienced other side effects. These include:

- Headache
- Swelling around the eyes and/or the eyelids

If you suffer these or any other symptoms, you should report them next time you visit the trial doctor. If you in any way become worried, please contact the trial doctor or the trial staff.

If trial gel gets in your eyes, it may cause severe irritation and include any or all of the following symptoms:

- Redness
- Irritation
- Pain
- Stinging
- Blurred vision
- Swelling of the eyelids

You must be careful not to get any trial gel in your eyes. Do not rub your eyes after touching, or scratching the area where trial gel was applied. If trial gel comes in contact with your eye, immediately flush your eye repeatedly with large quantities of water and visit an emergency room or urgent care center as soon as possible. Tell emergency personnel about your participation in this trial. Also notify your trial doctor. You will need to receive emergency treatment and you may need to visit an eye doctor if you get trial gel in your eyes.

Could I have an allergic reaction?

Some people have allergic reactions to drugs. If you have a very bad allergic reaction, you could die. Some things that can happen during an allergic reaction are:

- A rash
- Difficulty breathing
- Wheezing when you breathe
- A sudden drop in blood pressure
- Swelling around the mouth, throat, or eyes
- A fast pulse
- Sweating.

If you have an allergic reaction during the trial, it is likely that you will have the same type of reaction if you come in contact with small amounts of the trial gel in the future.

You should get immediate medical help and contact the trial doctor or trial staff if you experience any of these side effects during the trial. In the event of an emergency, call 911 or go to the nearest hospital emergency department. If you require emergency care, be sure to tell the emergency care provider about your participation in this trial. Contact the trial doctor or trial staff as soon as possible. Picato has caused serious allergic reactions.

FEMALE ONLY: Are there risks to me if I am pregnant or breastfeeding during the trial?

You cannot participate in this trial if you are pregnant, if you plan to become pregnant, or if you are breastfeeding while you participate in this trial, as there may be risks to the unborn baby or nursing child. Some drugs cause women to have their babies prematurely (early) or to have babies with birth defects. It is not known whether Picato will harm an unborn baby.

If you are a female and are capable of having children, you can participate in this trial, but it is very important that you use birth control throughout the entire duration of the trial (until Week 24). Acceptable methods of birth control for this trial include:

- Abstinence or partner's sterilization (vasectomy)
- Intrauterine device (IUD)
- The "double barrier" method, defined as condom in combination with diaphragm
- Hormonal contraceptive (oral hormonal birth control, estrogenic vaginal ring, percutaneous contraceptive patches, implants and injections) for at least one menstrual cycle prior to enrollment.

You will be required to take a urine pregnancy test to make sure that you are not pregnant before using the trial gel. A pregnancy test can be wrong. If you become pregnant during the trial, call the trial doctor at once.

Are there any other possible risks or inconveniences?

You may be limited as to what other medications, treatments, and procedures you can take or have during the trial, especially those for your molluscum contagiosum, but also in regards to using creams and lotions on the trial treatment area, or shaving of the trial treatment area. It is important that you discuss any new medication or treatment with your trial doctor before using them to make sure that they are allowed in this trial.

You will need to be available to attend your trial visits at the date and time agreed with your trial doctor or trial staff.

Can I be withdrawn from the trial?

The trial doctor, the sponsor or government agencies such as the FDA that reviewed this trial can remove you from the trial at any time, even if you want to stay in the trial. This could happen if:

- The trial doctor or trial staff believes it is best for you to stop being in the trial
- You do not follow directions about the trial
- The sponsor stops the trial for any reason

In either case, your trial doctor will explain the reasons and arrange for your treatment according to her/his recommendations.

What will happen if I don't want to carry on with the trial?

Your participation in this trial is voluntary. You may withdraw from the trial for any reason at any time, without any penalty or loss of benefits to which you are otherwise entitled. If you want to stop being in the trial, tell the trial doctor or trial staff.

In the event that you choose to withdraw your participation in the trial, no new data will be added to your trial records, but the data already collected will still be part of the trial results.

If you decide that you no longer want to take part in the trial, the trial doctor or trial staff may ask you to participate in some procedures or tests to help you leave the trial safely and/or to collect more information for the trial. You can refuse to do this.

What if new information about the trial treatment becomes available during the trial?

If new information becomes available which may affect your decision to take part in this trial, your trial doctor will inform you in a timely manner and ask if you want to continue in the trial.

What are possible benefits of taking part?

We cannot guarantee that you will receive any advantages from being part of this trial. However, it has been reported in the literature that patients treated with Picato get a reduction of the number of molluscum contagiosum lesions. Therefore, you may benefit from trial treatment with Picato gel in this trial, or your molluscum contagiosum lesions may stay the same or worsen.

The information obtained from this trial may help towards developing a better treatment for molluscum contagiosum in patients with immunocompromised conditions in the future.

What are the alternatives for treatment?

You do not have to be in this trial to obtain medical treatment for molluscum contagiosum. Your trial doctor will talk to you about other treatment options for molluscum contagiosum, including their risks and benefits. Some other things you can do are:

- have the molluscum contagiosum removed (for example, by using liquid nitrogen cryotherapy);
- get topical drug therapy (medication applied to the skin, such as salicylic acid, cantharidin, or tretinoin)
- have the molluscum contagiosum removed by surgery such as curettage and desiccation (scraping it off with a curette, a sharp round scraping instrument)
- watchful waiting (wait to see if the lesion will disappear on its own)

You should discuss your alternatives to participating in this trial with the trial doctor or trial staff. In addition, you may discuss your options with your regular health care provider.

What if something goes wrong?

You should call the trial doctor or trial staff if you have questions about the trial or if you get hurt or sick during the trial. If you become ill or injured as a result of participating in this trial, necessary medical treatment will be made available at no cost to you to the full extent provided for by law. The sponsor will cover reasonable and necessary medical costs not covered by your health care payer (if any) for injury or illness that is directly a result of participation in this trial.

The Center for Clinical Studies has taken out relevant insurances covering the subjects in the present trial in accordance with applicable laws and regulations.

Name of insurer: Liberty Mutual
Insurance policy number: BKS57042446

To pay these medical expenses, the sponsor will need to know some information about you like your name, date of birth, and social security number or Medicare Health Insurance Claim Number. This is because the sponsor has to check to see if you receive Medicare and if you do, report the payment it makes to Medicare.

By signing this consent form, you are not releasing the trial doctor(s), institution(s), and/or sponsor(s) from their legal and professional responsibilities.

You still have all your legal rights. Nothing said here about treatment or compensation in any way alters your right to claim damages.

Who is organizing and funding the research?

The trial is organized by the Center for Clinical Studies and funded by LEO Pharma A/S, Denmark.

LEO Pharma A/S will pay your trial doctor for his/her time, effort and expenses to conduct the trial, (your trial doctor is not permitted to charge you or your health care payer (if any) for her/his services related to this trial).

Will I be paid for taking part?

You will not receive any payment for participating in this trial.

If you are included in this trial, you will be reimbursed for expenses up to \$40.00 per trial visit, to cover your travel expenses. If you leave the trial before the end, you will receive an amount according to the trial visits that were attended. Payment will be provided to you following each completed visit.

Will there be any cost to me for taking part?

There is no cost to you, your health care payer (if any), private medical insurance (if any), or public health insurance plan for the trial procedures. The trial gel will be provided at no charge for the duration of the trial.

Will my taking part in this trial be kept confidential?

Personal data about you will be collected and processed during and after the completion of the trial.

The trial doctor will collect personal data about you (e.g. medical history and diagnosis, demographic details such as gender, race, height and weight, clinical evaluation of the treatment with trial drug, side effects) during the trial.

This data will be recorded into special trial forms, which may be on a computer. On these forms you will be identified only by your date of birth and a subject number, not your name.

You have the right to have recorded data corrected of errors by asking your trial doctor.

As part of this trial, the trial doctor will also record the results of your trial-related assessments in your personal medical records. Your personal medical records will also be reviewed by the trial doctor for health information such as past medical history and recent treatments you may have received.

Access to your medical records

Your original medical records will be inspected by authorized representatives of LEO, and possibly also by Institutional Review Boards/Independent Ethics Committees and government regulatory authorities from United States of America (such as the FDA) and other countries. The purpose of such inspections is to check that the information recorded on the trial forms is correct and to make sure that the trial is conducted correctly.

By signing the consent form, you are allowing direct access to your medical records. All information collected about you will be kept strictly confidential to the extent permitted by the applicable laws and regulations. Your name will not be disclosed outside of the trial center.

If you agree, your trial doctor will inform your General Practitioner (if you have one) of your participation in this trial.

What will happen to the results of the trial?

The trial data including personal data will be transferred to LEO and it may also be transferred to an affiliate of the sponsor or a third party contracted by the sponsor to provide a service related to the trial, or as part of the sponsor's ordinary business operation.

The data may also be transferred to and processed in other countries where the protection of personal data may not be as strict as in your own country. If your trial forms are transferred outside of United States of America, LEO will make sure that this transfer is according to applicable laws on data privacy.

The purpose of reviewing and processing this data is to make sure the trial is conducted correctly and enable the sponsor to analyze the data to gain more information about the trial drug. The data could be used for further research, development and safety evaluation of the trial drug or aimed at developing new and/or modifying/improving existing products; as such, the data collected may be analyzed again after this trial has finished. Your data will be processed by the trial doctor and the sponsor.

The analysis of the data is expected to take place in the United States, but this may change.

The Center for Clinical Studies will have responsibility for the registration of this information. Data from this trial may be submitted to the Food and Drug Administration (FDA) and possibly to governmental agencies in other countries.

To support the initiatives towards increased clinical trial transparency, LEO is committed to give access to the results of its clinical studies to advance the scientific understanding of the disease areas covered by the clinical studies sponsored by LEO. This means that data collected in this trial may be published on our website <http://www.LEO-Pharma.com> and researchers may be granted access to data of this trial for further research upon approval by LEO. Any publication or access will be subject to the protection of

your privacy and confidentiality. LEO will therefore ensure that it is not possible to identify you when a publication is made or access is granted.

The results may be published in a medical journal, but no information will be given from which you could be identified.

Your trial records will be kept at a secure location after trial completion, as required by clinical trial regulations.

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

What will happen when the trial stops?

When your participation in the trial comes to an end, your trial doctor will discuss the most appropriate way to continue your care.

After the trial is over for all subjects participating, the trial doctor will be informed of the results and can share these with you.

How can I get answers to my questions or concerns about the trial?

You can ask questions about this consent form or the study (before you decide to start the study, at any time during the study, or after completion of the study). Questions may include:

- Who to contact in the case of a research-related injury or illness;
- Payment or compensation for being in the study, if any;
- Your responsibilities as a study subject;
- Eligibility to participate in the research;
- The study doctor's or study site's decision to exclude you from participation;
- Results of tests and/or procedures;
- Other questions, concerns, or complaints

Contact the study doctor or study staff listed on the first page of this form with any questions, concerns, or complaints.

How can I get answers to my questions about my rights as a research subject?

This study has been reviewed by an Institutional Review Board (IRB). This Committee reviewed this study to help ensure that your rights and welfare are protected and that this study is carried out in an ethical manner.

If you have questions regarding your rights as a research participant, or if you have questions, concerns, complaints about the research, would like information, or would like to offer input, you may contact the Sterling Institutional Review Board Regulatory Department, 6300 Powers Ferry Road, Suite 600-351, Atlanta, Georgia 30339 (mailing address) at telephone number 1-888-636-1062 (toll free).

INFORMED CONSENT FORM – CONSENT STATEMENT

Subject No.:

(May be completed by LEO or a LEO representative)

A copy of this subject informed consent form (signed and dated) must be given to the subject.

By signing below, **I agree** that:

- I have read and understood this subject information sheet and informed consent form and the trial has been explained to me.
- I have had time to make my decision.
- I consent to the collection, processing and transfer of my personal data as described in this form for the purpose of conducting and evaluating the trial according to the protocol, doing further research, development and safety evaluation aimed at developing new and/or modifying/improving existing products, applying for market authorizations for products anywhere in the world and marketing such products.
- I understand that my medical records may be looked at by authorized individuals as explained in the subject information sheet. I give permission and authorization for these individuals to have access to my medical records. I understand that anyone else who has access to my personal medical records will also have access to the trial information recorded, but the information, and my participation in this trial, will be treated as confidential as any other information is in my medical records.
- I understand that data collected about me in this trial may be made available to third parties subject to anonymization (my personal identifier information will be removed from the data).
- I voluntarily agree to take part in the trial described in this subject information sheet and informed consent form.
- I agree to my primary care physician being informed of my participation in the trial: **(check one)**

Yes

No

Not applicable

If yes, state primary care physician name: _____

Printed name of Subject

Signature of Subject

Date (day/month/year)

Printed name of person explaining consent

Signature of person explaining consent

Date (day/month/year)

I attest that the participant named above had enough time to consider this information, had an opportunity to ask questions, and voluntarily agreed to participate in this trial as described. I confirm that I have conducted this informed consent discussion.

Printed name of investigator

Signature of investigator

Date (day/month/year)

HIPAA Authorization Agreement

Authorization to Use and Disclose Protected Health Information

During your participation in this research study, the investigator and study staff will collect or create personal health information about (for example, medical histories and results of any tests, examinations or procedures you undergo while in the study) and record it on study documents. The investigator will keep this personal health information in your study-related records (that we will refer to as “your study records”). In addition, the investigator may obtain, and include in your records, information regarding your past, present and/or future physical or mental health and/or condition. Your investigator may ask you to sign a separate authorization to obtain some or all of your medical records from your doctor. Your study records may include other personal information (such as social security number, medical record numbers, date of birth, etc.), which could be used to identify you. Health information that could identify you is called “Protected Health Information” (or “PHI”).

Under federal law (the “Privacy Rule”), your PHI that is created or obtained during this research study cannot be “used” to conduct the research or “disclosed” (given to anyone) for research purposes without your permission. This permission is called an “Authorization”. Therefore, you may not participate in this study unless you give your permission to use and disclose your PHI by signing this Authorization. By signing, you are agreeing to allow the investigator and staff to use your PHI to conduct this study.

By signing this Authorization, you also are agreeing to allow the investigator to disclose PHI as described below:

- The sponsor of this study and anyone working on behalf of the sponsor to conduct this study (referred to as “the sponsor”). The sponsor will analyze and evaluate the PHI and may use it to develop new tests, procedures and commercial products. The study staff will assign a code number and/or letters to your records, which means that you will not ordinarily be identified in the records sent to the sponsor. The sponsor may, however, look at your complete study records that identify you. In addition, the sponsor may visit the study site to oversee the way the study is being conducted and may review your PHI during these visits to make sure the information is correct.
- The Institutional Review Board (“IRB”) may have access to your PHI in relation to its responsibilities as an Institutional Review Board.

The investigator or sponsor may disclose your PHI to the United States Food and Drug Administration (“FDA”) or similar regulatory agencies in the United States and/or foreign countries.

These disclosures also help ensure that the information related to the research is available to all parties who may need it for research purposes.

Except for the disclosures described above, your PHI will not be shared with others unless required by law. If your PHI is given to the parties listed above and/or to others who are not required to comply with the federal law, your PHI will no longer be protected by this law and could possibly be used or disclosed in ways other than those listed here.

You have a right to see and make copies of your PHI. You are agreeing, however, by signing this document, not to see or copy some or all of your PHI until the sponsor has completed all work related to this study. At that time, you may ask to see your records.

This Authorization will expire 50 years from the date you sign it unless you revoke (cancel or withdraw) it sooner.

You have a right to revoke your Authorization at any time. If you revoke it, your PHI will no longer be used for this study, except to the extent the parties to the research have already taken action based upon your Authorization or need the information to complete analysis and reports for this research. To revoke your Authorization, you must write to the investigator, stating that you are revoking your Authorization to Use and Disclose Protected Health Information. If you revoke this Authorization, you will not be allowed to continue to be in this study.

You will receive a copy of this Authorization after you have signed it.

Printed name of Subject

Signature of Subject

Date (day/month/year)

Printed name of person obtaining the
Authorization

Signature of person obtaining the
Authorization

Date (day/month/year)